Scheda di Dati di Sicurezza / Safety Data Sheet

Conforme all'Allegato II del REACH - Regolamento (UE) 2020/878
According to Annex II to REACH - Regulation 2020/878

Codice / Code:	**3914003**
Nome prodotto / Product name:	**CALCULUS ANALYSIS III**
Descrizione d'uso / Intended use:	**Reagenti pronti all'uso per la determinazione semiquantitativa colorimetrica di Carbonati, Calcio, Ossalati, Ammonio, Fosfati, Magnesio, Acido urico e Cistina in calcoli renali con metodo manuale / Ready to use reagents for semiquantitative colorimetric determination of Carbonate, Calcium, Oxalate, Ammonium, Phosphate, Magnesium, Uric acid and Cystine on kidney stones by manual method**
Fornitore / Supplier:	**Mascia Brunelli S.p.A.** Viale Monza 272, 20128 Milano, Italia. Tel.: 0039 02 252091 E-mail: mktg@masciabrunelli.it

Componenti del kit / Kit components:

1. **R1 – H_2SO_4**
2. **R2 – NaOH**
3. **R3 – A.C. Calconcarboxylic in alchohol**
4. **R4 – EDTA**
5. **R5 – Borate Buffer**
6. **R6 – $FeCl_3$**
7. **R7 – $C_7H_6O_6S$**
8. **R8 – K_2HgI_4**
9. **R9 – $(NH_4)Mo_7O_{24}$**
10. **R10 – Reducing sol.**
11. **R11 – Buffer sol.**
12. **R12 – Dye sol.**
13. **R13 – Phosphomolibdic Ac.**
14. **R14 – NH_4OH**
15. **R15 – Reducing Powder**
16. **R16 – Nitroprussiate**
17. **RSC - Control**

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R1**
Product name: **CALCULUS ANALYSIS III_R1 (Reagent)**
Chemical name: Sulphuric acid CAS: 7664-93-9 EC No: 231-639-5 Index No: 016-020-00-8

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

CAS 7664-93-9 CEE 016-030-00-8 EINECS 231-639-5

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Corr. 1A, Eye Dam, 1

H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.

Corrosive product: causes severe skin burns and eye damage. If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS05

Signal words: Danger

Hazard statements:

H314	Causes severe skin burns and eye damage.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash ... thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+ P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/…
P321	Specific treatment (see ... on this label).
P363	Wash contaminated clothing before reuse.
P405	Store locked up.
P501	Dispose of contents/container to …

Contains:	Sulphuric acid …..%

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Identification	x = Conc. %	Classification 1272/2008 (CLP)
SULPHURIC ACID		
CAS 7664-93-9	75% ≤ x < 100%	Met. Corr. 1, H290
EC 231-639-5		Skin Corr. 1A, H314
REACH – No.: --		Eye Dam. 1, H318
INDEX – No.: 016-020-00-8		Limits: Skin Corr. 1A, H314 %C ≥ 15
		Skin Irrit, 2, H315 5 ≤ %C < 15
		Eye Irrit. 2, H319 5 ≤ %C < 15

3.2 Mixtures

Irrilevant.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell

seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. In case of contact with skin, wash immediately with water Consult a physician immediately

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Drink water with egg white; do not give bicarbonate. Absolutely do not induce vomiting or emesis. Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No data available

4.3. Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER/doctor/…

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
In residential areas do not use on large surfaces.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
Wear mask.

RESPIRATORY PROTECTION
Use adequate protective respiratory equipment (EN 14387:2008).

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices, avoiding spillage into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information

Appearance	Liquid clear
Colour	colourless
Odour	Odourless
Melting point / freezing point	10,31 °C
Initial boiling point	290°C – lit.
Flammability	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Flash point	Not available
Auto-ignition temperature	Not available
pH	1,2 at 5 g/L
Kinematic viscosity	Not available
Solubility	On water
Partition coefficient: n-octanol/water	Not determined
Vapour pressure	1,33 hPa at 145,8°C
Density and/or relative density	Not available
Relative vapour density	3,39 – (Air = 1.0)
Particle characteristics	Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

a) Explosives
- i) sensitivity to shock Irrilevant
- ii) effect of heating under confinement Irrilevant
- iii) effect of ignition under confinement Irrilevant
- iv) sensitivity to impact Irrilevant
- v) sensitivity to friction Irrilevant
- vi) thermal stability Irrilevant
- vii) package Irrilevant

b) Flammable gases
- i) Tci / explosion limits Irrilevant
- ii) fundamental burning velocity Irrilevant

c) Aerosols Irrilevant

d) Oxidising gases Irrilevant

e) Gases under pressure Irrilevant

f) Flammable liquids Irrilevant

g) Flammable solids
- i) burning rate, or burning time as regards metal powders Irrilevant
- ii) statement on whether the wetted zone has been passed Irrilevant

h) Self-reactive substances and mixtures
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power, if applicable Irrilevant

i) Pyrophoric liquids Irrilevant

j) Pyrophoric solids
- i) statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form Irrilevant
- ii) statement on whether pyrophoric properties could change over time Irrilevant

k) Self-heating substances and mixtures
- i) statement on whether spontaneous ignition occurs and the maximum temperature rise obtained Irrilevant
- ii) results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available Irrilevant

l) Substances and mixtures, which emit f lammable gases in contact with water. The following information may be provided
- i) identity of the emitted gas, if known Irrilevant
- ii) statement on whether the emitted gas ignites spontaneously Irrilevant
- iii) gas evolution rate Irrilevant

m) Oxidising liquids Irrilevant

n) Oxidizing solids Irrilevant

o) Organic peroxides
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power Irrilevant

p) Corrosive to metals
- i) metals that are corroded by the substance or mixture Irrilevant
- ii) corrosion rate and statement on whether it refers to steel or aluminium Irrilevant
- iii) reference to other sections of the safety data sheet with regard to compatible or incompatible materials Irrilevant

q) Desensitised explosives
- i) desensitising agent used Irrilevant
- ii) exothermic decomposition energy Irrilevant
- iii) corrected burning rate (Ac) Irrilevant
- iv) explosive properties of the desensitised explosive in that state Irrilevant

9.2.2. Other safety characteristics

a) mechanical sensitivity: Irrilevant

b) self-accelerating polymerisation temperature: Irrilevant

c) formation of explosible dust/air mixtures: Irrilevant

d) acid/alkaline reserve: Irrilevant

e) evaporation rate: Irrilevant

f) miscibility: Irrilevant

g) conductivity: Irrilevant

h) corrosiveness: Irrilevant

i) gas group: Irrilevant

j) redox potential: Irrilevant

k) radical formation potential: Irrilevant

l) photocatalytic properties: Irrilevant

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Animal/vegetal tissues. Contact with metals releases hydrogen gas.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: Corrosive product: causes severe skin burns and eye damage.
(c) severe ocular damage/eye irritation: Corrosive product: causes severe skin burns and eye damage. - If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace) and s.m.i., Regulation (EC) n. 1907/2006 (REACH) – Annex XIV, Annex XVII and s.m.i., Regulation (EC) n. 1272/2008 (CLP) and s.m.i., Delegated Regulation (EU) 2020/1182, Delegated Regulation (EU) 2021/643, Delegated Regulation (EU) 2021/849, Delegated Regulation (EU) 2023/1434, Delegated Regulation (EU) 2023/1435, Regulation (EU) 2020/878, Regulation (EC) n. 790/2009, D.Lgs. 105/2015 (Seveso Ter Directive) and s.m.i.
REGULATION (EU) N. 1357/2014 – waste:
HP8 – Corrosive

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H290 = May be corrosive to metals.
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H314 = Causes severe skin burns and eye damage. Classification procedure: Calculation method.
H318 = Causes serious eye damage. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R2**
Product name: **CALCULUS ANALYSIS III_R2 (Reagent)**
Chemical name: Sodium hydroxide CAS: 1310-73-2 EC No: 215-185-5 Index No: 011-002-00-6

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

CAS 1310-73-2 CEE 011-002-00-6 EINECS 215-185-5

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Corr. 1A, Eye Dam, 1

H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.

Corrosive product: causes severe skin burns and eye damage. If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS05

Signal words: Danger

Hazard statements:

H314	Causes severe skin burns and eye damage.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash ... thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+ P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/…
P321	Specific treatment (see ... on this label).
P363	Wash contaminated clothing before reuse.
P405	Store locked up.
P501	Dispose of contents/container to …

Contains: Sodium hydroxide

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
Sodium hydroxide		
CAS 1310-73-2	1% ≤ x < 2%	Met. Corr. 1, H290
EC 215-185-5		Skin Corr. 1A, H314
REACH – No.: --		Skin Irrit. 2, H315
INDEX – No.: 011-002-00-6		Eye Dam. 1, H318
		Eye Irrit. 2, H319
		Limiti: Skin Corr. 1A, H314 %C ≥ 15
		Skin Irrit, 2, H315 0,1 ≤ %C < 2
		Eye Irrit. 2, H319 0,1 ≤ %C < 2

3.2 Mixtures

Irrilevant.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. In case of contact with skin, wash immediately with water Consult a physician immediately

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Drink water with egg white; do not give bicarbonate. Absolutely do not induce vomiting or emesis. Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER/doctor/…

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
In residential areas do not use on large surfaces.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Related to the substances contained:
Sodium hydroxide:
2 mg/m^3

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
Wear mask.

RESPIRATORY PROTECTION
Use adequate protective respiratory equipment (EN 14387:2008).
THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Solid	
Colour	white	
Odour	Odourless	
Melting point / freezing point	Not available	
Initial boiling point	Not available	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	Not available	
Auto-ignition temperature	Not available	
pH	Not available	
Kinematic viscosity	Not available	
Solubility	Not available	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	
Density and/or relative density	Not available	
Relative vapour density	Not available	
Particle characteristics	Not available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

a) Explosives
- i) sensitivity to shock Irrilevant
- ii) effect of heating under confinement Irrilevant
- iii) effect of ignition under confinement Irrilevant
- iv) sensitivity to impact Irrilevant
- v) sensitivity to friction Irrilevant
- vi) thermal stability Irrilevant
- vii) package Irrilevant

b) Flammable gases
- i) Tci / explosion limits Irrilevant
- ii) fundamental burning velocity Irrilevant

c) Aerosols Irrilevant

d) Oxidising gases Irrilevant

e) Gases under pressure Irrilevant

f) Flammable liquids Irrilevant

g) Flammable solids
- i) burning rate, or burning time as regards metal powders Irrilevant
- ii) statement on whether the wetted zone has been passed Irrilevant

h) Self-reactive substances and mixtures
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power, if applicable Irrilevant

i) Pyrophoric liquids Irrilevant

j) Pyrophoric solids
- i) statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form Irrilevant
- ii) statement on whether pyrophoric properties could change over time Irrilevant

k) Self-heating substances and mixtures
i) statement on whether spontaneous ignition occurs and the maximum temperature rise obtained Irrilevant
ii) results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available Irrilevant
l) Substances and mixtures, which emit f lammable gases in contact with water. The following information may be provided
i) identity of the emitted gas, if known Irrilevant
ii) statement on whether the emitted gas ignites spontaneously Irrilevant
iii) gas evolution rate Irrilevant

m) Oxidising liquids Irrilevant

n) Oxidizing solids Irrilevant

o) Organic peroxides
i) decomposition temperature Irrilevant
ii) detonation properties Irrilevant
iii) deflagration properties Irrilevant
iv) effect of heating under confinement Irrilevant
v) explosive power Irrilevant

p) Corrosive to metals
i) metals that are corroded by the substance or mixture Irrilevant
ii) corrosion rate and statement on whether it refers to steel or aluminium Irrilevant
iii) reference to other sections of the safety data sheet with regard to compatible or incompatible materials Irrilevant

q) Desensitised explosives
i) desensitising agent used Irrilevant
ii) exothermic decomposition energy Irrilevant
iii) corrected burning rate (Ac) Irrilevant
iv) explosive properties of the desensitised explosive in that state Irrilevant

9.2.2. Other safety characteristics

a) mechanical sensitivity: Irrilevant

b) self-accelerating polymerisation temperature: Irrilevant

c) formation of explosible dust/air mixtures: Irrilevant

d) acid/alkaline reserve: Irrilevant

e) evaporation rate: Irrilevant

f) miscibility: Irrilevant

g) conductivity: Irrilevant

h) corrosiveness: Irrilevant

i) gas group: Irrilevant

j) redox potential: Irrilevant

k) radical formation potential: Irrilevant

l) photocatalytic properties: Irrilevant

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: Corrosive product: causes severe skin burns and eye damage.
(c) severe ocular damage/eye irritation: Corrosive product: causes severe skin burns and eye damage. - If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP8 – Corrosive

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H290 = May be corrosive to metals.
H314 = Causes severe skin burns and eye damage.
H315 = Causes skin irritation.
H318 = Causes serious eye damage.
H319 = Causes serious eye irritation.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H314 = Causes severe skin burns and eye damage. Classification procedure: Calculation method.
H318 = Causes serious eye damage. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R3**
Product name: **CALCULUS ANALYSIS III_R3 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye Irrit. 2

H319 Causes serious eye irritation.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

Signal words: Warning

Hazard statements:

H319 Causes serious eye irritation.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P337+P313 If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
ETHANOL		
CAS 64-17-5	75% ≤ x < 100%	Flam. Liq. 2, H225
EC 200-578-6		Eye Irrit. 2, H319
REACH – No.: 01-2119457610-43-XXXX		ATE oral > 5.000,000 mg/kg
INDEX – No.: 603-002-00-5		ATE dermal > 2.000,000 mg/kg

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If eye irritation persist: get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.

Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substance: ethanol
DNEL
Systemic effects Long term Workers inhalation = 114 mg/m^3
Systemic effects Long term Workers dermal = 206 mg/kg bw/day
Systemic effects Short term Workers inhalation = 1900 mg/m^3
PNEC
Sweet water = 0,96 mg/l
Sediment Sweet water = 3,6 mg/kg/sediment
Sea water = 0,79 mg/l
Sediment Sea water = 2,9 mg/kg/sediment

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
Wear mask.

RESPIRATORY PROTECTION
Use adequate protective respiratory equipment (EN 14387:2008).

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Related to contained substances:
ethanol:
Given that the use of appropriate technical measures should always take priority over personal protective equipment, ensure good ventilation in the workplace through effective local exhaust ventilation.
When choosing personal protective equipment, seek advice from your chemical suppliers if necessary.
Personal protective equipment should bear the CE marking attesting to its compliance with applicable standards.
Provide emergency shower with visocular tray.

Hand protection.
Protect hands with category III work gloves (ref. standard EN 374).
For the final choice of work glove material, the following should be considered: compatibility, degradation, breakthrough time and permeation. In the case of preparations, the resistance of work gloves to chemical agents must be verified before use because it cannot be predicted. Gloves have a wear time that depends on the duration and mode of use.

Skin protection.
Wear long-sleeved work clothes and category I occupational safety footwear (ref. Directive 89/686/EEC and EN ISO 20344). Wash with soap and water after removing protective clothing. Consider providing antistatic clothing if the work environment presents a risk of explosiveness.

Eye protection.
It is recommended to wear airtight protective goggles (ref. Standard EN 166).

Respiratory protection:
if the threshold value (e.g., TLV-TWA) of the substance or one or more of the substances in the product is exceeded, it is recommended to wear a mask with a type A filter, the class (1, 2 or 3) of which should be chosen in relation to the limit concentration of use. (ref. standard EN 14387). If gases or vapors of a different nature and/or gases or vapors with particles (aerosols, fumes, mists, etc.) are present, combined type filters should be provided. The use of respiratory protective means is necessary in case the technical measures taken are not sufficient to limit the worker's exposure to the threshold values taken into consideration. However, the protection offered by masks is limited. In case the substance under consideration is odorless or its odor threshold is higher than the relevant TLV-TWA and in case of emergency, wear an open-circuit self-contained compressed-air breathing apparatus (ref. Standard EN 137) or an air-supplied respirator (ref. Standard EN 138). For the correct choice of respiratory protective device, refer to EN 529.

Environmental exposure control.
Emissions from production processes, including those from ventilation equipment, should be controlled for compliance with environmental protection regulations

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

Related to contained substances:
ethanol:
No particular danger of reaction with other substances under normal conditions of use. Easily flammable liquid and vapors. Possible formation of explosive vapor/air mixtures.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Related to contained substances:
ethanol:
Avoid overheating. Avoid electrostatic charge buildup. Avoid any source of ignition. Avoid exposure to: heat sources, open flames. Heat. Sparks. Naked flame. Ignition sources. Direct sunlight.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: Ethanol: causes severe eye irritation. Ethanol: frequent or prolonged skin contact may cause dermatoses.
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:
ethanol:
LOAEL (oral, rat, 90 gg) : 3160 mg/kg of body weight/day - NOAEL (oral, rat, 90 gg) : 1730 mg/kg of body weight/day.
KINEMATIC VISCOSITY: 1,51898734 mm^2/s

LD50 (rat) Oral (mg/kg body weight) > 5000
LD50 Dermal (rat or rabbit) (mg/kg body weight) > 2000

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Related to contained substances:
ethanol:
ethanol, ethyl alcohol (64-17-5).
LC50 fish: 13500 - 15300 mg/l/96h (Pimephales promelas)
EC50 Daphnia: 12340 mg/l/48h (Daphnia magna)
ErC50 (algae): 275 mg/l/72h (Chlorella vulgaris) NOEC (chronic): >10 mg/l/21 g (Daphnia magna)
NOEC chronic algae: 3240 mg/l (Skeletonema costatum)
Acute toxicity M factor = 1

Chronic toxicity M factor = 1

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

Related to contained substances:
ethanol:
The paraffinic hydrocarbons present can be considered degradable in water and air. They mostly partition into the air. The small part that breaks down in water and does not biodegrade tends to accumulate in fish.
ETHANOL
Solubility in water 1000 - 10000 mg/l.
Rapidly degradable.

12.3. Bioaccumulative potential

Related to contained substances:
ethanol:
ETHANOL
Partition coefficient: n-octanol/water -0.35.

12.4. Mobility in soil

Related to contained substances:
ethanol:
ecology-soil: weak adsorption. The product evaporates quickly in the atmosphere.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H225 = Hyghly flammable liquid and vapour.
H319 = Causes serious eye irritation.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H319 = Causes serious eye irritation. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R4**
Product name: **CALCULUS ANALYSIS III_R4 (Reagent)**
Chemical name: EDTA CAS: 6381-92-6 EC No: 205-358-3 REACH: 01-2119486775-20-XXXX

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

CAS 638-92-6 EINECS 205-358-3 REACH 01-2119486775-20-XXXX

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is not classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: not hazardous

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: ---

Hazard statements: not hazardous

Supplemental Hazard Statement Code(s): EUH210 – Safety Data Sheet available on request.

Precautionary statements: none in particular.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Identification	x = Conc. %	Classification 1272/2008 (CLP)
EDTA		
CAS 6381-92-6	1% ≤ x < 5%	Acute Tox. 4, H332
EC 205-358-3		STOT RE 2, H373
REACH – No.: 01-2119486775-20-XXXX		
INDEX – No.: ---		

3.2 Mixtures

Irrilevant.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Related to the substances contained:
EDTA:
DNEL
Systemic effects Long term Workers inhalation = 0,6 mg/m3
PNEC
Sweet water = 2,2 mg/l
Sea water = 0,22 mg/l
ground = 0,72 mg/kg ground

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
Not needed for normal use.

SKIN PROTECTION
Wear normal work clothing.

EYE PROTECTION
Not needed for normal use.

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	crystals	
Colour	white	
Odour	Odourless	
Melting point / freezing point	248°C	
Initial boiling point	Not available	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	Irrilevant	
Auto-ignition temperature	Not available	
Decomposition temperature	255°C	
pH	Not available	
Kinematic viscosity	Not available	
Solubility	Not available	
Partition coefficient: n-octanol/water	Not available	
Vapour pressure	Not available	
Density and/or relative density	Not available	
Relative vapour density	Not available	
Particle characteristics	Not available	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

a) Explosives
- i) sensitivity to shock Irrilevant
- ii) effect of heating under confinement Irrilevant
- iii) effect of ignition under confinement Irrilevant
- iv) sensitivity to impact Irrilevant
- v) sensitivity to friction Irrilevant
- vi) thermal stability Irrilevant
- vii) package Irrilevant

b) Flammable gases
- i) Tci / explosion limits Irrilevant
- ii) fundamental burning velocity Irrilevant

c) Aerosols Irrilevant

d) Oxidising gases Irrilevant

e) Gases under pressure Irrilevant

f) Flammable liquids Irrilevant

g) Flammable solids
- i) burning rate, or burning time as regards metal powders Irrilevant
- ii) statement on whether the wetted zone has been passed Irrilevant

h) Self-reactive substances and mixtures
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power, if applicable Irrilevant

i) Pyrophoric liquids Irrilevant

j) Pyrophoric solids
- i) statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form Irrilevant
- ii) statement on whether pyrophoric properties could change over time Irrilevant

k) Self-heating substances and mixtures
- i) statement on whether spontaneous ignition occurs and the maximum temperature rise obtained Irrilevant
- ii) results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available Irrilevant

l) Substances and mixtures, which emit f lammable gases in contact with water. The following information may be provided
- i) identity of the emitted gas, if known Irrilevant
- ii) statement on whether the emitted gas ignites spontaneously Irrilevant
- iii) gas evolution rate Irrilevant

m) Oxidising liquids Irrilevant

n) Oxidizing solids Irrilevant

o) Organic peroxides
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power Irrilevant

p) Corrosive to metals
- i) metals that are corroded by the substance or mixture Irrilevant
- ii) corrosion rate and statement on whether it refers to steel or aluminium Irrilevant
- iii) reference to other sections of the safety data sheet with regard to compatible or incompatible materials Irrilevant

q) Desensitised explosives
- i) desensitising agent used Irrilevant
- ii) exothermic decomposition energy Irrilevant
- iii) corrected burning rate (Ac) Irrilevant
- iv) explosive properties of the desensitised explosive in that state Irrilevant

9.2.2. Other safety characteristics

a) mechanical sensitivity: Irrilevant

b) self-accelerating polymerisation temperature: Irrilevant

c) formation of explosible dust/air mixtures: Irrilevant

d) acid/alkaline reserve: Irrilevant

e) evaporation rate: Irrilevant

f) miscibility: Irrilevant

g) conductivity: Irrilevant

h) corrosiveness: Irrilevant

i) gas group: Irrilevant

j) redox potential: Irrilevant

k) radical formation potential: Irrilevant

l) photocatalytic properties: Irrilevant

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = 740,7 mg/l/4 h

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
(c) severe ocular damage/eye irritation: based on available data, the classification criteria are not met
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace) and s.m.i., Regulation (EC) n. 1907/2006 (REACH) – Annex XIV, Annex XVII and s.m.i., Regulation (EC) n. 1272/2008 (CLP) and s.m.i., Delegated Regulation (EU) 2020/1182, Delegated Regulation (EU) 2021/643, Delegated Regulation (EU) 2021/849, Delegated Regulation (EU) 2023/1434, Delegated Regulation (EU) 2023/1435, Regulation (EU) 2020/878, Regulation (EC) n. 790/2009, D.Lgs. 105/2015 (Seveso Ter Directive) and s.m.i.

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H332 = Harmful if inhaled.
H373 = May cause damage to organs through prolonged or repeated exposure.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

No hazard to report. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
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13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
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This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R5**
Product name: **CALCULUS ANALYSIS III_R5 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet
Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number
For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Irrit. 2, Eye Irrit. 2, Repr. 1B

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs, or edema.
Warning: this product may damage fertility and may damage the unborn child.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

GHS08

Signal words: Danger

Hazard statements:

H315	Causes skin irritation
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash ... thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water/…
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see ... on this label).
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container to ...

Contains: sodium hydroxide, sodium tetraborate decahydrate

RESTRICTED TO PROFESSIONAL USERS

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
Sodium tetraborate decahydrate		
CAS 1303-96-4 EC 215-540-4 REACH – No.: -- INDEX – No.: 005-011-01-1	1% ≤ x < 5%	Eye Irrit. 2, H319 Repr. 1B, H360FD ATE oral = 2.660,0 mg/kg
Sodium hydroxide		Met. Corr. 1, H290
CAS 1310-73-2 EC 215-185-5 REACH – No.: -- INDEX – No.: 011-002-00-6	1% ≤ x < 2%	Skin Corr. 1A, H314 Skin Irrit. 2, H315 Eye Dam. 1, H318 Eye Irrit. 2, H319 Limiti: Skin Corr. 1A, H314 %C ≥ 15 Skin Irrit, 2, H315 0,1 ≤ %C < 2 Eye Irrit. 2, H319 0,1 ≤ %C < 2

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.
Warning: This product is toxic to skin contact. Consult a physician.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If exposed or concerned: Get medical advice/attention.
If skin irritation occurs: Get medical advice/attention.
If eye irritation persist: get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Use extreme caution when handling or opening the container.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Related to the substances contained:
Sodium tetraborate decahydrate:
TWA (Italy)
Short-term value: 6 mg/m^3
Long-term value: 2 mg/m^3

REL (U.S.A.)
Long-term value: 5 mg/m^3

TLV (U.S.A.)
Short-term value: 6* mg/m^3
Long-term value: 2* mg/m^3

* As an inhalable fraction

DNEL
Dermal DNEL (workers-chronic systemic effects) 3 mg/kg
Inhalation DNEL (workers-chronic systemic effects) 12.8 mg/m3

PPNEC
Freshwater = 2.9 mg/L
Seawater = 2.9 mg/L
STP = 10 mg/L
Soil = 5,7 mg/kg

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (spectacles cage) (EN166).

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Related to contained substances:
sodium tetraborate decahydrate:
Respiratory protection.
Resort to respirators only in case of aerosol or mist formation. In short and minimal exposures use mask; in more intense and longer exposures wear self-contained breathing apparatus.
P2 filter
P1 filter.
The respiratory protection selected must comply with EN 136/140/143/145/149.

Hand protection.
Selection of glove material in consideration of passage times, permeation rates and degradation.
Protective gloves: The selected protective gloves must meet the requirements of REGULATION (EU) 2016/425 and the standards (EN 374) derived from it.
Rubber gloves

Material of gloves.
The glove material must be impermeable and stable against the product/substance/formulation.
Selection of glove material in consideration of breakthrough times, permeation rates and degradation. Selection of suitable gloves depends not only on the material but also on other quality characteristics that vary from one manufacturer to another.
Butyl rubber
Rubber gloves
Lightweight disposable gloves made of PVC or PE
Nitrile rubber

Permeation time of glove material
Request from the glove supplier the precise permeation time which must be observed.
Gloves made of the following materials are suitable for continuous contact:
Butyl rubber
Recommended material thickness: ≥ 0.5 mm
Fluoro rubber (Viton)
Recommended material thickness: ≥ 0.4 mm
Nitrile rubber
Recommended material thickness: ≥ 0.4 mm

Natural rubber (Latex)
Recommended material thickness: ≥ 0.5 mm
Chloroprene rubber
Recommended material thickness: ≥ 0.5 mm
PVC gloves
Recommended material thickness: ≥ 0.5 mm

Eye protection.
Tight-fitting goggles.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information

Appearance	Liquid
Colour	Not determined
Odour	Not determined
Melting point / freezing point	Not determined
Initial boiling point	Not determined
Flammability	Not determined
Lower explosive limit	Not determined
Upper explosive limit	Not determined
Flash point	Not determined
Auto-ignition temperature	Not determined
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Not determined
Partition coefficient: n-octanol/water	Not determined
Vapour pressure	Not determined
Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: if brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: Warning: this product may damage fertility and may damage the unborn child.
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:
Sodium tetraborate decahydrate:
Causes severe eye irritation.
Ingestion: May be harmful if swallowed.
Inhalation: May be harmful if inhaled
Reproductive toxicity May harm fertility. May harm the fetus.
LD50 (rat) Oral (mg/kg body weight) = 2660

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage
HP10 – Toxic for reproduction

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H319 = Causes serious eye irritation.
H360FD = May damage fertility. May damage the unborn child.
H290 = May be corrosive to metals.
H314 = Causes severe skin burns and eye damage.
H315 = Causes skin irritation.
H318 = Causes serious eye damage.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H315 - Causes skin irritation. Classification procedure: Calculation method
H319 = Causes serious eye irritation. Classification procedure: Calculation method.
H360FD - May damage fertility. May damage the unborn child. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R6**
Product name: **CALCULUS ANALYSIS III_R6 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Met. Corr. 1

H290 May be corrosive to metals

The product can be corrosive to metals.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS05

Signal words: Warning

Hazard statements:

H290 May be corrosive to metals.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P390 Absorb spillage to prevent material damage.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	x = Conc. %	Classification 1272/2008 (CLP)
Hydrogen chloride 32%		
CAS 7647-01-0	1% ≤ x < 5%	Met. Corr. 1, H290
EC 231-595-7		Skin Corr. 1B, H314
REACH – No.: --		Eye Dam. 1, H318
INDEX – No.: --		STOT SE 3, H335
		Limits: Met. Corr. 1, H290 %C ≥ 0,032
		Skin Corr. 1A, H314 %C ≥ 8
		Eye Irrit. 2, H319 3,2 ≤ %C < 8
		STOT SE 3, H335 %C ≥ 3,2

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product): Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Related to the substances contained:
Hydrogen chloride:
TLV: 2 ppm (Ceiling value) A4 (Not classifiable as a human carcinogen); (ACGIH 2004).
MAK: 2 ppm 3.0 mg//m^3 Peak limitation category: I(2); Pregnancy risk group: C; (DFG 2004).

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
Not needed for normal use

SKIN PROTECTION
Wear normal work clothing.

EYE PROTECTION
Not needed for normal use

RESPIRATORY PROTECTION
Not needed for normal use

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Related to the substances contained:
Hydrogen chloride 32%:
Eye/face protection: Tight-fitting safety goggles.

Skin protection.
Full contact
Material: Nitrile rubber
Minimum thickness: 0.11 mm
Permeation time: 480 min
Material tested: KCL 741 Dermatril® L)

Spray contact
Material: latex gloves
Minimum thickness: 0.6 mm
Permeation time: 120 min
Material tested: Lapren® (KCL 706 / Aldrich Z677558, Size M)

Physical protection
Acid-resistant protective clothing

Respiratory protection:
Suggested filter type: Filter type E-(P2)

Environmental exposure control.
Do not allow product to enter drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

a) Explosives
- i) sensitivity to shock Irrilevant
- ii) effect of heating under confinement Irrilevant
- iii) effect of ignition under confinement Irrilevant
- iv) sensitivity to impact Irrilevant
- v) sensitivity to friction Irrilevant
- vi) thermal stability Irrilevant
- vii) package Irrilevant

b) Flammable gases
- i) Tci / explosion limits Irrilevant
- ii) fundamental burning velocity Irrilevant

c) Aerosols Irrilevant

d) Oxidising gases Irrilevant

e) Gases under pressure Irrilevant

f) Flammable liquids Irrilevant

g) Flammable solids
- i) burning rate, or burning time as regards metal powders Irrilevant
- ii) statement on whether the wetted zone has been passed Irrilevant

h) Self-reactive substances and mixtures
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power, if applicable Irrilevant

i) Pyrophoric liquids Irrilevant

j) Pyrophoric solids
- i) statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form Irrilevant
- ii) statement on whether pyrophoric properties could change over time Irrilevant

k) Self-heating substances and mixtures

i) statement on whether spontaneous ignition occurs and the maximum temperature rise obtained Irrilevant
ii) results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available Irrilevant

l) Substances and mixtures, which emit f lammable gases in contact with water. The following information may be provided
i) identity of the emitted gas, if known Irrilevant
ii) statement on whether the emitted gas ignites spontaneously Irrilevant
iii) gas evolution rate Irrilevant

m) Oxidising liquids Irrilevant

n) Oxidizing solids Irrilevant

o) Organic peroxides
i) decomposition temperature Irrilevant
ii) detonation properties Irrilevant
iii) deflagration properties Irrilevant
iv) effect of heating under confinement Irrilevant
v) explosive power Irrilevant

p) Corrosive to metals
i) metals that are corroded by the substance or mixture Irrilevant
ii) corrosion rate and statement on whether it refers to steel or aluminium Irrilevant
iii) reference to other sections of the safety data sheet with regard to compatible or incompatible materials Irrilevant

q) Desensitised explosives
i) desensitising agent used Irrilevant
ii) exothermic decomposition energy Irrilevant
iii) corrected burning rate (Ac) Irrilevant
iv) explosive properties of the desensitised explosive in that state Irrilevant

9.2.2. Other safety characteristics

a) mechanical sensitivity: Irrilevant

b) self-accelerating polymerisation temperature: Irrilevant

c) formation of explosible dust/air mixtures: Irrilevant

d) acid/alkaline reserve: Irrilevant

e) evaporation rate: Irrilevant

f) miscibility: Irrilevant

g) conductivity: Irrilevant

h) corrosiveness: Irrilevant

i) gas group: Irrilevant

j) redox potential: Irrilevant

k) radical formation potential: Irrilevant

l) photocatalytic properties: Irrilevant

SECTION 10: Stability and reactivity

10.1. Reactivity

Related to the substances contained:
Hydrogen chloride 32%:
Corrosive in contact with metals.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Related to the substances contained:
Hydrogen chloride 32%:
heating

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = 102.669,4 mg/kg
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met.
(c) severe ocular damage/eye irritation: based on available data, the classification criteria are not met.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:
Hydrogen chloride 32%:
WAYS OF EXPOSURE: The substance can be absorbed into the body by inhalation.
RISKS BY INHALATION: Caused by a leak, a harmful concentration of this gas in air can be reached very quickly.
EFFECTS OF SHORT-TERM EXPOSURE: Rapid evaporation of the liquid may cause frostbite. The substance is corrosive to the eyes, skin and respiratory tract. Inhalation of high concentrations of the gas can cause pneumonia and pulmonary edema, causing reactive airway dysfunction syndrome (RADS) (see Notes). The effects may be delayed. Medical observation is indicated.
EFFECTS OF REPEATED OR LONG-TERM EXPOSURE: The substance may affect the lungs, causing chronic bronchitis. The substance may affect teeth, causing erosion.

ACUTE RISKS/ SYMPTOMS INHALATION Corrosive. Burning sensation. Coughing. Difficulty breathing. Shortness of breath. Sore throat. Symptoms may present late (see Notes).
COUGHING ON CONTACT WITH LIQUID: CONGELATION. corrosive. Severe skin burns. Pain.
EYES Corrosive. Pain. Blurred vision. Severe deep burns.

NOTE: The exposure limit value should not be exceeded at any time during work exposure. Symptoms of pulmonary edema often do not occur for several hours and are aggravated by physical exertion. Therefore, rest and medical observation are essential. Immediate administration of appropriate inhalation therapy by a physician or personnel authorized by him/her should be expected.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible.
Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H290 = May be corrosive to metals.
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.
H335 = May cause respiratory irritation.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H290 = May be corrosive to metals. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
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8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
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13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
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The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.
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SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R7**
Product name: **CALCULUS ANALYSIS III_R7 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Irrit. 2, Eye Irrit. 2

H315 Causes skin irritation.
H319 Causes serious eye irritation.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs,or edema.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

Signal words: Warning

Hazard statements:

H315 Causes skin irritation.
H319 Causes serious eye irritation.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P337+P313 If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
5-Sulfosalicylic acid x 2 H_2O		
CAS 5965-83-3	1% ≤ x < 5%	Skin Corr. 1A, H314
EC 202-555-6		
REACH – No.: --		
--		
INDEX – No.: 8.00691		

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If skin irritation occurs: Get medical advice/attention.
If eye irritation persist: Get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers upright and secure, avoiding the possibility of dropping or knocking. Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (spectacles cage) (EN166).

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	

Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: If brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group

None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H314 = Causes severe skin burns and eye damage.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H315 = Causes skin irritation. Classification procedure : Calculation method.
H319 = Causes serious eye irritation. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R8**
Product name: **CALCULUS ANALYSIS III_R8 (Reagent)**
Chemical Name: Nessler's reagent CAS: 7783-33-7 Index No: 21-0930

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

CAS 7783-33-7 CEE 21-0930

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Acute Tox. 3, Skin Corr. 1A, Eye Dam. 1, Muta 2, STOT RE 2, Aquatic Acute 1, Aquatic Chronic 2

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H341	Suspected of causing genetic defects >state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>
H373	May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H400	Very toxic to aquatic life. (Acute toxicity M-factor = 1).
H411	Toxic to aquatic life with long lasting effects.

Toxic product: do not ingest
Corrosive product: causes severe skin burns and eye damage.
If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
The product is suspected of causing genetic defects.
Warning: This product can cause serious irreversible damages to man's health through prolonged or repeated exposure.
The product is dangerous for the environment as it is very toxic to aquatic organisms.
The product is dangerous to the environment as it is toxic to aquatic life with long lasting effects.

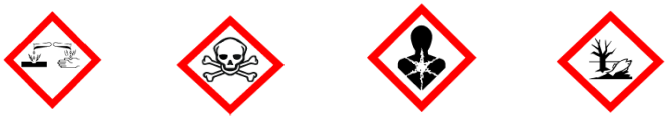
2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



GHS05 GHS06 GHS08 GHS09

Signal words: Danger

Hazard statements:

H301	Toxic if swallowed.
H314	Causes severe skin burns and eye damage.
H341	Suspected of causing genetic defects >state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>
H373	May cause damage to organs <or state all organs affected, if known> through prolonged or repeated exposure <state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard>.
H410	Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/…
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER/doctor/…..
P314	Get medical advice/attention if you feel unwell.
P321	Specific treatment (see ... on this label).
P330	Rinse mouth.
P363	Wash contaminated clothing before use.
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/container to ...

Contains: Nessler's reagent

RESTRICTED TO PROFESSIONAL USERS

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Identification NESSLER's reagent	x = Conc. %	Classification 1272/2008 (CLP)
CAS 7783-33-7 EC: -- REACH – No.: -- INDEX – No.: 21-0930	100%	Met. Corr. 1, H290 Acute Tox. 3, H301 Skin Corr. 1A, H314 Eye Dam. 1, H318 Muta. 2, H341 STOT RE 2, H373 Aquatic Chronic 2, H411 Acute toxicity Factor M = 1 Chronic toxicity Factor M = 1

3.2 Mixtures

Irrilevant.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. CALL A PHYSICIAN. If breathing has stopped, give artificial respiration.

Direct skin contact (of the pure product): Take contaminated clothing immediately off. Consult a physician immediately.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: The product is toxic and can cause serious irreversible damages even following a single exposure, if swallowed. Drink water with egg white; do not give bicarbonate. Absolutely do not induce vomiting or emesis. Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

IF SWALLOWED: immediately call a POISON CENTER/doctor/….
IF exposed or concerned: Get medical advice/attention.
Get medical advice/attention if you feel unwell.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Use extreme caution when handling or opening the container.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
In residential areas do not use on large surfaces.
Do not eat or drink while working.
So not eat, drink or smoke when using this product.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:

Professional uses:
No specific controls provided
Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
Wear mask.

RESPIRATORY PROTECTION
Use adequate protective respiratory equipment (EN 14387:2008).

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = 100,0 mg/kg
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: toxic product: do not ingest.
(b) skin corrosion/dermal irritation: corrosive product: causes severe skin burns and eye damage.
(c) severe ocular damage/eye irritation: corrosive product: causes severe skin burns and eye damage – if brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: the product is suspected of causing genetic defects.
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: Warning: this product may damage fertility and may damage the unborn child.
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: Warning: this product can cause serious irreversible damages to man's health through prolonged or repeated exposure.
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product is dangerous for the environment as it is very toxic to aquatic organisms following acute exposure.
The product is dangerous for the environment as it is toxic to aquatic organisms following acute exposure.

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
Seveso category:
H2 – ACUTE TOXIC
E1 – ENVIRONMENTAL HAZARDS

REGULATION (EU) N. 1357/2014 – waste:
HP5 – Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP8 – Corrosive
HP11 – Mutagenic
HP14 – Ecotoxic

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H290 = May be corrosive to metals.
H301 = Toxic if swallowed.
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.
H341 = Suspected of causing genetic defects .
H373 = May cause damage to organs through prolonged or repeated exposure .
H400 = Very toxic to aquatic life.
H411 = Toxic to aquatic life with long lasting effects.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H301 - Toxic if swallowed. Classification Procedure: Calculation Method
H314 - Causes severe skin burns and eye damage. Classification Procedure: Calculation Method
H318 - Causes serious eye damage Classification Procedure: Calculation Method
H341 - Suspected of causing genetic defects Classification Procedure: Calculation Method
H373 - May cause damage to organs through prolonged or repeated exposure. Classification Procedure: Calculation Method
H400 - Very toxic to aquatic life. Classification Procedure: Calculation Method
H411 - Toxic to aquatic life with long lasting effects. Classification Procedure: Calculation Method

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique

- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R9**
Product name: **CALCULUS ANALYSIS III_R9 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Irrit. 2, Eye Irrit. 2

H315 Causes skin irritation.
H319 Causes serious eye irritation.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs,or edema.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

Signal words: Warning

Hazard statements:

H315	Causes skin irritation.
H319	Causes serious eye irritation.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P337+P313	If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
Sulphuric acid		
CAS 7664-93-9	5% ≤ x < 10%	Met. Corr. 1, H290
EC 231-639-5		Skin Corr. 1A, H314
REACH – No.: --		Eye Dam. 1, H318
INDEX – No.: 016-020-00-8		Limits: Skin Corr. 1A, H314 %C ≥ 15
		Skin Irrit. 2, H315 5 ≤ %C < 15
		Eye Irrit. 2, H319 5 ≤ %C < 15

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product): Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If skin irritation occurs: Get medical advice/attention.
If eye irritation persist: Get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Related to the substances contained:
Sulphuric acid:
TLV: 1 mg/m^3 as TWA 3 mg/m^3 as STEL A2 (Suspected human carcinogen); (ACGIH 2004).
MAK: (Inhalable Fraction) 0.1 mg/m^3 Peak limitation category: I(1); Class of carcinogenicity: 4; Pregnancy risk group: C; (DFG 2004).

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (spectacles cage) (EN166).

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Related to contained substances:
Sulfuric acid:
Eye/face protection
Use eye protection devices tested and approved according to the requirements of appropriate technical standards such as NIOSH (US) or EN 166 (EU) adherent safety goggles
Skin protection. This recommendation applies only to the product identified in the MSDS, supplied by us and for the purpose we determine. When dissolving or mixing with other substances and under conditions other than those established by EN 374, please contact the EC-approved glove supplier (e.g. KCL GmbH, D-36124 Eichenzell, Internet:www.kcl.de).

Full contact
Material: Viton®
Minimum thickness: 0.7 mm
Permeation time:480 min
Material tested: Vitoject® (KCL 890 / Aldrich Z677698, Size M)

Spray contact
Material: butyl rubber
Minimum thickness: 0.7 mm
Permeation time:120 min
Material tested: Butoject® (KCL 898)

Physical protection
Acid-resistant protective clothing

Respiratory protection
Suggested filter type:P2 type filter
The contractor must ensure that maintenance, cleaning, and testing of protective equipment are carried out according to the manufacturer's instructions. These measures must be properly documented.

Environmental exposure control
Do not allow product to enter drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: If brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:
Sulfuric acid:
WAYS OF EXPOSURE: The substance can be absorbed into the body by inhalation of its aerosols and by ingestion.
RISKS BY INHALATION: Evaporation at 20°C is negligible; however, a harmful concentration of airborne particles can be reached rapidly by nebulization.
EFFECTS OF SHORT-TERM EXPOSURE: Corrosive. The substance is very corrosive to the eyes the skin and respiratory tract. Corrosive by ingestion. Inhalation of aerosols of this substance may cause pulmonary edema (see Notes).
EFFECTS OF REPEATED OR LONG-TERM EXPOSURE: Lungs may be damaged by repeated or prolonged exposure to aerosols of this substance. Danger of dental erosion from repeated or prolonged exposure to aerosols of this substance. Strong inorganic acid vapors containing this substance are carcinogenic to humans.
ACUTE HAZARDS/SYMPTOMS
INHALATION: Corrosive. Burning sensation. Sore throat. Coughing. Difficulty breathing. Shortness of breath. Symptoms may present late (see Notes).
CUTE Corrosive. Redness. Pain. Blistering. Severe skin burns.
EYES Corrosive. Redness. Pain. Severe deep burns.
INGESTION Corrosive. Abdominal pain. Burning sensation. Shock or collapse.

NOTE: Symptoms of pulmonary edema often do not occur for several hours and are aggravated by physical exertion. Therefore, rest and medical observation are essential.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Related to contained substances:
sulfuric acid:
The substance is harmful to aquatic organisms.
Acute toxicity M factor = 1
Chronic toxicity M factor = 1

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H290 = May be corrosive to metals.
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H315 = Causes skin irritation. Classification procedure : Calculation method.
H319 = Causes serious eye irritation. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R10**
Product name: **CALCULUS ANALYSIS III_R10 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye Irrit. 2, Aquatic Chronic 3

H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.
The product is dangerous to the environmental as it is harmful to aquatic life with long lasting effects.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

Signal words: Warning

Hazard statements:

H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Supplemental Hazard Statement Code(s): EUH208 – Contains 4-(Methylamino)phenol hemisulfate salt. May produce an allergic reaction.

Precautionary statements:

P264	Wash….thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container to…..

Contains: 4-(Methylamino)phenol hemisulfate salt

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
Citric acid monohydrate		
CAS 5949-29-1	1% ≤ x < 5%	Eye Irrit. 2, H319
EC 201-069-1		STOT SE 3, H335
REACH – No.: 01-2119457026-42-XXXX		
INDEX – No.: C1909		
Sodium Bisulfite	5% ≤ x < 10%	Acute Tox. 4, H302
CAS 7631-90-5		Eye Irrit. 2, H319
EC --		
REACH – No.: --		
INDEX – No.: --		
4-(Methylamino)phenol hemisulfate salt	0,1% ≤ x < 1%	Acute Tox. 4, H302
CAS 55-55-0		Skin Sens. 1, H317
EC 200-237-1		STOT RE 2, H373
REACH – No.: --		Aquatic Chronic 1, H410
INDEX – No.: 650-031-00-4		Acute Toxicity Factor M = 1
		Chronic Toxicity Factor M = 1

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product): Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If eye irritation persist: Get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (spectacles cage) (EN166).

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	

Colour	Not determined
Odour	Not determined
Melting point / freezing point	Not determined
Initial boiling point	Not determined
Flammability	Not determined
Lower explosive limit	Not determined
Upper explosive limit	Not determined
Flash point	Not determined
Auto-ignition temperature	Not determined
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Not determined
Partition coefficient: n-octanol/water	Not determined
Vapour pressure	Not determined
Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = 4.786,1 mg/kg
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product is dangerous for the environment as it is toxic for aquatic organisms following acute exposure.

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H302 = Harmful if swallowed.
H319 = Causes serious eye irritation.
H335 = May cause respiratory irritation.
H317 = May cause an allergic skin reaction.
H373 = May cause damage to organs through prolonged or repeated exposure .
H410 = Very toxic to aquatic life with long lasting effects.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H319 = Causes serious eye irritation. Classification procedure: Calculation method.
H412 = Harmful to aquatic life with long lasting effects. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R11**
Product name: **CALCULUS ANALYSIS III_R11 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet
Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number
For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Irrit. 2, Eye Irrit. 2, Repr. 1B

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours, if brought into contact with skin, it causes significant inflammation with erythema, scabs, or edema.
Warning: this product may damage fertility and may damage the unborn child.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

GHS08

Signal words: Danger

Hazard statements:

H315	Causes skin irritation
H319	Causes serious eye irritation.
H360FD	May damage fertility. May damage the unborn child.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P264	Wash ... thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water/…
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P321	Specific treatment (see ... on this label).
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P405	Store locked up.
P501	Dispose of contents/container to ...

Contains: boric acid, sodium hydroxide

RESTRICTED TO PROFESSIONAL USERS

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

SECTION 4: First aid measures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
BORIC ACID		
CAS 10043-35-3 EC 233-139-2 REACH – No.: 01-2119486683-25-XXXX	1% ≤ x < 3%	Repr. 1B, H360FD ATE oral = 3.450,000 mg/kg
INDEX – No.: 005-007-00-2		
Sodium hydroxide		Met. Corr. 1, H290
CAS 1310-73-2 EC 215-185-5	0,1% ≤ x < 1%	Skin Corr. 1A, H314 Skin Irrit. 2, H315
REACH – No.: --		Eye Dam. 1, H318 Eye Irrit. 2, H319
INDEX – No.: 011-002-00-6		Limiti: Skin Corr. 1A, H314 %C ≥ 15 Skin Irrit, 2, H315 0,1 ≤ %C < 2 Eye Irrit. 2, H319 0,1 ≤ %C < 2

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.
Warning: This product is toxic to skin contact. Consult a physician.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If exposed or concerned: Get medical advice/attention.
If skin irritation occurs: Get medical advice/attention.
If eye irritation persist: get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Use extreme caution when handling or opening the container.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (spectacles cage) (EN166).

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Boric acid:
Eye/face protection :
Use eye protection devices tested and approved according to the requirements of appropriate technical standards such as NIOSH (US) or EN 166 (EU).
Safety glasses.
Skin protection.

Full contact
Material: Nitrile rubber
Minimum thickness: 0.11 mm
Permeation time: 480 min
Material tested: KCL 741 Dermatril® L

Spray contact
Material: nitrile rubber
Minimum thickness: 0.11 mm
Permeation time: 480 min
Material tested: KCL 741 Dermatril® L)

Physical protection
Protective clothing

Respiratory protection:
Required when dust is generated. Our recommendations on respiratory protection filtering are based on the following standards: DIN EN 143, DIN 14387 and other associated standards related to the respiratory protection system used. Suggested filter type: filter type P3

Environmental exposure control
Do not allow product to enter drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	colourless	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: if brought into contact with the skin, the product causes significant inflammation with erythema, scabs, or edema.
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: Warning: this product may damage fertility and may damage the unborn child.
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:
boric acid:
Borate toxicity on humans: ingestion or absorption may cause nausea, vomiting, diarrhea, abdominal cramps, erythematous lesions of the skin and mucous membranes. Additional symptoms include circulatory collapse, tachycardia, cyanosis, delirium, convulsions and coma.

Liver - Irregularities
LD50 Oral (rat) (mg/kg body weight) = 3450

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage
HP10 – Toxic for reproduction

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H360FD = May damage fertility. May damage the unborn child.
H290 = May be corrosive to metals.
H314 = Causes severe skin burns and eye damage.
H315 = Causes skin irritation.
H318 = Causes serious eye damage.
H319 = Causes serious eye irritation.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H315 - Causes skin irritation. Classification procedure: Calculation method
H319 = Causes serious eye irritation. Classification procedure: Calculation method.
H360FD - May damage fertility. May damage the unborn child. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones..

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R12**
Product name: **CALCULUS ANALYSIS III_R12 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye Irrit. 2

H319 Causes serious eye irritation.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

Signal words: Warning

Hazard statements:

H319 Causes serious eye irritation.

Supplemental Hazard Statement Code(s): not applicable.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P337+P313 If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
Ethanol		
CAS 64-17-5	30% ≤ x < 50%	Flam. Liq. 2, H225
EC 200-578-6		Eye Irrit. 2, H319
REACH – No.: 01-2119457610-43-XXXX		ATE oral > 5.000,000 mg/kg
INDEX – No.: 603-002-00-5		ATE dermal > 2.000,000 mg/kg

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product): Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It’s possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If eye irritation persist: Get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.

Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

- Substance: ethanol
DNEL
Systemic effects Long term Workers inhalation = 114 mg/m
Systemic effects Long term Workers dermal = 206 mg/kg bw/day
Systemic effects Short term Workers inhalation = 1900 mg/m^3
PNEC
Sweet water = 0,96 mg/l
sediment Sweet water = 3,6 mg/kg/sediment
Sea water = 0,79 mg/l
sediment Sea water = 2,9 mg/kg/sediment

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (spectacles cage) (EN166).

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Related to contained substances:
Ethanol:
Considering that the use of appropriate technical measures should always take priority over personal protective equipment, ensure good ventilation in the workplace through effective local exhaust ventilation. When choosing personal protective equipment, seek advice from your chemical suppliers if necessary. Personal protective equipment should bear the CE marking attesting to its compliance with applicable standards. Provide emergency shower with visocular tray.

HAND PROTECTION.
Protect hands with category III work gloves (ref. standard EN 374).
For the final choice of work glove material, the following should be considered: compatibility, degradation, breakthrough time and permeation. In the case of preparations, the resistance of work gloves to chemical agents must be verified before use because it cannot be predicted. Gloves have a wear time that depends on the duration and mode of use.
SKIN PROTECTION
Wear long-sleeved work clothes and category I safety footwear for professional use (ref. Directive 89/686/EEC and EN ISO 20344). Wash with soap and water after removing protective clothing. Consider providing antistatic clothing if the work environment presents an explosive hazard.

EYE PROTECTION.
It is recommended to wear airtight protective goggles (ref. standard EN 166).

RESPIRATORY PROTECTION.
If the threshold value (e.g., TLV-TWA) of the substance or one or more of the substances in the product is exceeded, it is recommended to wear a mask with a type A filter, the class (1, 2 or 3) of which should be chosen in relation to the limit concentration of use. (ref. standard EN 14387). If gases or vapors of a different nature and/or gases or vapors with particles (aerosols, fumes, mists, etc.) are present, combined type filters should be provided. The use of respiratory protective means is necessary in case the technical measures taken are not sufficient to limit the worker's exposure to the threshold values taken into consideration. However, the protection offered by masks is limited. In case the substance under consideration is odorless or its odor threshold is higher than the relevant TLV -TWA and in case of emergency, wear an open-circuit self-contained compressed-air breathing apparatus (ref. Standard EN 137) or an air-supplied respirator (ref. Standard EN 138). Refer to EN 529 for the correct choice of respiratory protective equipment.

ENVIRONMENTAL EXPOSURE CONTROLS.

Emissions from production processes, including those from ventilation equipment should be controlled for compliance with environmental protection regulations.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

Related to contained substances:
ethanol:
No particular danger of reaction with other substances under normal conditions of use.
Easily flammable liquid and vapors. Possible formation of explosive vapor/air mixtures.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Related to contained substances:
ethanol:
Avoid overheating. Avoid electrostatic charge buildup. Avoid any source of ignition. Avoid exposure to: heat sources, open flames.
Heat. Sparks. Naked flame. Ignition sources. Direct sunlight.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

Related to contained substances:
ethanol:
LOAEL (oral, rat, 90 days) : 3160 mg/kg bw/day - NOAEL (oral, rat, 90 days) : 1730 mg/kg bw/day.
KINEMATIC VISCOSITY : 1.51898734 mm^2/s

LD50 (rat) Oral (mg/kg body weight) > 5000
LD50 Dermal (rat or rabbit) (mg/kg body weight) > 2000

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Related to contained substances:
ethanol:
Ethanol, ethyl alcohol (64-17-5).
LC50 fish: 13500 - 15300 mg/l/96h (Pimephales promelas)
EC50 Daphnia: 12340 mg/l/48h (Daphnia magna)
ErC50 (algae): 275 mg/l/72h (Chlorella vulgaris)NOEC (chronic): > 10 mg/l/ 21g (Daphnia magna)
NOEC chronic algae: 3240 mg/l (Skeletonema costatum)
Acute toxicity M factor = 1 Chronic toxicity M factor = 1

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

Related to contained substances:
ethanol:
The paraffinic hydrocarbons present can be considered degradable in water and air. They mostly partition into the air. The small part that breaks down in water and does not biodegrade tends to accumulate in fish.
ETHANOL
Solubility in water 1000 - 10000 mg/l
Rapidly degradable.

12.3. Bioaccumulative potential

Related to contained substances:
ethanol:
Partition coefficient: n-octanol/water -0.35

12.4. Mobility in soil

Related to contained substances:
ethanol:
ecology-soil: weak adsorption. The product evaporates quickly in the atmosphere.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) No 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H225 = Highly flammable liquid and vapour.
H319 = Causes serious eye irritation.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H319 = Causes serious eye irritation. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R13**
Product name: **CALCULUS ANALYSIS III_R13 (Reagent)**
Chemical name: Phosphomolybdic acid hydrate CAS: 51429-74-4 EC No: 234-713-5 Index No: 221856

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

CAS: 51429-74-4 EC No: 234-713-5 Index No: 221856

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Corr. 1B, Eye Dam, 1

H314 Causes severe skin burns and eye damage.
H318 Causes serious eye damage.

Corrosive product: causes severe skin burns and eye damage. If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS05

Signal words: Danger

Hazard statements:

H314	Causes severe skin burns and eye damage.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash ... thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+ P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/…
P321	Specific treatment (see ... on this label).
P363	Wash contaminated clothing before reuse.
P405	Store locked up.
P501	Dispose of contents/container to …

Contains:	Phosphomolybdic acid hydrate

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Identification	**x = Conc. %**	**Classification 1272/2008 (CLP)**
Phosphomolybdic acid hydrate		
CAS 51429-74-4	10% ≤ x < 20%	Ox. Liq. 2, H272
EC 234-713-5		Skin Corr. 1B, H314
REACH – No.: --		Eye Dam. 1, H318
INDEX – No.: 221856		

3.2 Mixtures

Irrilevant.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. In case of contact with skin, wash immediately with water. Consult a physician immediately.

Direct contact with eyes (of the pure product): Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Drink water with egg white; do not give bicarbonate. Absolutely do not induce vomiting or emesis. Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No data available

4.3. Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER/doctor/…

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
In residential areas do not use on large surfaces.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers.
Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
Wear mask.

RESPIRATORY PROTECTION
Use adequate protective respiratory equipment (EN 14387:2008).

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices, avoiding spillage into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	crystalline	

Colour	yellow
Odour	Not determined
Melting point / freezing point	Not determined
Initial boiling point	Not determined
Flammability	Not determined
Lower explosive limit	Not determined
Upper explosive limit	Not determined
Flash point	Not determined
Auto-ignition temperature	Not determined
pH	Not determined
Kinematic viscosity	Not determined
Solubility	Not determined
Partition coefficient: n-octanol/water	Not determined
Vapour pressure	Not determined
Density and/or relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information

9.2.1. Information with regard to physical hazard classes

a) Explosives
- i) sensitivity to shock Irrilevant
- ii) effect of heating under confinement Irrilevant
- iii) effect of ignition under confinement Irrilevant
- iv) sensitivity to impact Irrilevant
- v) sensitivity to friction Irrilevant
- vi) thermal stability Irrilevant
- vii) package Irrilevant

b) Flammable gases
- i) Tci / explosion limits Irrilevant
- ii) fundamental burning velocity Irrilevant

c) Aerosols Irrilevant

d) Oxidising gases Irrilevant

e) Gases under pressure Irrilevant

f) Flammable liquids Irrilevant

g) Flammable solids
- i) burning rate, or burning time as regards metal powders Irrilevant
- ii) statement on whether the wetted zone has been passed Irrilevant

h) Self-reactive substances and mixtures
- i) decomposition temperature Irrilevant
- ii) detonation properties Irrilevant
- iii) deflagration properties Irrilevant
- iv) effect of heating under confinement Irrilevant
- v) explosive power, if applicable Irrilevant

i) Pyrophoric liquids Irrilevant

j) Pyrophoric solids
- i) statement on whether spontaneous ignition occurs when poured or within five minutes thereafter, as regards solids in powder form Irrilevant
- ii) statement on whether pyrophoric properties could change over time Irrilevant

k) Self-heating substances and mixtures
- i) statement on whether spontaneous ignition occurs and the maximum temperature rise obtained Irrilevant
- ii) results of screening tests referred to in section 2.11.4.2 of Annex I to Regulation (EC) No 1272/2008, if relevant and available Irrilevant

l) Substances and mixtures, which emit f lammable gases in contact with water. The following information may be provided
- i) identity of the emitted gas, if known Irrilevant

ii) statement on whether the emitted gas ignites spontaneously Irrilevant
iii) gas evolution rate Irrilevant

m) Oxidising liquids Irrilevant

n) Oxidizing solids Irrilevant

o) Organic peroxides
i) decomposition temperature Irrilevant
ii) detonation properties Irrilevant
iii) deflagration properties Irrilevant
iv) effect of heating under confinement Irrilevant
v) explosive power Irrilevant

p) Corrosive to metals
i) metals that are corroded by the substance or mixture Irrilevant
ii) corrosion rate and statement on whether it refers to steel or aluminium Irrilevant
iii) reference to other sections of the safety data sheet with regard to compatible or incompatible materials Irrilevant

q) Desensitised explosives
i) desensitising agent used Irrilevant
ii) exothermic decomposition energy Irrilevant
iii) corrected burning rate (Ac) Irrilevant
iv) explosive properties of the desensitised explosive in that state Irrilevant

9.2.2. Other safety characteristics

a) mechanical sensitivity: Irrilevant

b) self-accelerating polymerisation temperature: Irrilevant

c) formation of explosible dust/air mixtures: Irrilevant

d) acid/alkaline reserve: Irrilevant

e) evaporation rate: Irrilevant

f) miscibility: Irrilevant

g) conductivity: Irrilevant

h) corrosiveness: Irrilevant

i) gas group: Irrilevant

j) redox potential: Irrilevant

k) radical formation potential: Irrilevant

l) photocatalytic properties: Irrilevant

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: Corrosive product: causes severe skin burns and eye damage.
(c) severe ocular damage/eye irritation: Corrosive product: causes severe skin burns and eye damage. - If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace) and s.m.i., Regulation (EC) n. 1907/2006 (REACH) – Annex XIV, Annex XVII and s.m.i., Regulation (EC) n. 1272/2008 (CLP) and s.m.i., Delegated Regulation (EU) 2020/1182, Delegated Regulation (EU) 2021/643, Delegated Regulation (EU) 2021/849, Delegated Regulation (EU) 2023/1434, Delegated Regulation (EU) 2023/1435, Regulation (EU) 2020/878, Regulation (EC) n. 790/2009, D.Lgs. 105/2015 (Seveso Ter Directive) and s.m.i.
REGULATION (EU) N. 1357/2014 – waste:
HP8 – Corrosive

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H272 = May intensify fire; oxidiser.
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H314 = Causes severe skin burns and eye damage. Classification procedure: Calculation method.
H318 = Causes serious eye damage. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.
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SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R14**
Product name: **CALCULUS ANALYSIS III_R14 (Reagent)**
Chemical Name: ammonia, aqueous solution CAS: 1336-21-6 EC No: 215-647-6 Index No: 007-001-01-2 REACH: 01-2119488876-14

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

CAS 1336-21-6 EINECS 215-647-6 CEE 007-001-01-2 REACH: 01-2119488876-14

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin Corr. 1A, Eye Dam. 1, STOT SE 3, Aquatic Acute 1, Aquatic Chronic 2

H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life. (Acute toxicity M-factor = 1).
H411	Toxic to aquatic life with long lasting effects.

Corrosive product: causes severe skin burns and eye damage.
If inhaled the product causes irritations to the respiratory tract.
If brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
The product is dangerous for the environment as it is very toxic to aquatic organisms.
The product is dangerous to the environment as it is toxic to aquatic life with long lasting effects.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS05 GHS07 GHS09

Signal words: Danger

Hazard statements:

H314	Causes severe skin burns and eye damage.
H373	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash ... thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/…..
P312	Call a POISON CENTER/doctor/….if you feel unwell.
P321	Specific treatment (see ... on this label).
P363	Wash contaminated clothing before use.
P391	Collect spillage.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to ...

Contains: ammonium hydroxide solution

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Legislative Decree n. 81 April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and amount of hazardous chemical agent and the method and frequency of exposure to the agent, you only a "moderate risk" for the health and safety of workers and that the measures envisaged in the same legislative decree are sufficient to reduce the risk.

SECTION 3: Composition/information on ingredients

3.1 Substances

Identification	x = Conc. %	Classification 1272/2008 (CLP)
AMMONIUM HYDROXIDE		
CAS 1336-21-6 EC: 215-647-6 REACH – No.: 01-2119488876-14- INDEX – No.: 007-001-01-2	30% ≤ x < 50%	Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Aquatic Chronic 2, H411 Acute Toxicity Factor M = 1 Chronic Toxicity Factor M = 1

3.2 Mixtures

Irrilevant.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. CALL A PHYSICIAN. If breathing has stopped, give artificial respiration.

Direct skin contact (of the pure product): Take contaminated clothing immediately off. Consult a physician immediately.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Drink water with egg white; do not give bicarbonate. Absolutely do not induce vomiting or emesis. Seek medical advice immediately.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

Immediately call a POISON CENTER/doctor/….
Call a POISON CENTER/doctor/ …if you feel unwell.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
In residential areas do not use on large surfaces.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Keep containers tightly closed. Always store in well ventilated areas. Never close the container tightly, leave a chance to vent. Store in a cool place, away from sources of heat and `direct exposure of sunlight

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided
Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
Wear mask.

RESPIRATORY PROTECTION
Use adequate protective respiratory equipment (EN 14387:2008).

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Liquid	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data the classification criteria are not met
(b) skin corrosion/dermal irritation: corrosive product: causes severe skin burns and eye damage.
(c) severe ocular damage/eye irritation: corrosive product: causes severe skin burns and eye damage – if brought into contact with eyes, the product causes serious damages to eyes, such as an opaque cornea or injury to iris.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: Warning: this product may damage fertility and may damage the unborn child.
(h) specific target organ toxicity (STOT) single exposure: if inhaled the product causes irritations to the respiratory tract.
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product is dangerous for the environment as it is very toxic to aquatic organisms following acute exposure.
The product is dangerous for the environment as it is toxic to aquatic organisms following acute exposure.

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Send to authorized discharge plants or for incineration under controlled conditions. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
Seveso category:
E1 – ENVIRONMENTAL HAZARDS

REGULATION (EU) N. 1357/2014 – waste:
HP5 – Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP8 – Corrosive
HP14 – Ecotoxic

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H314 = Causes severe skin burns and eye damage.
H318 = Causes serious eye damage.
H335 = May cause respiratory irritation.
H400 = Very toxic to aquatic life.
H410 = Very toxic to aquatic life with long lasting effects.
H411 = Toxic to aquatic life with long lasting effects.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H314 - Causes severe skin burns and eye damage. Classification Procedure: Calculation Method
H318 - Causes serious eye damage Classification Procedure: Calculation Method
H335 - May cause respiratory irritation. Classification Procedure: Calculation Method
H400 - Very toxic to aquatic life. Classification Procedure: Calculation Method
H411 - Toxic to aquatic life with long lasting effects. Classification Procedure: Calculation Method

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.
.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R15**
Product name: **CALCULUS ANALYSIS III_R15 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is not classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: not hazardous

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: ---

Hazard statements: not hazardous

Supplemental Hazard Statement Code(s): not applicable.

Precautionary statements: none in particular.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards

This document is outside the scope of Article 3 of REACH.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

No substance to signal.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
Not needed for normal use.

SKIN PROTECTION
Wear normal work clothing.

EYE PROTECTION
Not needed for normal use.

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS

Use according to good practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	powder	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
Decomposition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = ∞
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
(c) severe ocular damage/eye irritation: based on available data, the classification criteria are not met
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace) and s.m.i., Regulation (EC) n. 1907/2006 (REACH) – Annex XIV, Annex XVII and s.m.i., Regulation (EC) n. 1272/2008 (CLP) and s.m.i., Delegated Regulation (EU) 2020/1182, Delegated Regulation (EU) 2021/643, Delegated Regulation (EU) 2021/849, Delegated Regulation (EU) 2023/1434, Delegated Regulation (EU) 2023/1435, Regulation (EU) 2020/878, Regulation (EC) n. 790/2009, D.Lgs. 105/2015 (Seveso Ter Directive) and s.m.i.

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

No hazard to report. Classification procedure: Calculation method.
GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates

- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_R16**
Product name: **CALCULUS ANALYSIS III_R16 (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet
Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number
For urgent inquiries refer to NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is not classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: not hazardous

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: ---

Hazard statements: not hazardous

Supplemental Hazard Statement Code(s): EUH210 – Safety data sheet available on request.

Precautionary statements: none in particular.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	x = Conc. %	Classification 1272/2008 (CLP)
SODIUM NITROPRUSSIATE x $2H_2O$		
CAS 13755-38-9	0,1 ≤ x < 1	Acute Tox. 3, H301
EC: 238-373-9		
REACH – No.: --		
INDEX – No.: --		

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water for at least 10 minutes.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear, gloves and protective clothing.

6.1.2 For direct interveners: Wear gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
Not needed for normal use.

SKIN PROTECTION
Wear normal work clothing.

EYE PROTECTION
Not needed for normal use.

RESPIRATORY PROTECTION
Not needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	powder	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
Decomposition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	
Relative vapour density	Not determined	
Particle characteristics	Not determined	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = 22.222,2 mg/kg
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
(c) severe ocular damage/eye irritation: based on available data, the classification criteria are not met
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace) and s.m.i., Regulation (EC) n. 1907/2006 (REACH) – Annex XIV, Annex XVII and s.m.i., Regulation (EC) n. 1272/2008 (CLP) and s.m.i., Delegated Regulation (EU) 2020/1182, Delegated Regulation (EU) 2021/643, Delegated Regulation (EU) 2021/849, Delegated Regulation (EU) 2023/1434, Delegated Regulation (EU) 2023/1435, Regulation (EU) 2020/878, Regulation (EC) n. 790/2009, D.Lgs. 105/2015 (Seveso Ter Directive) and s.m.i.

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3:

H301 = Toxic if swallowed.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

No hazard to report. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.

SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifiers

Code: **3914003_RSC**
Product name: **CALCULUS ANALYSIS III_RSC (Reagent)**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified use: **Reagent for in-vitro diagnostics**
Sectors of use: **professional use**
Use advised against: **do not use for purposes other than those listed**

1.3 Details of the supplier of the safety data sheet

Name **Mascia Brunelli S.p.A.**
Full address **Viale Monza, 272**
District and Country **20128 Milano (Milano)**
Italia

Tel. 0039 02 252091

e-mail address of the competent person,

responsible for the Safety Data Sheet **mktg@masciabrunelli.it**

1.4 Emergency telephone number

For urgent inquiries refer to

NHS111 in England: 111
NHS24 in Scotland: 111
NHS Direct in Wales: 111 or 0845 4647
In an emergency, if the patient has collapsed or is not breathing properly, call 999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) N. 1272/2008:

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Eye Irrit. 2

H319 Causes serious eye irritation.

If brought into contact with eyes, the product causes significant irritations which may last for more than 24 hours.

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:

GHS07

Signal words: Warning

Hazard statements:

H319 Causes serious eye irritation.

Supplemental Hazard Statement Code(s): non applicable.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P337+P313 If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

No information on other hazards.

SECTION 3: Composition/information on ingredients

3.1 Substances

Irrilevant.

3.2 Mixtures

Identification	x = Conc. %	Classification 1272/2008 (CLP)
Ammonium oxalate monohydrate		
CAS 6009-70-7	20% ≤ x < 30%	Acute Tox. 4, H302
EC 611-933-3		Eye Irrit. 2, H319
REACH – No.: 01-2120757936-37-XXXX		
INDEX – No.: 607-007-00-3		
N-Acetil-L-cisteina		
CAS 616-91-1	1 ≤ x < 5	Eye Irrit. 2, H319
EC 210-498-3		
REACH – No.: 01-2120766167-47-XXXX		
INDEX – No.: 1.12422		

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: air the area. Immediately move the patient from the contaminated area and keep him at rest in a well-ventilated area. If you feel unwell seek medical advice.

Direct skin contact (of the pure product): Take contaminated clothing Immediately off. Wash immediately with plenty of running water and possibly with soap, the areas of the body that have, or are only suspected to have, come in contact with the product.

Direct contact with eyes (of the pure product).: Wash immediately and thoroughly with running water, keeping eyelids open for at least 10 minutes, then protect your eyes with a dry sterile gauze. Seek medical advice immediately Do not use eye drops or ointments of any kind before the examination or advice from an oculist.

Ingestion: Not hazardous. It's possible to give activated charcoal in water or liquid paraffin medicine.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If eye irritation persist: get medical advice/attention.

SECTION 5: Firefighting measures

5.1. Extinguishing agents

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: Foam. Dry powder. Carbon dioxide. Water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
Water jets. Use 'water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture

Information not available.

5.3. Advice for firefighters

Use respiratory protection. Safety helmet and full protective clothing. Water spray can be used to protect people engaged in extinguishing. It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if halogenated extinguishing agents (fluobrene, solkane 123, naf etc.) are used. Cool containers with jets of water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For those not taking direct action: Move away from the area surrounding the spill or release. Do not smoke. Wear mask, gloves and protective clothing.

6.1.2 For direct interveners: Wear mask, gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Do not smoke. Provide adequate ventilation. Evacuate the hazard area and, if necessary, consult an expert.

6.2. Environmental precautions

Contain spill with earth or sand. If the product has entered a watercourse in sewers or has contaminated soil or vegetation, notify the appropriate authorities.
Dispose of the residue in accordance with applicable regulations.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment. Rapidly recover the product, wear a mask and protective clothing. Collect the product for reuse, if possible, or for disposal. Possibly absorb it with inert material. Prevent it from entering the sewer system.

6.3.2 For cleanup. After collection, wash the affected area and materials with water.

6.3.3 Other information: None in particular.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors.
Wear protective gloves/protective clothing/eye protection/face protection.
Do not eat or drink while working.
See also section 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabeled containers. Keep containers upright and safe by avoiding the possibility of falls or collisions. Store in a cool place, away from sources of heat and `direct exposure of sunlight.

7.3. Specific end use(s)

Professional uses:
Handle with caution.
Store in ventilated place and away from heat sources.
Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available.

8.2. Exposure controls

Suitable engineering controls:
Professional uses:
No specific controls provided

Personal protective measures:

HAND PROTECTION
When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

SKIN PROTECTION
When handling the pure product wear full protective skin clothing.

EYE PROTECTION
When handling the pure product use safety glasses (Spectacles cage) (EN166).

RESPIRATORY PROTECTION
No needed for normal use.

THERMAL HAZARDS
No Hazard to report

ENVIRONMENTAL EXPOSURE CONTROLS
Use according to good working practices to avoid pollution into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	Powder	
Colour	Not determined	
Odour	Not determined	
Melting point / freezing point	Not determined	
Initial boiling point	Not determined	
Flammability	Not determined	
Lower explosive limit	Not determined	
Upper explosive limit	Not determined	
Flash point	Not determined	
Auto-ignition temperature	Not determined	
pH	Not determined	
Kinematic viscosity	Not determined	
Solubility	Not determined	
Partition coefficient: n-octanol/water	Not determined	
Vapour pressure	Not determined	
Density and/or relative density	Not determined	

Relative vapour density	Not determined
Particle characteristics	Not determined

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Irrilevant.

9.2.2. Other safety characteristics

Irrilevant.

SECTION 10: Stability and reactivity

10.1. Reactivity

No reactivity hazards.

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions.

10.4. Conditions to avoid

Nothing to report.

10.5. Incompatible materials

Nothing in particular.

10.6. Hazardous decomposition products

Does not decompose when used for its intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

ATE(mix) oral = 2.083,3 mg/kg
ATE(mix) dermal = ∞
ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met
(b) skin corrosion/dermal irritation: based on available data, the classification criteria are not met
(c) severe ocular damage/eye irritation: If brought into contact with eyes, the product, causes significant irritations which may last for more than 24 hours.
(d) respiratory or skin sensitization: based on available data the classification criteria are not met
(e) germ cell mutagenicity: based on available data the classification criteria are not met
(f) carcinogenicity: based on available data the classification criteria are not met
(g) reproductive toxicity: based on available data the classification criteria are not met
(h) specific target organ toxicity (STOT) single exposure: based on available data the classification criteria are not met
(i) specific target organ toxicity (STOT) repeated exposure: based on available data the classification criteria are not met
(j) aspiration hazard: based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

11.2.2. Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Use according to good working practices, avoiding dispersing the product into the environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on the available data, no PBT or vPvB substances are present in accordance with Regulation (EC) 1907/2006, annex XIII.

12.6. Endocrine disrupting properties

Based on available data, there are no substances that interfere with the Endocrine System in accordance with Regulation (EU) 2017/2100

12.7. Other adverse effects

No adverse effects observed

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with current regulations. Any product residues should be disposed of according to current regulations by contacting authorized companies. Recover if possible. Operate according to current local or national regulations.

SECTION 14: Transport information

14.1. UN number or ID number
The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.2. UN proper shipping name
None

14.3. Transport hazard class(es)
None

14.4. Packing group
None

14.5. Environmental hazards
None

14.6. Special precautions for user
No data available

14.7. Maritime transport in bulk according to IMO instruments
There is no provision for bulk transport

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

D.Lgs 3/2/1997 No. 52 (Classification, packaging and labeling of dangerous substances), D.Lgs 14/3/2003 No. 65 (Classification, packaging and labeling of dangerous preparations), D.Lgs 81/08 (Consolidated text on the protection of health and safety in the workplace), D. M. 03/04/2007 (Implementation of Directive No. 2006/8/EC), Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008 (CLP), Regulation (EC) No. 790/2009, Legislative Decree 105/2015 (Seveso Ter Directive), Regulation (EU) 2019/1021, Regulation (EU) 2020/878.
REGULATION (EU) N. 1357/2014 – waste:
HP4 – Irritant – skin irritation and eye damage

Substances on Candidate List (art.59 REACH).
Based on available data, there are no SVHC substances present.

15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16: Other information

Description of the hazard statements exposed to point 3
H302 = Harmful if swallowed.
H319 = Causes serious eye irritation.

Classification and procedure used to derive it under Regulation (EC)1272/2008 [CLP] in relation to mixtures:

Classification according to Regulation (EC) Nr. 1272/2008

H319 = Causes serious eye irritation. Classification procedure: Calculation method.

GENERAL BIBLIOGRAPHY
1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EC) 758/2013 of the European Parliament
4. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
7. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
8. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
9. Regulation (EU) 517/2013 of Council
10. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
11. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
12. Regulation (EU) 2015/491 of the European Parliament
13. Regulation (EU) No. 1297/2014 of the Commission
14. Regulation (EC) 528/2012 of the European Parliament and subsequent updates
15. Regulation (EC) 648/2004 of the European Parliament and subsequent updates
- The Merck Index.
- Handling Chemical Safety
- Niosh – Registry of Toxic Effects of Chemical Substances
- INRS - Fiche Toxicologique
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

This SDS replaces and cancels all previous ones.