



Safety data sheet

According to 1907/2006/EC (REACH), 453/2010/EU, 2015/830/EU

BIOLABO SAS - STONE ANALYSIS SET Positive and Negative Controls - REF95315 R1 1 x 5.5 g FDS 95315 1

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** BIOLABO SAS - STONE ANALYSIS SET Positive and Negative Controls - REF95315
R1 1 x 5.5 g
FDS 95315 1
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: In vitro diagnostic. For professional use only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:** BIOLABO SAS
Les Hautes Rives
02160 Maizy - France
Phone.: 0323251550 -
Fax: 0323256256
info@biolabo.fr
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 (08h00-18h00), ORFILA (33)
(0)145 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

Directive 67/548/EC and Directive 1999/45/EC:

This product was classified in accordance with Directive 67/548/EC and Directive 1999/45/EC, adapting the requirements to Regulation (EC) n°1907/2006 (REACH regulation).

Xn: R21/22 - Harmful in contact with skin and if swallowed

CLP Regulation (EC) n° 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) n° 1272/2008.

Acute Tox. 4: Acute toxicity, Category 4, H302+H312

2.2 Label elements:

Directive 67/548/EC and Directive 1999/45/EC:

In accordance with the legislation, the elements on the label are as follows:



R Phrases:

R21/22: Harmful in contact with skin and if swallowed

S Phrases:

S36/37: Wear suitable protective clothing and gloves

Supplementary information:

Non-applicable

Substances that contribute to the classification:

oxalate de calcium

CLP Regulation (EC) n° 1272/2008:

Warning



Hazard statements:

Acute Tox. 4: H302+H312 - Harmful if swallowed or in contact with skin

Precautionary statements:

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SECTION 2: HAZARDS IDENTIFICATION (continue)

P264: Wash thoroughly after use
P270: Do not eat, drink or smoke when using this product
P280: Wear protective gloves/protective clothing/eye protection/face protection
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302+P352: IF ON SKIN: Wash with plenty of water
P312: Call a POISON CENTER or doctor/physician if you feel unwell
P330: Rinse mouth
P501: Dispose of contents and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively

Substances that contribute to the classification

oxalate de calcium

2.3 Other hazards:

Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Non-applicable

3.2 Mixture:

Chemical description: Mixture of substances

Components:

In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

| Identification | Chemical name/Classification | Concentration |
|-----------------------|--|---------------|
| CAS: 5794-28-5 | oxalate de calcium Self-classified | 25 - <50 % |
| EC: Non-applicable | Directive 67/548/EC Xn: R21/22 | |
| Index: Non-applicable | Regulation 1272/2008 Acute Tox. 4: H302+H312 - Warning | |
| REACH Non-applicable | | |

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Request medical assistance immediately, showing the SDS of this product. Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. In the case of loss of consciousness do not administer anything orally unless supervised by a doctor. Rinse out the mouth and throat, as they may have been affected during ingestion. Keep the person affected at rest.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

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SECTION 4: FIRST AID MEASURES (continue)

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

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SECTION 7: HANDLING AND STORAGE (continue)

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.



B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the professional exposure limits are exceeded.





C.- Specific protection for the hands

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|---|---|---|--|
|  Mandatory hand protection | NON-disposable chemical protective gloves |  | EN 374-1:2003 EN 374-3:2003/AC:2006 EN 420:2003+A1:2009 | The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin. |



D.- Ocular and facial protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|-----------|---|---|---|
|  Mandatory face protection | Face mask |  | EN 166:2001 EN 167:2001 EN 168:2001 EN ISO 4007:2012 | Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. |

E.- Bodily protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|---|---|---|--|---|
|  Mandatory complete body protection | Disposable clothing for protection against chemical risks |  | EN 13034:2005+A1:2009 EN 168:2001 EN ISO 13982-1:2004/A1:2010 EN ISO 6529:2001 EN ISO 6530:2005 EN 464:1994 | For professional use only. Clean periodically according to the manufacturer's instructions. |
|  Mandatory foot protection | Safety footwear for protection against chemical risk |  | EN ISO 20345:2011 EN 13832-1:2006 | Replace boots at any sign of deterioration. |

F.- Additional emergency measures

| Emergency measure | Standards | Emergency measure | Standards |
|---|--------------------------------|--|-------------------------------|
|  Emergency shower | ANSI Z358-1 ISO 3864-1:2002 |  Eyewash stations | DIN 12 899 ISO 3864-1:2002 |

Environmental exposure controls:

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

| | |
|--------------------------|--------------------------------|
| Physical state at 20 °C: | Solid |
| Appearance: | Crystalline |
| Color: | <input type="checkbox"/> White |
| Odor: | Not available |

Volatility:

| | |
|--|------------------|
| Boiling point at atmospheric pressure: | Non-applicable * |
| Vapour pressure at 20 °C: | Non-applicable * |
| Vapour pressure at 50 °C: | Non-applicable * |
| Evaporation rate at 20 °C: | Non-applicable * |

Product description:

| | |
|--|------------------|
| Density at 20 °C: | Non-applicable * |
| Relative density at 20 °C: | Non-applicable * |
| Dynamic viscosity at 20 °C: | Non-applicable * |
| Kinematic viscosity at 20 °C: | Non-applicable * |
| Kinematic viscosity at 40 °C: | Non-applicable * |
| Concentration: | Non-applicable * |
| pH: | Non-applicable * |
| Vapour density at 20 °C: | Non-applicable * |
| Partition coefficient n-octanol/water 20 °C: | Non-applicable * |
| Solubility in water at 20 °C: | Non-applicable * |
| Solubility properties: | Non-applicable * |
| Decomposition temperature: | Non-applicable * |
| Melting point/freezing point: | Non-applicable * |

Flammability:

| | |
|---------------------------|------------------------|
| Flash Point: | Non Flammable (>60 °C) |
| Autoignition temperature: | Non-applicable * |
| Lower flammability limit: | Non-applicable * |
| Upper flammability limit: | Non-applicable * |

9.2 Other information:

| | |
|---------------------------|------------------|
| Surface tension at 20 °C: | Non-applicable * |
| Refraction index: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

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SECTION 10: STABILITY AND REACTIVITY (continue)

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight | Humidity |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Combustive materials | Combustible materials | Others |
|----------------|----------------|----------------------|-----------------------|-------------------------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Avoid alkalis or strong bases |

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion:

- Acute toxicity: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes:

- Contact with the skin: Above all, may have harmful effects for health if the product is absorbed through the skin. For more information on the secondary effects of contact with the skin see section 2.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensibilizing effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT)-time exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

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SECTION 11: TOXICOLOGICAL INFORMATION (continue)

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

| Identification | Acute toxicity | | Genus |
|--------------------|-----------------|------------------|-------|
| | LD50 oral | 500 mg/kg (ATEi) | |
| oxalate de calcium | LD50 dermal | 1100 mg/kg | |
| CAS: 5794-28-5 | LC50 inhalation | Non-applicable | |
| EC: Non-applicable | | | |

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

| Code | Description | Waste class (Regulation (EU) No 1357/2014) |
|-----------|--|--|
| 16 05 06* | Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals | Dangerous |

Type of waste (Regulation (EU) No 1357/2014):

HP6 Acute Toxicity

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

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SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Texts of the legislative phrases mentioned in section 2:

H302+H312: Harmful if swallowed or in contact with skin

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

Directive 67/548/EC and Directive 1999/45/EC:

R21/22: Harmful in contact with skin and if swallowed

CLP Regulation (EC) n° 1272/2008:

Acute Tox. 4: H302+H312 - Harmful if swallowed or in contact with skin

Classification procedure:

Acute Tox. 4: Calculation method

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

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SECTION 16: OTHER INFORMATION (continue)

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
CL50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol–water partition coefficient
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -



Safety data sheet

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** BIOLABO SAS - STONE ANALYSIS SET Positive and Negative Controls - REF95315 R2 1 x 5.5 g
FDS 95315 2
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: In vitro diagnostic. For professional use only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:** BIOLABO SAS
Les Hautes Rives
02160 Maizy - France
Phone.: 0323251550 -
Fax: 0323256256
info@biolabo.fr
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 (08h00-18h00), ORFILA (33) (0)145 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
Directive 67/548/EC and Directive 1999/45/EC:
In accordance with Directive 67/548/EC and Directive 1999/45/EC, the product is not classified as dangerous.
CLP Regulation (EC) n° 1272/2008:
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**
Directive 67/548/EC and Directive 1999/45/EC:
In accordance with the legislation, the elements on the label are as follows:
Not classified as dangerous. Safety data sheet available to professional users that request it.
CLP Regulation (EC) n° 1272/2008:
None
- 2.3 Other hazards:**
Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Non-applicable
- 3.2 Mixture:**
Chemical description: Mixture of substances
Components:
None of the substances contained in the mixture are above the values fixed in Annex II of Regulation (EC) n°1907/2006

SECTION 4: FIRST AID MEASURES

- 4.1 Description of first aid measures:**
Consult a doctor in case of discomfort with this Safety data Sheet.
- By inhalation:**
In case of symptoms, move the person affected into fresh air.
- By skin contact:**
In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

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SECTION 4: FIRST AID MEASURES (continue)

By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor with the SDS of this product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable, low risk of fire by the inflammability characteristics of the product in normal conditions of storage, manipulation and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

5.2 Special hazards arising from the substance or mixture:

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

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Safety data sheet

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SECTION 7: HANDLING AND STORAGE (continue)

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

8.2 Exposure controls:

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.



B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the professional exposure limits are exceeded.



C.- Specific protection for the hands

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|---------------------------------------|---|--------------|---|
|  Mandatory hand protection | Protective gloves against minor risks |  | | Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374. |

D.- Ocular and facial protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|--|---|---|---------------------------------|---|
|  Mandatory face protection | Panoramic glasses against liquid splash |  | EN 166:2001 EN ISO 4007:2012 | Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. |

E.- Bodily protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|-----------|----------------------|---|-------------------|----------------------------|
| | Work clothing |  | | For professional use only. |
| | Anti-slip work shoes |  | EN ISO 20347:2012 | None |

F.- Additional emergency measures

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

| | |
|--------------------------|--------------------------------|
| Physical state at 20 °C: | Solid |
| Appearance: | Crystalline |
| Color: | <input type="checkbox"/> White |
| Odor: | Not available |

Volatility:

| | |
|--|------------------|
| Boiling point at atmospheric pressure: | Non-applicable * |
| Vapour pressure at 20 °C: | Non-applicable * |
| Vapour pressure at 50 °C: | Non-applicable * |
| Evaporation rate at 20 °C: | Non-applicable * |

Product description:

| | |
|--|------------------------|
| Density at 20 °C: | 1773 kg/m ³ |
| Relative density at 20 °C: | 1,773 |
| Dynamic viscosity at 20 °C: | Non-applicable * |
| Kinematic viscosity at 20 °C: | Non-applicable * |
| Kinematic viscosity at 40 °C: | Non-applicable * |
| Concentration: | Non-applicable * |
| pH: | Non-applicable * |
| Vapour density at 20 °C: | Non-applicable * |
| Partition coefficient n-octanol/water 20 °C: | Non-applicable * |
| Solubility in water at 20 °C: | Non-applicable * |
| Solubility properties: | Non-applicable * |
| Decomposition temperature: | Non-applicable * |
| Melting point/freezing point: | Non-applicable * |

Flammability:

| | |
|---------------------------|------------------------|
| Flash Point: | Non Flammable (>60 °C) |
| Autoignition temperature: | Non-applicable * |
| Lower flammability limit: | Non-applicable * |
| Upper flammability limit: | Non-applicable * |

9.2 Other information:

| | |
|---------------------------|------------------|
| Surface tension at 20 °C: | Non-applicable * |
| Refraction index: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

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SECTION 10: STABILITY AND REACTIVITY (continue)

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight | Humidity |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Combustive materials | Combustible materials | Others |
|----------------|----------------|----------------------|-----------------------|-------------------------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Avoid alkalis or strong bases |

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

LD50 oral > 2000 mg/kg (rat)

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Cutaneous: Based on available data, the classification criteria are not met

F- Specific target organ toxicity (STOT)-time exposure:

Based on available data, the classification criteria are not met

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

H- Aspiration hazard:

Based on available data, the classification criteria are not met

Other information:

Non-applicable

Specific toxicology information on the substances:

Not available

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SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

| Code | Description | Waste class (Regulation (EU) No 1357/2014) |
|----------|--|--|
| 16 05 09 | Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08 | Non dangerous |

Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

Specific provisions in terms of protecting people or the environment:

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SECTION 15: REGULATORY INFORMATION (continue)

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

Directive 67/548/EC and Directive 1999/45/EC:

Non-applicable

CLP Regulation (EC) n° 1272/2008:

Non-applicable

Classification procedure:

Non-applicable

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol–water partition coefficient

Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -



Safety data sheet

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** BIOLABO SAS - STONE ANALYSIS SET Positive and Negative Controls - REF95315 R3 1 x 5.5 g
FDS 95315 3
D-mannitol
- CAS: 69-65-8
EC: 200-711-8
Index: Non-applicable
REACH: Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: In vitro diagnostic. For professional use only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:** BIOLABO SAS
Les Hautes Rives
02160 Maizy - France
Phone.: 0323251550 -
Fax: 0323256256
info@biolabo.fr
www.biolabo.fr
- 1.4 Emergency telephone number:** BIOLABO (33) (0) 323251550 (08h00-18h00), ORFILA (33) (0)145 42 59 59

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
Directive 67/548/EC and Directive 1999/45/EC:
In accordance with Directive 67/548/EC and Directive 1999/45/EC, the product is not classified as dangerous.
CLP Regulation (EC) n° 1272/2008:
The product is not classified as dangerous according to CLP Regulation (EC) n° 1272/2008.
- 2.2 Label elements:**
Directive 67/548/EC and Directive 1999/45/EC:
In accordance with the legislation, the elements on the label are as follows:
Not classified as dangerous. Safety data sheet available to professional users that request it.
CLP Regulation (EC) n° 1272/2008:
None
- 2.3 Other hazards:**
Non-applicable

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:**
Chemical description: Mixture of substances
Components:
In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

| Identification | Chemical name/Classification | Concentration |
|--|--|---------------|
| CAS: 69-65-8 EC: 200-711-8 Index: Non-applicable REACH Non-applicable | D-mannitol Not classified Directive 67/548/EC Regulation 1272/2008 | 100 % |

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 and 16.

- 3.2 Mixture:**
Non-applicable

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SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

Consult a doctor in case of discomfort with this Safety data Sheet.

By inhalation:

In case of symptoms, move the person affected into fresh air.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of modifications on the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety data Sheet

By eye contact:

Rinse with water until the product has been eliminated. In case of problems, consult a doctor with the SDS of this product.

By ingestion/aspiration:

In case of consumption in large quantities, it is recommended to seek medical assistance.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Product is non-flammable, low risk of fire by the inflammability characteristics of the product in normal conditions of storage, manipulation and use. In the case of the existence of sustained combustion as a result of improper manipulation, storage or use any type of extinguishing agent can be used (ABC Powder, water,...)

5.2 Special hazards arising from the substance or mixture:

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Sweep up and shovel product or other means and place in container for reuse (preferred) or disposal

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

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SECTION 7: HANDLING AND STORAGE (continue)

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Due to its non-flammable nature, the product does not present a fire risk under normal conditions of storage, manipulation and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the work environment

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the professional exposure limits are exceeded.

C.- Specific protection for the hands

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|-------------------------------|---------------------------------------|-----------------|--------------|---|
| Mandatory hand protection | Protective gloves against minor risks | CE CAT I | | Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374. |

D.- Ocular and facial protection

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|-------------------------------|---|------------------|---------------------------------|---|
| Mandatory face protection | Panoramic glasses against liquid splash | CE CAT II | EN 166:2001 EN ISO 4007:2012 | Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. |

E.- Bodily protection

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Safety data sheet

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continue)

| Pictogram | PPE | Labelling | CEN Standard | Remarks |
|-----------|----------------------|-----------|-------------------|----------------------------|
| | Work clothing | | | For professional use only. |
| | Anti-slip work shoes | | EN ISO 20347:2012 | None |

F.- Additional emergency measures

| Emergency measure | Standards | Emergency measure | Standards |
|----------------------|--------------------------------|----------------------|-------------------------------|
| Emergency shower | ANSI Z358-1 ISO 3864-1:2002 | Eyewash stations | DIN 12 899 ISO 3864-1:2002 |

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Solid
 Appearance: Not available
 Color: Not available
 Odor: Not available

Volatility:

Boiling point at atmospheric pressure: Non-applicable *
 Vapour pressure at 20 °C: Non-applicable *
 Vapour pressure at 50 °C: Non-applicable *
 Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: 1489 kg/m³
 Relative density at 20 °C: 1,489
 Dynamic viscosity at 20 °C: Non-applicable *
 Kinematic viscosity at 20 °C: Non-applicable *
 Kinematic viscosity at 40 °C: Non-applicable *
 Concentration: Non-applicable *
 pH: Non-applicable *
 Vapour density at 20 °C: Non-applicable *
 Partition coefficient n-octanol/water 20 °C: Non-applicable *
 Solubility in water at 20 °C: Non-applicable *
 Solubility properties: Non-applicable *
 Decomposition temperature: Non-applicable *
 Melting point/freezing point: 166 °C

*Not relevant due to the nature of the product, not providing information property of its hazards.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continue)

Flammability:

| | |
|---------------------------|------------------------|
| Flash Point: | Non Flammable (>60 °C) |
| Autoignition temperature: | Non-applicable * |
| Lower flammability limit: | Non-applicable * |
| Upper flammability limit: | Non-applicable * |

9.2 Other information:

| | |
|---------------------------|------------------|
| Surface tension at 20 °C: | Non-applicable * |
| Refraction index: | Non-applicable * |

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

| Shock and friction | Contact with air | Increase in temperature | Sunlight | Humidity |
|--------------------|------------------|-------------------------|----------------|----------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |

10.5 Incompatible materials:

| Acids | Water | Combustive materials | Combustible materials | Others |
|----------------|----------------|----------------------|-----------------------|-------------------------------|
| Not applicable | Not applicable | Not applicable | Not applicable | Avoid alkalis or strong bases |

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

LD50 oral > 2000 mg/kg (rat)

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A.- Ingestion:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B- Inhalation:

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C- Contact with the skin and the eyes:

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

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SECTION 11: TOXICOLOGICAL INFORMATION (continue)

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Cutaneous: Based on available data, the classification criteria are not met

F- Specific target organ toxicity (STOT)-time exposure:

Based on available data, the classification criteria are not met

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

H- Aspiration hazard:

Based on available data, the classification criteria are not met

Other information:

Non-applicable

Specific toxicology information on the substances:

| Identification | Acute toxicity | | Genus |
|----------------|----------------|----------------|-------|
| | LD50 oral | LD50 dermal | |
| D-mannitol | 13500 mg/kg | Non-applicable | Rat |
| CAS: 69-65-8 | Non-applicable | Non-applicable | |
| EC: 200-711-8 | Non-applicable | Non-applicable | |

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Non-applicable

12.6 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

| Code | Description | Waste class (Regulation (EU) No 1357/2014) |
|----------|--|--|
| 16 05 09 | Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08 | Non dangerous |

Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) n°1907/2006 (REACH) the community or state provisions related to waste management are stated

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SECTION 13: DISPOSAL CONSIDERATIONS (continue)

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII, REACH):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

Modifications related to the previous security card which concerns the ways of managing risks. :

Non-applicable

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

Directive 67/548/EC and Directive 1999/45/EC:

Non-applicable

CLP Regulation (EC) n° 1272/2008:

Non-applicable

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://esis.jrc.ec.europa.eu>

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

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SECTION 16: OTHER INFORMATION (continue)

ADR: European agreement concerning the international carriage of dangerous goods by road
IMDG: International maritime dangerous goods code
IATA: International Air Transport Association
ICAO: International Civil Aviation Organisation
COD: Chemical Oxygen Demand
BOD5: 5-day biochemical oxygen demand
BCF: Bioconcentration factor
LD50: Lethal Dose 50
CL50: Lethal Concentration 50
EC50: Effective concentration 50
Log-POW: Octanol–water partition coefficient
Koc: Partition coefficient of organic carbon

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -