Revision nr. 1
Dated 22/07/2024
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Distributed by:

Omnident Dental- Handelsgesellschaft mbH Gutenbergring 5, 63110 Rodgau

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# **Safety Data Sheet**

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

# SECTION 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name

901278 - 219273 Smart Alginat mango - chromatic alginate

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

		J		
Identified Uses	Industrial	Professional	Consumer	
Non-chromatic alginate for dental impressions.	-	✓	-	

#### Uses Advised Against

All uses not indicated in the identified uses.

#### 1.3. Details of the supplier of the safety data sheet

Name LASCOD S.p.A. Full address VIA LUIGI LONGO 18

District and Country 50019 SESTO FIORENTINO (FI)

Italv

tel. +39 055 421 5768

e-mail address of the competent person

responsible for the Safety Data Sheet Supplier:

info@lascod.it LASCOD S.p.A.

#### 1.4. Emergency telephone number

For urgent inquiries refer to

LASCOD S.p.A. +39 055 421 5768 (08:00 - 17:00, Monday to Friday, Italian time zone) (AT): +43 1 406 43 43, (BE): +32 070/245.245, (BG): +359 2 9154 233, (CY): 1401, (HR): +385 1-23-48-342,112, (DK): +45 8212 1212, (EE): 16662, 112, (FI): 0800 147 111, 09 471 977, (FR): +33 (0)1 45 42 59 59, (DE): +49 030 - 192 40, +49 0228 - 192 40, +49 0361 - 730 730, +49 761 - 192 40, +49 0551 - 192 40, +49 06131 - 192 40, +49 06131 - 192 40, (GR): 0030 210 7793777, (IE): +353 01 837 9964, (IS): +354 543 2222, (LV): 112, +371 67042473, (LI): +43 1 406 43 43, (LT): +370 (5) 236 2052, (LU): (+352) 8002 5500, (MT): 112, (NO): +47 22 59 13 00, (NL): +31 (0)88 755 8000, (PL): 112, (PT): +351 800 250 250, (GB): 111, (CZ): +420 224 919 293, +420 224 915 402, (RO): +40 215992300, 021 112, (SK): +421 2 5477 4166, (SI): 112, (ES): +34 91 562 04 20, (SE): 112, (CH): 145, (HU): +36-80-20-11-99

#### **SECTION 2. Hazards identification**

# 2.1. Classification of the substance or mixture

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:

Specific target organ toxicity - repeated exposure, category 2 H373

May cause damage to organs through prolonged or repeated

exposure.

Eye irritation, category 2

H319

Causes serious eye irritation.

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#### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:





Signal words: Warning

Hazard statements:

H373 May cause damage to organs through prolonged or repeated exposure.

H319 Causes serious eye irritation.

Precautionary statements:

P280 Wear eye protection / face protection.

P337+P313 If eye irritation persists: Get medical advice / attention.

Contains: DIATOMITE

#### 2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%. The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

# **SECTION 3. Composition/information on ingredients**

#### 3.2. Mixtures

Contains:

Identification x = Conc. % Classification (EC) 1272/2008 (CLP)

DIATOMITE

INDEX - 70 ≤ x < 85 STOT RE 2 H373

EC 272-489-0 CAS 68855-54-9

REACH Reg. 01-2119488518-22

**DIPOTASSIUM HEXAFLUOROTITANATE** 

INDEX -  $1 \le x < 3$  Acute Tox. 4 H302, Eye Dam. 1 H318

LD50 Oral: 324 mg/kg EC 240-969-9

CAS 16919-27-0

REACH Reg. 01-2119978268-20

The full wording of hazard (H) phrases is given in section 16 of the sheet.

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### **SECTION 4. First aid measures**

#### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present, if the situation allows you to carry out the operation easily. Wash immediately and abundantly with water for at least 15 minutes, opening the eyelids well. Consult a doctor immediately.

SKIN: Remove all contaminated clothing immediately. Wash immediately and abundantly with running water. If symptoms occur, consult a doctor.

INGESTION: Rinse mouth with water. Do not induce vomiting unless specifically authorized by your doctor. Do not give anything by mouth if the person is unconscious. If symptoms occur, consult a doctor.

INHALATION: Move the subject to fresh air, away from the accident site. In case of respiratory symptoms, keep the victim in a position comfortable for breathing. If necessary administer oxygen. Consult a doctor immediately.

#### Rescuer protection

It is good practice for the rescuer who helps a person who has been exposed to a chemical substance or mixture to wear personal protective equipment. The nature of these protections depends on the hazard of the substance or mixture, the mode of exposure and the extent of contamination. In the absence of other more specific indications, it is recommended to use disposable gloves in case of possible contact with biological liquids. For the type of PPE suitable for the characteristics of the substance or mixture, refer to section 8.

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

EYES: irritation, redness and tearing. INHALATION: May cause lung damage.

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

If you experience symptoms, consult a doctor immediately.

Means to have available in the workplace for specific and immediate treatment Running water for skin and eye washing.

# **SECTION 5. Firefighting measures**

### 5.1. Extinguishing media

#### SUITABLE EXTINGUISHING MEANS

The extinguishing media are traditional ones: foam, chemical powder, carbon dioxide. For product leaks and spills that have not ignited, water spray can be used to disperse flammable vapors and protect those trying to stop the leak.

UNSUITABLE EXTINGUISHING MEANS

Do not use water jets.

Water is not effective at extinguishing fire, however, it can be used to cool closed containers exposed to flame, preventing explosions and explosions.

#### 5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products.

#### 5.3. Advice for firefighters

#### SPECIFIC PROTECTIVE MEANS

Wear self-contained breathing apparatus and full heat and flame resistant protective suits.

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# **SECTION 6. Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

#### 6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

#### 6.3. Methods and material for containment and cleaning up

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

#### 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

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

### 7.2. Conditions for safe storage, including any incompatibilities

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

#### 7.3. Specific end use(s)

Refer to the uses identified in section 1.2. For applications other than those described, contact the supplier.

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# **SECTION 8. Exposure controls/personal protection**

#### 8.1. Control parameters

**DIPOTASSIUM HEXAFLUOROTITANATE** 

Predicted no-effect concentratio	n - PNEC							
Normal value in fresh water				0,02	mg	/I		
Normal value in marine water				0,002	mg	/I		
Normal value for fresh water sec	diment			24,45	mg	/kg/d		
Normal value for marine water s	ediment			4,89	mg	/kg/d		
Normal value for marine water, i	ntermittent release			0,11	mg	/I		
Normal value of STP microorgan				1,5	mg	/I		
Normal value for the terrestrial of				19,1	mg	/kg/d		
Health - Derived no-effect	•	MEL						
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		20,8 µg/kg bw/d		20,8 µg/kg bw/d		_		
Inhalation		0,145 mg/m3		0,145 mg/m3		0,823 mg/m3		0,823 mg/m3
Skin		2,08 mg/kg bw/d		2,08 mg/kg bw/d		5,83 mg/kg bw/d		5,83 mg/kg bw/d
DIATOMITE								
Predicted no-effect concentratio	n - PNEC							
Normal value of STP microorgar	nisms			100	mg	/I		
Health - Derived no-effect	level - DNEL / D	MEL						
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral				18,7 mg/kg bw/d				
Inhalation				0,05 mg/m3				0,05 mg/m3

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for particulate not otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment. The above values are not TLVs, but guide values, to be used for particles that do not have their own TLV and that are insoluble or poorly soluble in water and have low toxicity.

# 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

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Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

#### HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374). Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

#### SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

#### EYE PROTECTION

Wear airtight protective goggles (see standard EN ISO 16321).

#### RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

#### ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

# **SECTION 9. Physical and chemical properties**

#### 9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	powder	
Colour	vellow	
Odour	characteristic	
Melting point / freezing point	not available	Reason for missing data:not relevant for the characterization of the product
Initial boiling point	not available	Reason for missing data:not relevant for the characterization of the product
Flammability	not flammable	
Lower explosive limit	not applicable	Reason for missing data:the substance/mixture is a solid
Upper explosive limit	not applicable	Reason for missing data:the substance/mixture is a solid
Flash point	not applicable	Reason for missing data:the substance/mixture is a solid
Auto-ignition temperature	not applicable	Reason for missing data:the substance/mixture is a solid
Decomposition temperature	not available	Reason for missing data:not relevant for the characterization of the product
рH	not applicable	Reason for missing data:substance/mixture is non-soluble (in water)
Kinematic viscosity	not applicable	Reason for missing data:the substance/mixture is a solid
Solubility	insoluble in water	•
Partition coefficient: n-octanol/water	not applicable	Reason for missing data:the product is a mixture
Vapour pressure	not available	Reason for missing data:not relevant for the characterization of the product
Density and/or relative density	2,3 g/cm3	·
Relative vapour density	not applicable	Reason for missing data:the substance/mixture is a solid
Particle characteristics	not available	Reason for missing data:not relevant for the characterization of the product

# 9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

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9.2.2. Other safety characteristics

Information not available

# **SECTION 10. Stability and reactivity**

#### 10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

#### 10.2. Chemical stability

The product is stable in normal conditions of use and storage.

#### 10.3. Possibility of hazardous reactions

The powders are potentially explosive when mixed with air.

#### 10.4. Conditions to avoid

Avoid environmental dust build-up.

#### 10.5. Incompatible materials

No known incompatible materials.

#### 10.6. Hazardous decomposition products

The product does not decompose under normal conditions of use and storage.

# **SECTION 11. Toxicological information**

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information Information not available

#### Information on likely routes of exposure

The most likely routes of exposure are dermal and oral

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Refer to section 4.2

Interactive effects

None known

ACUTE TOXICITY

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Not classified (no significant component)

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>2000 mg/kg ATE (Oral) of the mixture:

Not classified (no significant component) ATE (Dermal) of the mixture:

DIPOTASSIUM HEXAFLUOROTITANATE

ATE (Inhalation) of the mixture:

324 mg/kg OECD 401 LD50 (Oral):

DIATOMITE

> 2000 mg/kg OECD 401 LD50 (Oral):

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

May cause damage to organs

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

#### 11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

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# **SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

#### 12.1. Toxicity

DIPOTASSIUM HEXAFLUOROTITANATE

 LC50 - for Fish
 172 mg/l/96h OECD 203

 EC50 - for Crustacea
 48,2 mg/l/48h OECD 203

 EC50 - for Algae / Aquatic Plants
 11 mg/l/72h OECD 211

 EC10 for Algae / Aquatic Plants
 1,4 mg/l/72h OECD 201

 Chronic NOEC for Fish
 8,4 mg/l/21d

 Chronic NOEC for Crustacea
 10 mg/l OECD 211

DIATOMITE

 LC50 - for Fish
 > 100 mg/l/96h OECD 203

 EC50 - for Crustacea
 > 100 mg/l/48h OECD 202

 EC50 - for Algae / Aquatic Plants
 > 100 mg/l/72h OECD 201

#### 12.2. Persistence and degradability

DIPOTASSIUM HEXAFLUOROTITANATE Degradability: information not available

DIATOMITE

Degradability: information not available

#### 12.3. Bioaccumulative potential

Information not available

#### 12.4. Mobility in soil

Information not available

#### 12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

#### 12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

#### 12.7. Other adverse effects

Information not available

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# **SECTION 13. Disposal considerations**

#### 13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

# **SECTION 14. Transport information**

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.

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

# **SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

None

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Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

Not applicable

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

#### Healthcare controls

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

#### 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**

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute toxicity, category 4 Acute Tox. 4

Specific target organ toxicity - repeated exposure, category 2 STOT RE 2

Serious eye damage, category 1 Eye Dam. 1

Eye irritation, category 2 Eye Irrit. 2 Harmful if swallowed. H302

May cause damage to organs through prolonged or repeated exposure. H373

Causes serious eye damage. H318 Causes serious eye irritation. H319

#### LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP

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- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

#### GENERAL BIBLIOGRAPHY

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (Il Annex of REACH Regulation)
- Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament

- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP)
- 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP) 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP) 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- 23. Delegated Regulation (UE) 2023/707
- 24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
- 24. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- **FCHA** website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

#### 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.

Provide appointed staff with adequate training on how to use chemical products.

#### CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

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Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.						