



SAFETY DATA SHEET
according to 1907/2006/CE

Compilation date: 15/03/2012

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Product: **ALGINELLE**

1. Identification of the substance/preparation and of the Company/Undertaking

1.1 Identification of the product: ALGINELLE

1.2 Intended or recommended uses of the substance or preparation:
Dust free alginate for dental use

1.3 Details of the supplier of the safety data sheet

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2. Hazards identification

2.1 Classification of the substance/preparation :

The preparation fulfils the classification criteria of Directive 1999/45. The preparation therefore requires a safety data sheet in compliance with the requirements of Regulation 1907/2006/EC as amended.

Hazard symbol: HARMFUL

R phrase: R48/20
R20/22

Hazards identification:

Harmful: danger of serious damage to health by prolonged exposure
Harmful by inhalation

2.2 Elements of labelling:

For the preparation:

Hazard symbol:

Xn



R phrases:

R48/20	Harmful: danger of serious damage to health by prolonged exposure
R20/22	Harmful by inhalation and ingestion

S phrases:

S36/37/39	Wear suitable protective clothing, gloves and eye / face protection
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2.3. Other hazards :

At the date of compilation of the present sheet, none known.



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3. Composition /information on ingredients

Preparations:

Classification of the substances in the preparation according to Directive 67/548/EEC as amended and Regulation 1272/2008/EC

Name	Conc. (C)	Clas. 67/548/EEC		Clas. 1272/2008/EC	
Diatomaceous earth Cas No. 68855-54-9 EC No. 272-489-0 Index No. - REACH No. 01-2119488518-22-0005	65<C≤75	Xn	R48/20	STOT RE 2	H373
Sodium hexafluorotitanate Cas No. 16919-27-0 EC No. 240-969-9 Index No. - REACH No. -	1<C≤3	Xn	R20 / R22	Acute Tox. 4	H332
				Acute Tox. 4	H302

Full text of relevant R and H phrase is listed in the Section 16 of this Safety Data Sheet.

4. First aid measures

4.1 First aid measures description

4.1.1 Inhalation: Remove the subject from the contaminated area and have him breathe fresh air and blow his nose. In case of persistent symptoms consult a doctor.

Skin contact: Remove all contaminated clothing and use soap and water to wash the skin that has come into contact with the product.

Eye contact: Rinse with plenty of running water while holding the eyelids open. Consult a doctor in case of symptoms attributable to contact with the product.

Ingestion: No significant effects or critical dangers are known. In case of symptoms consult a doctor.

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

The product may cause serious damage to health in case of prolonged exposure by inhalation.

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

In the event of consulting a doctor refer to Section 4.1.1.

5. Fire-fighting measures

5.1 Extinguishing media:

Suitable extinguishing media: not applicable, the product is not inflammable.

Extinguishing media which must not be used for safety reasons: not applicable, the product is not inflammable.

5.2 Special exposure hazards arising from the substance or preparation itself: not applicable.



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5.3 Special protective equipment for fire-fighters: Always use suitable protective devices while working. Use a protective helmet with a visor, fire-resistant clothing, protective gloves for fire fighters, a mask under positive pressure with a face shield that covers the operator's entire face or a self-contained breathing apparatus if there is a significant amount of smoke. Collect the water used to fight the fire; this water must not be discharged into the sewer system. Dispose of the contaminated water used to fight the fire and of the residues of the fire according to the regulations in effect.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures :

6.1.1. For persons who do not take any direct action: evacuate the release area. Do not take any action unless trained for the operations to be carried out.

6.1.2. For persons who take direct action: Avoid contact with eyes and skin. Remove all persons who are not involved in the operations. Do not handle damaged containers or released product without first putting on suitable protective equipment.

6.2 Environmental precautions: Prevent the product from entering sewers, surface waters, groundwater and confined areas. If the product has entered a watercourse or the sewer network, or if it has contaminated the soil or vegetation, inform the competent authorities.

6.3 Methods and material for containment and cleaning up:

Use suitable mechanical means to remove the powder without raising it, and dispose of the powder according to the specific regulations in effect.

6.4 Reference to other sections (see 8 and 13): The contaminated material must be disposed of in compliance with the regulations indicated in Section 13.

7. Handling and storage

7.1 Precautions for safe handling:

Avoid contact with skin and eyes and inhalation of the powder. Contaminated clothing must be replaced. Do not eat or drink during work. Avoid the formation of dust. See Section 8 for recommended protective equipment.

7.2 Conditions for safe storage, including any incompatibilities:

- a. No risks are known with respect to explosive atmospheres, corrosive conditions, flammability dangers, incompatible substances and mixtures, evaporation conditions, potential ignition sources
- b. Keep the container in a cool and dry place. Avoid exposure to direct sunlight.
- c. The product is stable under normal conditions of use and storage.
- d. Use the original and undamaged containers

7.3 Specific end use(s): not known.



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8. Exposure controls/personal protection

8.1 Control parameters:

Description	Type	State	TWA/8h		STEL/15min		
			mg/m3	ppm	mg/m3	ppm	
Inorganic powder	TLV-ACGIH		3	-		-	Respirable particles
Inorganic powder	OEL	IT	3				
Inorganic powder	TLV-ACGIH		10	-		-	Inhalable particles
Inorganic powder	OEL	IT	10				

8.2 Exposure controls: Considering that the use of suitable technical means should always have priority over the use of personal protective equipment, ensure good ventilation of the workplace by means of efficient local aspiration or discharge of the polluted air. Operate and handle according to the usual precautionary measures for the handling of chemical products. Do not eat, drink or smoke during use. Accurately wash the hands with water and soap before meals and take a shower at the end of the work shift.

8.2.1. Appropriate engineering controls:

8.2.2. Individual protection measures, such as personal protective equipment:

8.2.2.1. Use a suitable respiratory device; a P3 filter is suggested.

8.2.2.2. Eye/face protection: Protective devices for eyes/face: hermetic protective goggles are recommended (acc. to norm EN 166).

Skin protection:

Hand protection: work gloves (acc. to norm EN 374).

Other: protective work clothes, work clothes (acc. to norm EN 344).

Respiratory protection: mask with universal filter.

Thermal hazards: not applicable.

8.2.3. Environmental exposure controls: Based on the use of the product in the various environmental compartments, compliance with any national or community regulations for environmental protection is required..



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9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance		Orange powder
Odour		Characteristic
Odour threshold		Not determined
pH		8 at 20°C (suspension of 10 g of powder per litre of water after 2 min.)
Melting point/freezing point		Not pertinent
Initial boiling point and boiling range	°C	Not pertinent
Flash point	°C	Not pertinent
Solubility in water		Reacts by forming a hydrophilic gel
Evaporation rate		Not pertinent
Flammability (solid/gas)		Not flammable
Upper/lower flammability or explosive limits		Not flammable or explosive
Vapour pressure	mmHg	Not pertinent
Vapour density		Not pertinent
Relative density	g/cm ³	2.3
Apparent density	g/l	300
Partition coefficient: n-octanol/water		Not pertinent
Auto-ignition temperature	°C	Not pertinent
Decomposition temperature	°C	Not pertinent
Explosive properties		Not explosive
Oxidising properties		Not oxidising

10. Stability and reactivity

10.1 Reactivity: The product reacts with water by forming a hydrogel.

10.2 Chemical stability: the products do not decompose if used according to the instructions for used and stored according to the instructions provided by the manufacturer.

10.3 Possibility of hazardous reactions: there is no possibility of any hazardous reactions.

10.4 Conditions to avoid: heat, humidity

10.5 Incompatible materials: none known.

10.6 Hazardous decomposition products: none



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11. Informazioni tossicologiche

11.1 Toxicological effects information:

No episodes of damages to health due to exposure to the product are known. It is advisable in any case to work in compliance with the rules of good industrial hygiene.

Indication of LD50 or LC50:

Diatomaceous earth		
Oral	LD50	> 2000 mg/Kg (rat)
Potassium hexafluorotitanate		
Oral	LD50	169 mg/kg (rat)

Information on likely routes of exposure: the likely routes of exposure are by inhalation, via the skin and, much less likely, by ingestion.

Symptoms related to the physical, chemical and toxicological characteristics: the mixture is harmful by inhalation.

Delayed and immediate effects as well as chronic effects from short and long term exposure: the product is harmful by inhalation. Danger of serious damage to health in case of prolonged exposure by inhalation.

Interactive effects: unknown

Further information: none known

12. Ecological information

Use according to good work practices; avoid releasing the product into the environment and into the soil or into sewers and into watercourses.

The product does not have any harmful effects on the environment; nevertheless, the data for diatomaceous earth and potassium hexafluorotitanate are shown below.

12.1 Ecotoxicity: acute toxicity (fish, aquatic invertebrates, aquatic plants, micro-organisms): No effect up to the solubility limit.

12.2 Persistence and degradability: Not applicable for inorganic substances.

12.3 Bioaccumulative potential: not applicable, not organic.

12.4 Mobility in soil: no data available.

12.5 Results of PBT and vPvB assessment: not pertinent, not organic.

12.6 Other adverse effects: harmful for aquatic organisms (potassium hexafluorotitanate).



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13. Disposal considerations

13.1 Disposal treatment methods

- a. containers and treatment methods: seeing the nature of the product, its containers cannot be cleaned and recycled; they must be sent to a special decontamination system or be disposed of as hazardous waste.
- b. physical/chemical properties that may affect waste treatment: the Product is stable under normal conditions.
- c. sewage disposal is discouraged: disposal may take place via biological treatment systems.
- d. special precautions during treatment: none in particular

14. Transport information

The product is not subject to transport regulations.

15. Regulatory information

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

Seveso category: none

Restrictions relating to the product or contained substances according to Annex XVII to Regulation (EC) 1907/2006: none

Substances in Candidate List (art.59 REACH): none

Substances subject to authorization (Annex XIV REACH): none

D. Lgs. 152/2006 and subsequent amendments:
Emissions into the atmosphere: not applicable

15.2 Chemical safety assessment: no assessment of chemical safety was made for the mixture.



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16. Other information

This edition of the safety data sheet replaces each point of the previous versions.

Key and legend to abbreviations and acronyms used in the safety data sheet

ADR: Accord européen relative au transport international des marchandises dangereuses par route (European agreement regarding the international road transport of hazardous goods)

ASTM: ASTM International, originally known as American Society for Testing and Materials (ASTM)

ATE: Acute toxicity estimate

EINECS: European Inventory of Existing Commercial Chemical Substances (Registro Europeo delle Sostanze chimiche in Commercio)

EC50: Effective Concentration 50 (Concentrazione Effettiva Massima per il 50% degli Individui)

LC50: Lethal Concentration 50 (Concentrazione Letale per il 50% degli Individui)

IC50: Inhibitor Concentration 50 (Concentrazione Inibente per il 50% degli Individui)

NOEL: No Observed Effect Level (Dose massima senza effetti)

DNEL: Derived No Effect Level (Dose derivata di non effetto)

DMEL: Derived Minimum Effect Level (Dose derivata di minimo effetto)

CLP: Classification, Labelling and Packaging (Classificazione, Etichettatura e Imballaggio)

CSR: Rapporto sulla Sicurezza Chimica (Chemical Safety Report)

IATA: International Air Transport Association (Associazione Internazionale del Trasporto Aereo)

ICAO: International Civil Aviation Organization (Organizzazione Internazionale dell'Aviazione Civile)
Codice IMDG: International Maritime Dangerous Goods code (Codice sul Regolamento del Trasporto Marittimo)

PBT: Persistent, bioaccumulative and toxic (sostanze persistenti bioaccumulabili e tossiche)

vPvB: Very persistent very bioaccumulative (sostanze molto persistenti e molto bioaccumulabili)

RID: Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulation regarding the international rail transport of hazardous goods)

STEL: Short term exposure limit (limite di esposizione a breve termine)

TLV: Threshold limit value (soglia di valore limite)

TWA: Time Weighted Average (media ponderata nel tempo)

EU: European Union

Main bibliographic references and data sources

1. Direttiva 1999/45/CE e successive modifiche
2. Direttiva 67/548/CEE e successive modifiche ed adeguamenti (XXIX adeguamento tecnico)
3. Regolamento (CE) 1907/2006 del Parlamento Europeo (REACH)
4. The Merck Index. Ed. 10
5. Handling Chemical Safety
6. Niosh - Registry of Toxic Effects of Chemical Substances
7. INRS - Fiche Toxicologique
8. Patty - Industrial Hygiene and Toxicology
9. N.I. Sax-Dangerous properties of Industrial Materials-7 Ed., 1989



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For mixtures, explanation of the classification assessment methods according to 1272/2008:

The mixture has not been classified according to the criteria of Regulation 1272/2008/EC but based on Directive 1999/45/EC.

List of R phrases:

R48/20	Harmful: Danger of serious damage to health in case of prolonged exposure by inhalation
R20/22	Harmful by inhalation and if swallowed

List of H phrases:

H373	May cause damage to organs through prolonged or repeated exposure
H332	Harmful if inhaled
H302	Harmful if swallowed

Abbreviations used:

Acute Tox. 4	Acute toxicity of category 4
STOT RE 2	Specific toxicity by target organ - repeated exposure, hazard category 2

Note for the user:

The information in this data sheet is based on our knowledge at the date of the latest version. The user must ensure the suitability and completeness of the information with respect to the product's specific use.

This document must not be interpreted as a guarantee of any specific property of the product.

Since the product's use is not under our direct control, the user himself is responsible for compliance with the laws and regulations in effect in matters of hygiene and safety. We do not accept any responsibility for improper uses.

Data sheet issued by: Lascod