

MATERIAL SAFETY DATA SHEET

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

Commercial name: ALGIPERF
Relevant use of product: Dental alginate for impressions
Product references: AA-500

Information concerning safety data sheet supplier:

G-PHARMA
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SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the mixture

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/ 45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP):

Eyes irrit. 2: **H319**, STOT SE 3: **H335**, STOT RE 2: **H373**

2.1.2 Classification according to the directive N° 67/548/CEE:

Xi: **R36, R37**, Xn : **R48/20**

2.1.3 Additional Information

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

2.2 Label elements

Labeling according to Regulation (EC) No 1272/2008 (CLP)

Pictogram:

SGH08



SGH07



Signal word:

Warning

Cautious

H statements:

H317: Can cause a severe eyes irritation

H335: Can irritate the respiratory track

H373: May cause damage to the respiratory track or lungs from multiple or long-term exposure

P statements:

P260: Avoid breathing dust/fume/gas/mist/vapours/spray.

P271: Only use outdoor or in a well ventilated area

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P314: Seek medical advice if not feeling well.

Additional hazards information: N/A

2.3 Other hazards: the mixtures do not contain PBT or vPvP.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Products contain:

EC designation : N/A

EEC classification : Class I

3.2 Mixture of substances listed below

The mixture contains in a small amount benzalkonium chlorure (Detected at a very low concentration beyond the generic limit)

CE/CAS index	Chemical name	Mass %	Classification according to directive N° 67/548/CEE (DPD)	Classification according to rules (CE) N° 1272/2008 (CLP)	Generic threshold
Index : N/A CE : 272-489-0 CAS : 68855-54-9 REACH : 01-2119488518-22-0005	diatomaceous earth	50-65	Xn : R48/20	H373 : STOT RE 2	≥ 1 % Classification of the mixture C ≥ 10%
Index N/A CE : 264-151-6 CAS : 7778-18-9	Calcium sulfate	10-20	Xi: R36/38	Skin irrit 2: H315 STOT SE 3: H335	≥ 1 % ≥ 1 % Classification of the mixture C ≥ 10%
Index : N/A CE : 16919-27-0 CAS : 240-969-9	Hexafluorotitanate Potassium	1-3	Xn: R20/R22	H332: Acute tox. 4 H302: Acute tox. 4	≥ 1 % ≥ 1 % Classification of the mixture C ≥ 10%

Note: The full text of hazard H and R-phrases is specified in section 16.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation: Pull away the contaminated person and make him breathe fresh air and blow his nose. In case of persistent problems: consult a doctor.

Swallowing: Not known to have significant or hazardous effect, if not feeling well seek medical advice.

Skin contact: Remove all contaminated clothes and wash with soap and water.

Eye contact: Rinse opened eye with precaution for several minutes under running water. Seek medical advice

4.2 Most important symptoms and effects, both acute and delayed: Product may cause serious damage to health by prolonged exposure through inhalation

4.3 Indication of any immediate medical attention and special treatment needed: If you seek medical advice, see section 4.1

SECTION 5 - FIREFIGHTING MEASURES

5.1. Extinguishing media:

Suitable Extinguishing media: None. The product is inflammable

Unsuitable Extinguishing media: None. The product is inflammable

5.2 Special hazards arising from the substance or mixture: N/A

5.3. Advice for firefighter: Use always the appropriate protection. Use an helmet with visor, fireproof clothes and gloves, an overpressure mask with a facial piece that cover all the face or with an self-contained breathing in case of a big quantity of smoke. Do not release runoff from fire to drains. Contaminated extinguishing water must be disposed of in accordance with official regulations

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid skin and eye contact. Ensure that the room is well ventilated. Wear goggles, gloves and mask (in case of a large quantity of product accidentally dispersed)

6.2 Environmental precautions:

Do not discharge into the sewage system.

6.3 Methods and material for containment and cleaning up:

Large quantity: Dispose of material according to regional, provincial and federal regulations (Into an approved container or by incineration)

6.4 Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

This product is for dental professional use only. Use in accordance to good dental professional practices

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry and cool place. Keep containers tightly closed

7.3 Specific end use(s): Dental professional use only.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Respiratory and ventilating protection: Not necessary in normal condition of use.

Personal protective equipment: Goggles, mask gloves and blouse

SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES

9.1 Information regarding the physicals and chemicals properties

Appearance: Powder

Colour: Green

Boiling point: N/A

Melting point: N/A

Density: 300g/l

Auto flammability: No

Odour: mint

Solubility with solvent: Yes

Relative density: 2.3

PH (10g/liter of water, after 20mn): 8 to 20°C

Solubility in water: Soluble. Reacts to form a hydrophilic gel

SECTION 10 – STABILITY & REACTIVITY

10.1 Reactivity: N/A.

10.2 Chemical stability: Stable

10.3 Possibility of hazardous reactions: No dangerous reactions known

10.4 Conditions to avoid: Avoid exposure to high temperature ($T^{\circ} > 40^{\circ}\text{C}$) and to humidity

10.5 Incompatible materials: N/A

10.6 Hazardous decomposition products: UN/A

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

On the basis of the practical experience gained, no specific health effects are known if used according to the manufacturer's indication.

Indication on LD50 or CL50.

Diatomaceous Earth		
Oral	LD50	> 2000 mg/Kg (rat)
Hexafluorotitanate Potassium		
Orale	LD50	169 mg/kg (rat)

Information on likely routes of exposure: by inhalation, skin and less likely by swallowing.

Symptoms due to the physico-chemical and toxicological properties: The mixture is dangerous if inhaled.

Signs and symptoms of exposure: The mixture is dangerous if inhaled. Danger of severe damages in case of a long exposure.

11.2 Other Information: N/A

SECTION 12 – ECOLOGICAL INFORMATION

Use the following proper procedures. Do not allow the product to enter sewers, surface and ground water. No ecological or environmental impact known. Nevertheless, below, the data for the Diatomaceous Earth and the hexafluorotitanate potassium.

12.1 Toxicity

Acute toxicity (fish, marine invertebrates, aquatic plant, microorganism). No effect until solubility limitation

12.2 Persistence and degradability: N/A

12.3 Bioaccumulative potential: N/A

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment: N/A

12.6 Other adverse effects: Dangerous for the aquatic organisms (Hexafluorotitanate potassium)

SECTION 13 - DISPOSAL MEASURES

13.1 Waste treatment methods

- a. **Containers and treatment method:** Given the nature of the product, its containers can't be cleaned or recycled. They have to be delivered to proper installation for the cleaning or the removal of toxic waste
- b. **Physical and chemical properties that can influence the waste treatment:** The product is stable in normal condition of use.
- c. **The removal by the sewer is not advised:** The removal can be made by a biological wastewater
- d. **Special precautions during the treatment:** None in particular

SECTION 14 - TRANSPORT INFORMATION

The product is not subject to the transportation standards. No restriction for the road, boat or plane transportation. Avoid high temperatures during transportation.

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: Class I medical device according to the Directive 93/42 / EEC

15.2 Chemical safety assessment: N/A

SECTION 16 - OTHER INFORMATION

N/A : Non applicable

CL50 : Lethal Concentration 50

DL50 : Lethal dose 50

STOT RE 2 : Target organ toxicity - multiple exposure hazard category 2

STOT SE 3: Specific target organ toxicity - single exposure hazard category 3

Commercial Name: ALGIPERF

Symbol of potential danger:

Xi : Irritating

Xn: toxic

R phrases

R20/20: Toxic if inhaled or swallowed

R 36: Irritating to eyes

R 37: Irritating to respiratory system.

R48/20 : Toxic : Can cause serious damage to health by prolonged exposure through inhalation

H phrases

H373: May cause damage to respiratory track or lungs due to a prolonged or repeated exposure

H335: May irritate respiratory tracks

H319: Causes serious eye irritation.

H302: Toxic if swallowed

H332: Toxic if inhaled

P phrases:

P260: Avoid breathing dust/fume/gas/mist/vapours/spray.

P271: Use only outdoor or in a well ventilated area

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P314: Seek medical advice if not feeling well

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