

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

- **Product identifier**
- **Trade name:** *Maxima Alginate Plus Regular* **REF 5720873 / 5720874**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** *Dental impression material.*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:** *Authorized EU Representative:* **Contact :**
- *Henry Schein Inc.* *Henry Schein Services GmbH* *cbdeurope@henryschein.com*
- *135 Duryea Road* *Monzastrasse 2a* *www.henryscheinbrand.com*
- *Melville, NY 11747 / USA* *63225 Langen / Germany* *Tel: +49 6103 757 5000*

- **Responsible for the Safety Data Sheet:** *Regulatory Affairs Europe - cbdeurope@henryschein.com*
- **Emergency Number INTERNATIONAL:** *+49 (0)6132 84463 - GBK GmbH (24h 7d/w - 365d/a)*



2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Additional information:**
Safety data sheet available on request.
- **Labelling of packages where the contents do not exceed 125 ml**
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

3 Composition/information on ingredients

- **Chemical characterisation:** *Mixtures*
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

- **Dangerous components:**

CAS: 16919-27-0	<i>dipotassium hexafluorotitanate</i>	<i>1-≤2.5%</i>
EINECS: 240-969-9	 <i>Eye Dam. 1, H318;  <i>Acute Tox. 4, H302; STOT SE 3, H335</i></i>	
CAS: 1309-48-4	<i>magnesium oxide</i>	<i>0.1-≤2.5%</i>
EINECS: 215-171-9	<i>substance with a Community workplace exposure limit</i>	

- **Additional information:** *For the wording of the listed risk phrases refer to section 16.*

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4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

1309-48-4 magnesium oxide

WEL	Long-term value: 10* 4** mg/m ³ (as Mg) *inhalable dust **fume and respirable dust
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- **Additional information:** *The lists valid during the making were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** *Not required.*
- **Protection of hands:**
*The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*
- **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye protection:** *Not required.*

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Powder
Colour:	Pink
Odour:	Pleasant
Odour threshold:	Not determined.
- **pH-value:** *Not applicable.*
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** *Not applicable.*
- **Flammability (solid, gaseous):** *Not determined.*
- **Ignition temperature:**

Decomposition temperature:	Not determined.
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- **Self-igniting:** *Product is not selfigniting.*
- **Danger of explosion:** *Product does not present an explosion hazard.*
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure:** *Not applicable.*
- **Density:** *Not determined.*
- **Relative density** *Not determined.*
- **Vapour density** *Not applicable.*
- **Evaporation rate** *Not applicable.*

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|---|---|
| · Solubility in / Miscibility with water: | <i>Insoluble.</i> |
| · Partition coefficient (n-octanol/water): | <i>Not determined.</i> |
| · Viscosity: | |
| Dynamic: | <i>Not applicable.</i> |
| Kinematic: | <i>Not applicable.</i> |
| · Solvent content: | |
| Organic solvents: | <i>0.0 %</i> |
| VOC (EC) | <i>0.00 %</i> |
| · Solids content: | <i>100.0 %</i> |
| · Other information | <i>No further relevant information available.</i> |

10 Stability and reactivity

- **Reactivity** *No further relevant information available.*
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Possibility of hazardous reactions** *No dangerous reactions known.*
- **Conditions to avoid** *No further relevant information available.*
- **Incompatible materials:** *No further relevant information available.*
- **Hazardous decomposition products:** *No dangerous decomposition products known.*

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** *Based on available data, the classification criteria are not met.*

· LD/LC50 values relevant for classification:
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16919-27-0 dipotassium hexafluorotitanate
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Oral	LD50	324 mg/kg (rat) (LDL50)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** *Based on available data, the classification criteria are not met.*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*
- **Carcinogenicity** *Based on available data, the classification criteria are not met.*
- **Reproductive toxicity** *Based on available data, the classification criteria are not met.*
- **STOT-single exposure** *Based on available data, the classification criteria are not met.*
- **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*
- **Aspiration hazard** *Based on available data, the classification criteria are not met.*

12 Ecological information

- **Toxicity**

· Aquatic toxicity:

16919-27-0 dipotassium hexafluorotitanate
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EC50	48.2 mg/kg (daphnia)
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- **Persistence and degradability** *No further relevant information available.*
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** *No further relevant information available.*

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- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
*Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
 Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.*
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation** Smaller quantities can be disposed of with household waste.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

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|---|-----------------|
| · UN-Number | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | not regulated |
| · Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | not regulated |
| · Packing group | |
| · ADR, IMDG, IATA | not regulated |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| · UN "Model Regulation": | not regulated |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
*H302 Harmful if swallowed.
 H318 Causes serious eye damage.*

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H335 May cause respiratory irritation.

- **Department issuing MSDS:** Regulatory Affairs Europe
- **Contact:** cbdeurope@henryschein.com

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity, Hazard Category 4

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

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