

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 20.04.2017


Version number 6

Revision: 20.04.2017

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

- **1.1 Product identifier**
- **Trade name: *Blueprint Xcreme***
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Dental impression material
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
 - Departement Research & Development for technical information
 - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
STOT RE 2 H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**
- 

GHS08
- **Signal word** Warning
- **Hazard-determining components of labelling:**
crystalite
- **Hazard statements**
H373 May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P314 Get medical advice/attention if you feel unwell.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

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

- **Dangerous components:**

CAS: 14464-46-1	crystalite	2.5-<10%
EINECS: 238-455-4	☠ STOT RE 1, H372	
CAS: 16919-27-0	dipotassium hexafluorotitanate	2.5-<10%
EINECS: 240-969-9	☠ Eye Dam. 1, H318; ☠ Acute Tox. 4, H302	

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

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information**
Remove breathing equipment only after contaminated clothing have been completely removed.
- **After inhalation** Supply fresh air and to be sure call for a doctor.
- **After skin contact** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **Information for doctor** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents** Water with full jet.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Avoid formation of dust.
Ensure adequate ventilation
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Pick up mechanically.
- **6.4 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.

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SECTION 7: Handling and storage

· **7.1 Precautions for safe handling**

Observe normal care for working with chemicals.
Prevent formation of dust.

· **Handling** Product is intended for dental use only.

· **Information about fire - and explosion protection:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage**

· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** Store in cool, dry conditions in well sealed receptacles.

· **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

· **8.1 Control parameters**

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

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· **Additional information:** The lists valid during the making were used as basis.

· **8.2 Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:**

In occurrence of dust use respiratory protection

Filter P2.

· **Protection of hands:**



Protective gloves.

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:** Safety glasses

· **Body protection:** Protective work clothing.

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

· Form:	Powder
· Colour:	Blue
· Odour:	Product specific
· Odour threshold:	Not determined.

· pH-value: Not applicable.

· Change in condition

· Melting point/freezing point:	undetermined
· Initial boiling point and boiling range:	Undetermined.

· Flash point: Not applicable

· Flammability (solid, gaseous) Not determined.

· Ignition temperature: Not applicable

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: 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.

· Solubility in / Miscibility with

· Water: Partly soluble

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

· dynamic:	Not applicable.
· kinematic:	Not applicable.

· Solvent content:

· Organic solvents: 0.0 %

· Solids content: > 95 %

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· 10.3 Possibility of hazardous reactions Risk of dust explosion

· 10.4 Conditions to avoid No further relevant information available.

· 10.5 Incompatible materials: No further relevant information available.

· 10.6 Hazardous decomposition products: No dangerous decomposition products known

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SECTION 11: Toxicological information

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

- **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)		
Oral	LD50	11172 mg/kg (rat)

CAS: 14464-46-1 cristobalite		
Oral	LD50	> 2000 mg/kg (rat) (OECD 401)

CAS: 16919-27-0 dipotassium hexafluorotitanate		
Oral	LD50	324 mg/kg (rat)

- **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.
- **Other information (about experimental toxicology):**
Test carried out on a similar Alginate with a higher content of corrosive components
Eye Irritation/Corrosion: NEGATIVE (OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014)
- **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**
May cause damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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· European waste catalogue	
18 01 06*	chemicals consisting of or containing hazardous substances
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**SECTION 14: Transport information**· **14.1 UN-Number**· **ADR, ADN, IMDG, IATA** Void· **14.2 UN proper shipping name**· **ADR, ADN, IMDG, IATA** Void· **14.3 Transport hazard class(es)**· **ADR, ADN, IMDG, IATA**· **Class** Void· **14.4 Packing group**· **ADR, IMDG, IATA** Void· **14.5 Environmental hazards:**

Not applicable.

· **14.6 Special precautions for user**

Not applicable.

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **UN "Model Regulation":**

Void

SECTION 15: Regulatory information· **15.1 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.· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· **Relevant phrases**

H302 Harmful if swallowed.

H318 Causes serious eye damage.

H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

· **Department issuing SDS:** Research & Development· **Contact:** HotLine for urgent technical support: +49-7531-583-350· **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

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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)
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 – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
· *** Data compared to the previous version altered.**

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