

Safety Datasheet

according to 1907/2006/EC, Article 31

Printing date 18.06.2018

Version number 3

Revision: 18.06.2018

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

- **1.1 Product identifier**
- **Trade name:** *CLEARsplint Powder*
- **Article number:** according to Catalog
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Sector of Use** SU20 Health services
- **Environmental release category** ERC2 Formulation into mixture
- **Application of the substance / the mixture** Dental material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Manufacturer:
Astron Dental Corporation
815 Oakwood Road, Unit G
Lake Zurich, IL. 60047 (USA)
E-Mail: customerservice@astrondental.com
Supplier:
Kentzler-Kaschner Dental GmbH
Mühlgraben 36
D-73479 Ellwangen
Tel: +49/7961/90730
Fax: +49/7961/52031
E-Mail: info@kkd-topdent.de
- **Further information obtainable from:**
During normal business hours
Monday-Thursday 08:30 - 12:30 and 13:00 - 16:30 CET
Friday 08:30 - 12:30 and 13:00 - 15:00 CET
- **1.4 Emergency telephone number:** Vergiftungs-Informationen-Zentrale Freiburg, Tel. +49 761 19240

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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**



- **Signal word** Warning
- **Hazard-determining components of labelling:**
dibenzoyl peroxide
- **Hazard statements**
H319 Causes serious eye irritation.

(Contd. on page 2)

Safety Datasheet

according to 1907/2006/EC, Article 31

Printing date 18.06.2018

Version number 3

Revision: 18.06.2018

(Contd. of page 1)

H317 May cause an allergic skin reaction.

· **Precautionary statements**

- P240 Ground/bond container and receiving equipment.
 P261 Avoid breathing dust.
 P264 Wash contaminated skin areas thoroughly after handling
 P272 Contaminated work clothing should not be allowed out of the workplace.
 P280 Wear protective gloves / eye protection / face protection.
 P302+P352 IF ON SKIN: Wash with plenty of soap and water.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P321 Specific treatment (see on this label).
 P337+P313 If eye irritation persists: Get medical advice/attention.
 P363 Wash contaminated clothing before reuse.
 P501 Dispose of contents/container to according to local regulations, the disposal company

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
 · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Dental material

· **Dangerous components:**

CAS: 94-36-0 EINECS: 202-327-6 Index number: 617-008-00-0 RTECS: DM 8575000	dibenzoyl peroxide ⚠️ ⚠️ Org. Perox. B, H241; ⚠️ Eye Irrit. 2, H319; Skin Sens. 1, H317	0.1-3.0%
CAS: 9003-42-3	Methacrylat Polymer	75-100%

· **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:**

- Take affected persons out of danger area and lay down.
 Do not leave affected persons unattended.
 Take affected persons out into the fresh air.

· **After inhalation:**

- Take affected persons into fresh air and keep quiet.
 Supply fresh air and to be sure call for a doctor.
 In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:**

- If skin irritation continues, consult a doctor.
 Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** Inform doctor. Do not give milk or fatty oils.

· **4.2 Most important symptoms and effects, both acute and delayed** 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:** Use fire extinguishing methods suitable to surrounding conditions.

(Contd. on page 3)

Safety Datasheet

according to 1907/2006/EC, Article 31

Printing date 18.06.2018

Version number 3

Revision: 18.06.2018

(Contd. of page 2)

- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture** Carbon dioxide (CO₂)
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information**
Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Ensure adequate ventilation.
- **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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:**
Do not spray onto a naked flame or any incandescent material.
- **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:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **Storage class:** VCI: 11
- **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:**

94-36-0 dibenzoyl peroxide

WEL	Long-term value: 5 mg/m ³
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- **Additional information:** The lists valid during the making were used as basis.

8.2 Exposure controls

- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
- **Respiratory protection:**



Dust mask

Particle filter P2

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

(Contd. on page 4)

GB

Safety Datasheet
according to 1907/2006/EC, Article 31

Printing date 18.06.2018

Version number 3

Revision: 18.06.2018

(Contd. of page 3)

· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

Fluorocarbon rubber (Viton)

Butyl rubber, BR

Recommended material thickness:

Butylkautschuk: 0,50 mm +/- 0,10 mm

Fluorkautschuk: 0,75 mm +/- 0,10 mm

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**

Basis: DGUV 212-007

Permeation (Fluorkautschuk): + Level 6 (> 240 min)

Permeation (Butylkautschuk): + Level 6 (> 480 min)

The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact gloves made of the following materials are suitable:**

Fluorocarbon rubber (Viton)

Butyl rubber, BR

· **Eye protection:**

Tightly sealed goggles

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

Form:	Powder
Colour:	Light yellow
Odour:	Mild
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:** 305 °C· **Flammability (solid, gas):** Not determined.· **Decomposition temperature:** Not determined.· **Auto-ignition temperature:** Product is not selfigniting.· **Explosive properties:** Product does not present an explosion hazard.

(Contd. on page 5)

Safety Datasheet
according to 1907/2006/EC, Article 31

Printing date 18.06.2018

Version number 3

Revision: 18.06.2018

(Contd. of page 4)

· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	1.25 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC (EC)	0.00 %
· 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** No dangerous reactions known.
- **10.4 Conditions to avoid** Open fire, hot surfaces, high temperatures
- **10.5 Incompatible materials:** oxidants, acids, bases
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **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.

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.

(Contd. on page 6)

Safety Datasheet
according to 1907/2006/EC, Article 31

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Version number 3

Revision: 18.06.2018

(Contd. of page 5)

- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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.

- **European waste catalogue**

18 02 06	chemicals other than those mentioned in 18 02 05
18 02 08	medicines other than those mentioned in 18 02 07
20 01 32	medicines other than those mentioned in 20 01 31

- **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. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · ADR
· Remarks: | No Dangerous Goods |
| · IMDG
· Remarks: | No Dangerous Goods |
| · IATA
· Remarks: | Not restricted |
| · UN "Model Regulation": | Void |

GB

(Contd. on page 7)

Safety Datasheet
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(Contd. of page 6)

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.

- **Relevant phrases**

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

- **Department issuing SDS:**

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- **Contact:** *info@logar.de*

- **Date of preparation / last revision** 27.03.2017

- **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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Org. Perox. B: Organic peroxides – Type B

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

- *** Data compared to the previous version altered.**