

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

Printing date 07.11.2018

Revision: 10.10.2018

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

- **Product identifier**
- **Trade name:** Chromaclone® PVS - Catalyst
- **Article number:** 5010, 5011, 5012, 5013, 5020, 5021, 5022, 5023, 5030, 5031, 5032, 5033, 7601
- **Index number:** SDS 422-001.01
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Dental Impression Material
- **Application of the substance / the mixture** Professional Dental Impression Material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ultradent Products Inc.
505 W. Ultradent Drive (10200 S)
South Jordan, UT 84095-3942
USA
onlineordersupport@ultradent.com

- **EC Responsible Person**
Ultradent Products GmbH
Am Westhoyer Berg 30
51149 Cologne Germany
Email: infoDe@ultradent.com
Emergency Phone: +49(0)2203-35-92-0
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**
CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887

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**
The Regulation EC 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5(d). Therefore, the product is exempted from the CLP labelling requirements, and no SDS is required by Regulation 1907/2006, Art 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Additional information:**
Safety data sheet available on request.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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3 Composition/information on ingredients

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

- **Dangerous components:**

CAS: 14464-46-1	Cristobalite	5 - <8.5%
EINECS: 238-455-4	⚠ STOT RE 1, H372	
CAS: 68439-50-9	Alcohols, C12-14, ethoxylated	0.2 - < 0.4%
	⚠ Aquatic Acute 1, H400; ⚠ Eye Irrit. 2, H319; Aquatic Chronic 3, H412	

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

4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:**
Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.
- **After skin contact:**
Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.
- **After eye contact:**
Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
- **After swallowing:**
Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
Specific information on symptoms and effects caused by the product are unknown.
For symptoms and effects caused by the contained substances, see Sect 11.
- **Indication of any immediate medical attention and special treatment needed** Information not available

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
- **Special hazards arising from the substance or mixture** Do not breathe combustion products.
- **Advice for firefighters:**
- **Protective equipment:**
GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

- **Environmental precautions:**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

- **Methods and material for containment and cleaning up:**

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

- **Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

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:**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

- **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:**

Store only in the original container. Store the containers sealed, in a well ventilated place and dry place, away from direct sunlight (storage temperature: 5-27° C). Keep containers away from any incompatible materials, see section 10 for details.

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

- **Further information about storage conditions:** See product labelling.

- **Specific end use(s)** Professional Dental Impression Material

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:**

CRISTOBALITE

Threshold Limit Value.

Type Country TWA/8h STEL/15min

mg/m³ ppm mg/m³ ppm

VLEP BEL 0,05 RESP.

TLV DNK 0,15 RESP.

VLEP FRA 0,05 RESP.

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AK HUN 0,15 RESP.
 OEL IRL 0,1 RESP.
 VLEP ITA 0,05 (USA-NIOSH)
 MAC NLD 0,075 RESP.
 MAK SWE 0,05 RESP.
 TLV-ACGIH 0,025

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

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

· **Exposure controls**· **Personal protective equipment:**· **General protective and hygienic measures:**

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local ventilation. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times). The usual precautionary measures are to be adhered to when handling chemicals.

· **Respiratory protection:**

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

· **Protection of hands:**

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use

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** Protect hands with category III work gloves (see standard EN 374).· **Penetration time of glove material**

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

· **Eye protection:** Wear airtight protective goggles (see standard EN 166).

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· Body protection:

Wear category III professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

9 Physical and chemical properties

· Information on basic physical and chemical properties**· General Information****· Appearance:****Form:** Viscous fluid**Colour:** White**· Odour:** Odourless**· Odour threshold:** Not available**· pH-value:** Not available**· Change in condition****Melting point/freezing point:** Not available**Initial boiling point and boiling range:** Not available**· Flash point:** Not available**· Flammability (solid, gas):** Not available**· Ignition temperature:** Not available**· Decomposition temperature:** Not available**· Auto-ignition temperature:** Product is not selfigniting.**· Explosive properties:** Product does not present an explosion hazard.**· Explosion limits:****Lower:** Not available**Upper:** Not available**· Vapour pressure:** Not available**· Density:** Not available**· Relative density** Not available**· Vapour density** Not available**· Evaporation rate** Not available**· Solubility in / Miscibility with water:**

Insoluble

· Partition coefficient: n-octanol/water: not available**· Viscosity:****Dynamic:** Not available**Kinematic:** Not available**· Solvent content:****VOC (EC)** 0.00 %**· Other information** Information not available

10 Stability and reactivity

· Reactivity There are no particular risks of reaction with other substances in normal conditions of use.

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- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
The product is stable in normal conditions of use and storage.
- **Possibility of hazardous reactions:**
No hazardous reactions are foreseeable in normal conditions of use and storage.
- **Conditions to avoid:** Protect against heat, solar radiation and light
- **Incompatible materials:** Information not available
- **Hazardous decomposition products:** Information not available

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **Skin corrosion/irritation** Does not meet the classification criteria for this hazard class.
- **Serious eye damage/irritation** Does not meet the classification criteria for this hazard class.
- **Respiratory or skin sensitisation** Does not meet the classification criteria for this hazard class.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Does not meet the classification criteria for this hazard class.
- **Carcinogenicity** Does not meet the classification criteria for this hazard class.
- **Reproductive toxicity** Does not meet the classification criteria for this hazard class.
- **STOT-single exposure** Does not meet the classification criteria for this hazard class.
- **STOT-repeated exposure** Does not meet the classification criteria for this hazard class.
- **Aspiration hazard** Does not meet the classification criteria for this hazard class.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** Information not available
- **Mobility in soil** Information not 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:**
12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.
- **vPvB:** Not applicable.
- **Other adverse effects** Information not available

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Reuse, when possible. Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

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Avoid littering. Do not contaminate soil, sewers and waterways.

Solid residues may be suitable for disposal in an authorised landfill site.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Smaller quantities can be disposed of with household waste.

· **European waste catalogue**

HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
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· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information· **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**

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

Product: None

Contained substance: None.

Substances in Candidate List (Art. 59 REACH): None.

Substances subject to authorisation (Annex XIV REACH): None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None

Substances subject to the Rotterdam Convention: None.

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Substances subject to the Stockholm Convention: None.

Healthcare controls: Information not available.

· **Chemical safety assessment:**

Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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**

H319 Causes serious eye irritation.

H372 Causes damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H412 Harmful to aquatic life with long lasting effects.

· **Department issuing SDS:** Regulatory Affairs

· **Contact:** Customer Service

· **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

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

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

GB2