

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/21/2021

Reviewed on 09/21/2021

1 Identification

- **Product identifier**
- **Trade name:** *Chromaclone™ Ortho & Chromaclone™ 5 Day Stability*
- **Article number:** *SDS 298-001.05, 4033, 4034, 5502, & 5503*
- **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*
- **Information department:** *Customer Service*
- **Emergency telephone number:**
*CHEMTREC (NORTH AMERICA) : (800) 424-9300
(INTERNATIONAL) : +(703) 527-3887*

2 Hazard(s) identification

- **Classification of the substance or mixture**

*GHS08 Health hazard**Carc. 1A H350 May cause cancer.**STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.*

- **Label elements**
- **GHS label elements** *Void*
- **Hazard pictograms** *GHS08*
- **Signal word** *Danger*
- **Health Hazard-determining components of labeling:**
Cristobalite
- **Hazard statements**
*May cause cancer.
Causes damage to organs through prolonged or repeated exposure.*
- **Precautionary statements**
*P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P314 Get medical advice/attention if you feel unwell.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.*

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· **Classification system:**· **NFPA ratings (scale 0 - 4)**· **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = *2
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

14464-46-1	Cristobalite	≥0.1-<10%
	☠ Carc. 1A, H350; STOT RE 1, H372	
16919-27-0	Dipotassium Hexafluotitanate	≥1-<3%
	☠ Acute Tox. 2, H300; Acute Tox. 3, H311; ☠ Eye Dam. 1, H318; ☠ Acute Tox. 4, H332; STOT SE 3, H335	

4 First-aid measures

· **Description of first aid measures**· **General information:**

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:**

Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.

· **After skin contact:**

Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. 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 immediately. Do not induce vomiting. Do not administer anything not explicitly 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 chap. 11.

· **Indication of any immediate medical attention and special treatment needed** Information not available

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5 Fire-fighting measures

- **Extinguishing media**

- **Suitable extinguishing agents:**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

Use fire fighting measures that suit the environment.

- **Special hazards arising from the substance or mixture**

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air.

Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

During heating or in case of fire poisonous gases are produced.

- **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).

Mouth respiratory protective device.

6 Accidental release measures

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

If there are no contraindications, spray powder with water to prevent the formation of dust.

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.

Mount respiratory protective device.

- **Environmental precautions:**

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

Do not allow to enter sewers/ surface or ground water.

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

Collect the leaked product and place it in containers for recovery or disposal. If the product is flammable, use explosion-proof equipment. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

- **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.

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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.
 Ensure good ventilation/exhaustion at the workplace.
 Open and handle receptacle with care.*
- **Information about protection against explosions and fires:** *Keep respiratory protective device available.*
- **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. 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.
 Keep receptacle tightly sealed.*
- **Specific end use(s)** *Professional Dental Impression Material*

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** *No further data; see item 7.*
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
*The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
 At this time, the remaining constituent has no known exposure limits.*

14464-46-1 Cristobalite

PEL	Long-term value: 0.05* mg/m ³ *resp. dust; ½ value from resp.dust formulae Quartz
REL	Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m ³ *as respirable fraction

- **Additional information:** *The lists that were valid during the creation 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.
 Keep away from foodstuffs, beverages and feed.
 Wash hands before breaks and at the end of work.
 Store protective clothing separately.*

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· **Breathing equipment:**

Use a type P filtering facemask (see standard EN 149) or equivalent device, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment.

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **Protection of hands:**

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.



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 is based on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of 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 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).



Tightly sealed goggles

· **Body protection:**

Wear category II 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:	Powder
Color:	Light blue
Odor:	Bubble Gum
Odor threshold:	Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range:	Not applicable
Boiling point/Boiling range:	Not applicable

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· Flash point:	Not Determined
· Flammability (solid, gaseous):	Not determined.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density at 20 °C:	>0.31545-<11.03 g/cm ³
· Bulk density:	>315-<11,030 kg/m ³
· Relative density at 20 °C	0.2-0.5 g/cm ³
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with	
Water:	Partially soluble in water
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC content:	0.00 %
Solids content:	100.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** There are no particular risks of reaction with other substances in normal conditions of use.
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
The product is stable in normal conditions of use and storage.
- **Possibility of hazardous reactions** The powders are potentially explosive when mixed with air.
- **Conditions to avoid** Avoid environmental dust build-up. Avoid moisture and high temperatures.
- **Incompatible materials:** Not known
- **Hazardous decomposition products:** Not known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· LD/LC50 values that are relevant for classification:		
ATE (Acute Toxicity Estimate)		
Oral	LD50	>167-500 mg/kg

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Dermal	LD50	>10,000-30,000 mg/kg
Inhalative	LC50/4 h	>367-1,100 mg/l

16919-27-0 Dipotassium Hexafluotitanate

Oral	LC50 Fish	172.4 mg/l (Brachydanio rerio) (Toxicity to fish)
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· **Primary irritant effect:**

- **on the skin:** Does not meet the classification criteria for this hazard class.
- **on the eye:** Does not meet the classification criteria for this hazard class.
- **Sensitization:** Does not meet the classification criteria for this hazard class.

· **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

· **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
14464-46-1	Cristobalite	I

· NTP (National Toxicology Program)		
14464-46-1	Cristobalite	K

· OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients is listed.		

- **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.
- **Specific target organ toxicity - single exposure** Does not meet the classification criteria for this hazard class.
- **Specific target organ toxicity - repeated exposure** May cause damage to organs.
- **Aspiration hazard** Does not meet the classification criteria for this hazard class.

12 Ecological information

· **Toxicity**

· Aquatic toxicity:		
16919-27-0 Dipotassium Hexafluotitanate		
EC50	0.646 mg/kg (Algae) (Toxicity to aquatic invertebrates)	
	48.2 mg/kg (Crustacean) (Toxicity to fish)	

· **Persistence and degradability** No further relevant information available.

· **Behavior in environmental systems:**

- **Bioaccumulative potential** Information not available
- **Mobility in soil** Information not available

· **Additional ecological information:**

· **General notes:**

Water hazard class 1 (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** Information not available

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13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Disposal should be in accordance with applicable regional, national and local laws and regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- | | |
|----------------------------------------------------------------------------------|-----------------|
| · UN-Number | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | Not Regulated |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | Not Regulated |
| · Packing group | |
| · DOT, IMDG, IATA | Not Regulated |
| · Environmental hazards: | Not Applicable. |
| · Special precautions for user | Not Applicable |
| · Transport in bulk according to Annex II of MARPOL73/78 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**
- **Sara**

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

14464-46-1 | Cristobalite

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

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· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

14464-46-1 Cristobalite

A2

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

14464-46-1 Cristobalite

· **National regulations:**

· **Information about limitation of use:**

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

· **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.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 09/21/2021 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Carc. 1A: Carcinogenicity – Category 1A

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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