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

Printing date 10.04.2019 *Revision: 26.10.2018*

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

· **Product identifier**

· **Trade name: Chromaclone™ Ortho & Chromaclone™ 5 Day Stability**

· **Article number:** 4033, 4034, 5502, & 5503
· **Index number:** SDS 298-001.05
· **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@utradent.com

EC Responsible Person
Ultradent Products GmbH
Am Westhover 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**



GHS08 health hazard

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The Regulation EC 1272/2008 on classification, labeling 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 labeling 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** GHS08
· **Signal word** Warning

· **Hazard-determining components of labelling:**
Cristobalite
· **Hazard statements**
H373 May cause damage to organs through prolonged or repeated exposure.
· **Precautionary statements**
P101 If medical advice is needed, have product container or label at hand.

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P102 Keep out of reach of children.
P103 Read label before use.
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.

· **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: 14464-46-1 EINECS: 238-455-4	Cristobalite STOT RE 1, H372	<8%
CAS: 16919-27-0 EINECS: 240-969-9	Dipotassium Hexafluorotitanate Acute Tox. 3, H301; Eye Dam. 1, H318; Acute Tox. 4, H332; STOT SE 3, H335	<3%

· **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:**
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 Firefighting measures

· ***Extinguishing media***
· ***Suitable extinguishing agents:***
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
Use fire extinguishing methods suitable to surrounding conditions.
· ***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.
· ***Information about fire - and explosion protection:*** *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.*
· ***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:***
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.*

· ***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.
· ***Respiratory protection:***
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 self-contained respiratory protective device.
· ***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.

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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 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*
Colour:	*Light blue*
· ***Odour:***	*Bubble Gum*
· ***Odour threshold:***	*Not determined.*
· ***pH-value:***	*Not applicable.*
· ***Change in condition***	
Melting point/freezing point:	*Not applicable*
Initial boiling point and boiling range:	*Not applicable*
· ***Flash point:***	*Not determined*
· ***Flammability (solid, gas):***	*Not determined.* *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.*

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· **Vapour pressure:**	Not applicable.
· **Density at 20 °C:**	>0.31545-<11.03 g/cm³
· **Bulk density:**	>315-<11,030 kg/m³
· **Relative density at 20 °C**	0.2-0.5 g/cm³
· **Vapour 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 (EC)	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** Based on available data, the classification criteria are not met.

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

ATE (Acute Toxicity Estimates)

Oral	LD50	>3,333-10,000 mg/kg
Inhalative	LC50/4 h	>50-150 mg/l

16919-27-0 Dipotassium Hexafluorotitanate

Oral	LC50 Fish	172.4 mg/l (Brachydanio rerio) (Toxicity to fish)

· **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 (carcinogenity, 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.

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· **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**
May cause damage to organs.
May cause damage to organs through prolonged or repeated exposure.
· **Aspiration hazard** Does not meet the classification criteria for this hazard class.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**	
16919-27-0 Dipotassium Hexafluototitanate	
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.
· **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:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** Information not available

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **European waste catalogue**	
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number**	
· **ADR, ADN, IMDG, IATA**	not regulated
· **UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	not regulated

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· ***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 authorisarion (Annex XIV REACH): None
Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None
Substances subject to the Rotterdam Convention: None
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***
H301 Toxic if swallowed.
H318 Causes serious eye damage.
H332 Harmful if inhaled.
H335 May cause respiratory irritation.
H372 Causes damage to organs through prolonged or repeated exposure.

· ***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)

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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. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2