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

Printing date 26.10.2018 *Revision: 16.10.2018*

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

· **Product identifier**

· **Trade name: Chromaclone® 5 Day Stability**

· **Article number:** 4033, 4034
· **Index number:** SDS 114-001.05
· **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

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· **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.
P102	Keep out of reach of children.
P103	Read label before use.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314	Get medical advice/attention if you feel unwell.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Other hazards**
On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

Classification of the mixture is based on the results of an in vitro assay conducted in accordance with the guidelines provided by OCSE (OECD Test Guideline 437 resp. EU Method B.47 – Bovine Corneal Opacity and Permeability (BCOP) Test Method) and GLP certified - Good Laboratory Practices. For more information refer to section 11.
· **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	1 - < 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	1 - < 3%

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

4 First aid measures

· **Description of first aid measures**
· **After inhalation:**
Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately. In case of unconsciousness place patient stably in side position for transportation.
· **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.
Rinse opened eye for several minutes under running water. Then consult a doctor.

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· **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

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.
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

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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.

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 (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.
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.

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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 aspiration. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

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).
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.

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:***

Tightly sealed goggles

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· **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:	White
· **Odour:**	Bubble Gum
· **Odour threshold:**	Not available
· **pH-value:**	Not applicable.
· **Change in condition**	
Melting point/freezing point:	Not available (Melting point). Not applicable (freezing point).
Initial boiling point and boiling range:	Not applicable
· **Flash point:**	Not available
· **Flammability (solid, gas):**	Not available
· **Decomposition temperature:**	Not available
· **Auto-ignition temperature:**	Not available
· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits:**	
Lower:	Not available
Upper:	Not available
· **Vapour pressure:**	Not applicable.
· **Density:**	Not available
· **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.

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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:*** *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 (INTERNAL TEST (Bridging Principle) - Negative (OECD 437 resp. EU Method B.47, GLP, in vitro, study report 2014).
· ***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.*
· ***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***
In 1997, IARC (the International Agency for Research on Cancer) concluded that crystalline silica inhaled from occupational sources can cause lung cancer in humans. However it pointed out that not all industrial circumstances, nor all crystalline silica types, were to be incriminated (IARC Monographs on the evaluation of the carcinogenic risks of chemicals to humans, Silica, silicates dust and organic fibres, 1997, Vol. 68, IARC, Lyon, France).
In June 2003, SCOEL (the EU Scientific Committee on Occupational Exposure Limits) concluded that the main effect in humans of the inhalation of respirable crystalline silica dust is silicosis. "
There is sufficient information to conclude that the relative risk of lung cancer is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore preventing the onset of silicosis will also reduce the cancer risk" (SCOEL SUM Doc 94-final, June 2003).
There is a body of evidence supporting the fact that increased cancer risk would not be limited to people already suffering from silicosis. According to the current state of the art, worker protection against silicosis can be consistently assured by respecting the existing regulatory occupational exposure limits. Occupational exposure to nuisance dust (total and respirable) and respirable crystalline silica should be monitored and controlled.
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.*

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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***
CRISTOBALITE
NOT rapidly biodegradable.

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

13 Disposal considerations

· ***Waste treatment methods***
· ***Recommendation***
Reuse, when possible. Product residues should be considered special hazardous waste (HP 5). The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.
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.*

14 Transport information

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

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· ***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 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.

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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)
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