

**SAFETY DATA SHEET**  
 according to Regulation (EC) No. 453/2010  
 Dental Use



Date Issued : 04/22/2009  
 SDS No : 114-001.4  
 Date Revised : 07/14/2015  
 Revision No : 4

**Chromaclone® Alginate- Walterberry, Bubblegum & Chromaclone® 5-day stability-  
Bubblegum**

**SECTION 1 : Identification of the substance/preparation and of the company/undertaking**

**1.1. Product identifier**

**Product code** : Catalog Part# 671, 672, 4031, 4032, 4033, 4034  
**Product name** : Chromaclone® Alginate- Walterberry, Bubblegum & Chromaclone® 5-day stability- Bubblegum  
**Product description** : Alginate Impression Material

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**Relevant identified uses** : Professional Dental Impression Material

**1.3. Details of the supplier of the safety data sheet**

**Manufacturer**

Ultradent Products, Inc.  
 505 W. 10200 S.  
 South Jordan, UT 84095

**Distributor**

Ultradent Products GmbH  
 Am Westhoven Berg 30  
 51149 Cologne Germany  
 Email: infoDE@ultradent.com

**Emergency Phone** : +49(0)2203-35-92-0

**1.4. Emergency telephone number**

**CHEMTREC (NORTH AMERICA)** :(800) 424 - 9300  
**(INTERNATIONAL)** :+1(703) 527 - 3887

**SECTION 2: Hazards identification**

**2.1. Classification of the substance or mixture**

**Classification according to Directive 1999/45/EC**

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.  
 This material is not considered hazardous to health.

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Health** : Not Classified

**2.2. Label elements**

**Classification according to Directive 1999/45/EC** : This material is not considered to be hazardous for the health.

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

**Hazard statement(s)** : 2932RS6S: This Material Is Not Considered Hazardous For The Health

**Precautionary statement(s)**

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:

P351: Rinse cautiously with water for several minutes.

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P337+P313: If eye irritation persists: Get medical advice/attention.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P332+P313: If skin irritation occurs: Get medical advice/attention.  
P304+P312: IF INHALED: Call a POISON CENTER/doctor if you feel unwell.  
P304+P341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

**Storage**

: P273: Avoid release to the environment.

**Disposal**

: P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-10/11/2003)

### 2.3. Other hazards

#### Immediate concerns

: 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

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Dipotassium hexafluorotitanate	16919-27-0	240-969-9	< 5	Xi; Xn; R37/38; R22; R41	EYE DMG.,Cat. 1; STOT SE,Cat 3; Acute Tox. (O),Cat. 4; Skin Irr.,Cat. 2; H302; H318; H315; H335

For full text of H-statements and R-phrases: see SECTION 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes**

: Immediately flush eyes with plenty of water. Get medical attention, if

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irritation persists.

**Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.

**Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

**Following inhalation** : If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.

**4.2. Most important symptoms and effects, both acute and delayed**

**Eyes** : Contact may cause eye irritation.

**Skin** : None expected for this product.

**Ingestion** : None expected for this product.

**Inhalation** : None expected for this product.

**4.3. Indication of any immediate medical attention and special treatment needed**

**Notes to physician** : Not Applicable

**SECTION 5: Fire fighting measures**

**5.1. Extinguishing media**

**Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

**5.2. Special hazards arising from the substance or mixture**

**General hazard** : 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.

**Hazardous combustion products** : Information not available

**Explosion hazards** : Not Determined

**Fire explosion** : Not Determined

**Sensitive to static discharge** : Not Determined

**Sensitivity to impact** : Not Determined

**5.3. Advice for firefighters**

**Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.

**Fire fighting equipment** : CO<sub>2</sub>, Foam, Powder, and Water spray

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

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**General procedures** : Refer to Section 8 for Personal Protective Equipment.

**6.2. Environmental precautions**

**Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

**6.3. Methods and material for containment and cleaning up**

**Large spill** : Use spark-proof mechanical equipment to collect the leaked product and place in containers for recovery or disposal. If there are not contraindications, use jets of water to eliminate product residues.

**6.4. Reference to other sections**

**Reference to other sections** : Not Applicable

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

**Handling** : Before handling the product, consult all the other sections of the SDS. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothing and ppe before entering places in which people eat.

**Storage** : See product labeling.

**7.2. Conditions for safe storage, including any incompatibilities**

**Shelf life** : See product labeling

**7.3. Specific end use(s)**

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

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

**Control parameters** : Not Determined

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection.

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : Use only in well-ventilated areas.

**SECTION 9: Physical and chemical properties**

**9.1. Information on basic physical and chemical properties**

**Colour** : Color dependent

**Odour** : Bubblegum

**Solubility in water** : Partially soluble in water.

**9.2. Other information**

**Percent volatile** : Not Determined

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**SECTION 10: Stability and reactivity**

**10.1. Reactivity**

**Reactivity** : Stable

**10.2. Chemical stability**

**Chemical stability** : Stable when stored and handled under recommended conditions.

**10.3. Possibility of hazardous reactions**

**Hazardous polymerization** : None

**10.4. Conditions to avoid**

**Conditions to avoid** : None in particular

**10.5. Incompatible materials**

**Incompatible materials** : Information not available

**10.6. Hazardous decomposition products**

**Hazardous decomposition products** : Information not available

**SECTION 11: Toxicological information**

**11.1. Information on toxicological effects**

**Acute**

**Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

**SECTION 12: Ecological information**

**12.1. Toxicity**

**Toxicity** : DIPOTASSIUM HEXAFLUOROTITANATE  
 EC50 = 18mg/l (microorganisms, 24h)

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : Not Determined

**12.2. Persistence and degradability**

**Persistence and degradability** : Information not available.

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Information not available

**12.4. Mobility in soil**

**Mobility in soil** : Information not available

**12.5. Results of PBT and vPvB assessment**

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**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%.

**12.6. Other adverse effects**

**Environmental data** : Not Available

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

**Disposal method** : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

**SECTION 14: Transport information**

**14.1. UN number**

**UN number** : N/A

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : N/A

**14.4. Packing group**

**Packing group** : N/A

**14.5. Environmental hazards**

**Marine pollutant #1** : N/A

**14.6. Special precautions for user**

**ADR - road** : Not Dangerous Goods

**RID - rail** : Not Dangerous Goods

**IMDG - sea** : Not Dangerous Goods

**IATA - air** : Not Dangerous Goods

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : Not Dangerous Goods

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**RoHS** : Please refer to Medical Devices Directive 93/42/EEC

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : This product is not considered dangerous for transportation

**SECTION 16: Other information**

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<b>Relevant R-phrases and/or H-statements (number and full text)</b>	<p>: R22: Harmful if swallowed.    R37/38: Irritating to respiratory system and skin.    R41: Risk of serious damage to eyes.    Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4    EYE DMG., Cat. 1: Eye Damage, Category 1    STOT SE, Cat 3: Target Organ Toxicity (Single exposure), respiratory tract, Category 3    Skin Irr., Cat. 2: Skin Irritation, Category 2    H302: Harmful if swallowed.    H315: Causes skin irritation.    H318: Causes serious eye damage.    H335: May cause respiratory irritation.</p>
<b>Prepared by</b>	: Anu Kattoju
<b>Revision summary</b>	<p>: This SDS replaces the 07/26/2012 SDS. Revised: <b>Section 1:</b> GENERAL USE, PREPARED BY. <b>Section 2:</b> EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. <b>Section 3:</b> Wt.%. <b>Section 4:</b> NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INGESTION, INHALATION, SKIN ). <b>Section 5:</b> EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, GENERAL HAZARD, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. <b>Section 6:</b> GENERAL PROCEDURES, LARGE SPILL, SMALL SPILL, . <b>Section 7:</b> HANDLING, SHELF LIFE, STORAGE, . <b>Section 8:</b> PERSONAL PROTECTIVE EQUIPMENT ( EYES AND FACE ), . <b>Section 9:</b> ODOR, PERCENT VOLATILE, pH. <b>Section 10:</b> CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE. <b>Section 11:</b> ACUTE. <b>Section 12:</b> CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. <b>Section 14:</b> ROAD AND RAIL (ADR/RID) ( ROAD AND RAIL (ADR/RID), MARINE POLLUTANT #1 ), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. <b>Section 15:</b> COMMENTS, RoHS, SECTION 15: Regulatory information. <b>Section 16:</b> GENERAL STATEMENTS.</p>
<b>General statements</b>	: N/A= Not Applicable
<b>Manufacturer disclaimer</b>	<p>: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.</p>

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