

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



Date Issued : 04/12/2011
SDS No : 298-001.4
Date Revised : 07/14/2015
Revision No : 3

Chromaclone® Ortho & Chromaclone® Ortho 5-day Stability

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

1.1. Product identifier

Product code : Catalog Part# 4033, 4034 (Fast Set), 5502, 5503 (Extra Fast Set)
Product name : Chromaclone® Ortho & Chromaclone® Ortho 5-day Stability
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

Opal® Orthodontics
 505 W 10200 S
 South Jordan, UT 84095

Distributor

MPG Service GmbH
 Gereonstrasse 34-36
 D-50670 Cologne, Germany
 Email: mpgservicekoeln@googlemail.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) : 84648EQ8: This Material Is Not Considered Hazardous To 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.
 P337+P313: If eye irritation persists: Get medical advice/attention.

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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
Mineral Oil (USP Grade)	8042-47-5	232-455-8	< 5	Xn; R65	Asp. Tox.,Cat. 1; H304

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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- Following eyes** : Immediately flush eyes with plenty of water. Get medical attention, if 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** : CO₂, Foam, Powder, and Water spray

SECTION 6: Accidental release measures

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6.1. Personal precautions, protective equipment and emergency procedures

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 : Fast Set:Pink Extra Fast Set:Blue

Odour : Bubblegum

Solubility in water : Partially soluble in water.

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9.2. Other information

Percent volatile : Not Determined

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 LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : 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

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Mobility in soil : Information not available

12.5. Results of PBT and vPvB assessment

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

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Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
 R37/38: Irritating to respiratory system and skin.
 R41: Risk of serious damage to eyes.
 R65: Harmful: may cause lung damage if swallowed.
 Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 Asp. Tox., Cat. 1: Aspiration Toxicity, Category 1
 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.
 H304: May be fatal if swallowed and enters airways.
 H315: Causes skin irritation.
 H318: Causes serious eye damage.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 07/26/2012 SDS. Revised: **Section 1:** GENERAL USE, PREPARED BY, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** Wt.%. **Section 4:** NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, GENERAL HAZARD, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, LARGE SPILL, SMALL SPILL, . **Section 7:** HANDLING, SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT (EYES AND FACE), . **Section 9:** COLOR, PERCENT VOLATILE, pH. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE. **Section 11:** ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** 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. **Section 15:** COMMENTS, RoHS, SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements : N/A= Not Applicable

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Manufacturer disclaimer

: 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.