

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

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

1.1. Product identifier

Product code : 5000, 5001, 5010, 5011, 5012, 5013, 5020, 5021, 5022, 5023, 5030, 5031, 5032, 5033, 7601, 7602
Product name : Chromaclone® PVS, all setting times
Product description : Hydrophilic Polyvinyl Siloxane 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. Please note that this material is not considered hazardous for the health according to the Classification according to Regulation(EC) No 1272/2008[CLP]

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

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.

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

P337+P313: If eye irritation persists: Get medical advice/attention.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 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.
 (EC1975L0442-10/11/2003)

2.3. Other hazards

Immediate concerns

: There is no exposure to breathable , free crystalline silica during normal use of this product. For more information see Section 11.

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]
Silica, Cristobalite	14464-46-1	238-455-4	≤ 15	Xn; R48/20	STOT RE,Cat 1; H372
Quartz, Silicon Dioxide	14808-60-7	238-878-4	≤ 3	Xn; R48/20	STOT RE,Cat 1; H372
Nonylphenol Ethoxylate	9016-45-9	N/A	0.4	Xi; N; R36/38; R51/53	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2; Aquatic Chronic,Cat. 2; H315; H319; H411

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 irritation persists.

Following skin

: Wash with soap and water.

Following ingestion

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

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

Following inhalation : Remove to open air. In the event of breathing difficulties get medical advice/attention immediately.

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

Eyes : May cause mild eye irritation.
Skin : None expected for this product.
Ingestion : May be harmful if swallowed in large quantities.
Inhalation : May cause mild irritation.

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 : Do not breathe combustion products.
Hazardous combustion products : None known.
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 : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

SECTION 6: Accidental release measures

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

Small spill : Shovel or vacuum spill and place in a container for disposal.
Large spill : Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Reference to other sections : Not Applicable

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

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** : Cristobalite: Type: OEL. Country: IRL. TWA/8h: 0,1 mg/m³. Type: TLV-ACGIH: TWA/8h: 0,025 mg/m³.
 Quartz: Type: WEL. Country: UK. TWA/8h: 0,3 mg/m³. Type: OEL. Country: IRL. TWA/8h: 0,1 mg/m³. Type: TLV-ACGIH. TWA/8h: 0,025 mg/m³.

8.2. Exposure controls

- Eye/face protection** : Wear eye protection
- Skin protection** : Wear suitable protective clothing and gloves.
- Respiratory protection** : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state** : Liquid
- Colour** : Color dependent
- Odour** : Bubblegum
- Solubility in water** : Insoluble

9.2. Other information

- Percent volatile** : Not Volatile

SECTION 10: Stability and reactivity

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

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 : Not Determined

10.5. Incompatible materials

Incompatible materials : The "Base" component may produce hydrogen in contact with alkaline and acid substances.

10.6. Hazardous decomposition products

Hazardous decomposition products : None

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

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

12.2. Persistence and degradability

Persistence and degradability : Cristobalite
 Not rapidly biodegradable

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

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 : Substance of very high concern because, due their degradation to substances of very high concern (4-nonphenol, branched and linear)

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

with endocrine disrupting properties, they cause probable serious effects to the environment (SVHC support document, ECHA 2013)

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 : Quartz is listed by IARC, NTP, or OSHA as a carcinogen.
 Nonylphenol Ethoxylated is on the Candidate list (Art 59 REACH)
 This product is not considered dangerous for transportation.

SECTION 16: Other information

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



Date Issued : 04/01/2013
SDS No : 314-001.2
Date Revised : 08/11/2015
Revision No : 1

Chromaclone® PVS, all setting times

Relevant R-phrases and/or H-statements (number and full text)	<ul style="list-style-type: none"> : R36/38: Irritating to eyes and skin. R48/20: Harmful : danger of serious damage to health by prolonged exposure through inhalation. R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Aquatic Chronic, Cat. 2: Chronic Hazards to the Aquatic Environment, Category 2 Eye Irr., Cat. 2: Eye Irritation, Category 2 STOT RE, Cat 1: Target Organ Toxicity (Repeated exposure), lungs, Category 1 Skin Irr., Cat. 2: Skin Irritation, Category 2 H315: Causes skin irritation. H319: Causes serious eye irritation. H372: Causes damage to lungs. H411: Toxic to aquatic life with long lasting effects.
Prepared by	: Anu Kattoju
Revision summary	: This SDS replaces the 04/01/2013 SDS. Revised: Section 1: Date-Revised, GENERAL USE, PREPARED BY, PRODUCT CODE/ PART #. Section 16: Revision Summary.
General statements	: N/A= Not Applicable
Additional SDS information	: Revision #:1
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.