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Produktnamn: Sealtemp

Artikelnr: 57602-03, 57740-41

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MATERIAL SAFETY DATA SHEET

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

Commercial name: SEAL TEMP

Relevant uses of the products: resin-based temporary luting cement – Dental use only

Products references : STS-25, STDS-16

Manufacturer/Supplier:

G-PHARMA

ZI des Bellevues – 35, avenue du Gros Chêne

BP 50072 HERBLAY

95612 CERGY PONTOISE cedex France

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Section 2 - Hazards identification

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending and repealing Directives 67/548 / EEC and 1999/45 / EC, and amending Regulation 1907/2006 / EC (CLP Regulation). The mixture requires a safety plug in accordance with the requirements requested.

2.1.1 Classification according to regulation 1272/2008 EC:

Eyes irrit. 2: **H319**; STOT SE 3: **H335**; skin irrit. 2: **H315**; skin sens.1: **H317**

2.1.2 Classification according to the directive N° 67/548/CEE :

Xi: **R36, R37, R38, R43**: skin sens., eyes & skin irrit., resp. irrit.,

2.1.3 Additional information

The full wording of the classes and categories of danger, hazard statements H and R phrases, is mentioned in Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP) and its exceptions to Article 17 (relating to labeling and packaging requirements) provided for products with a capacity of less than 125 ml (Appendix I Regulation section 1.5.2.1).

Pictogram

SGH07



Signal word

Warning

H statement

H317 : May cause an allergic skin reaction.

P statements

P261 : Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 : Contaminated work clothing should not be allowed out of the workplace.

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

Additional hazards information: N/A

2.3 Other hazards: the mixtures do not contain PBT or vPvP.

Section 3 - Composition/information on ingredients

3.1 Products

EEC classification : Class IIa

3.2 Mixture of substances listed below

CE/CAS index	Chemical name	Mass%	Classification according to directive N° 67/548/CEE (DPD)	Classification according to regulation N° 1272/2008 EC (CLP)	Generic threshold
Index : N/A CAS : 6606-59-3	UDMA Urethane dimethacrylate	20-40	Irritat, Xi, eyes, resp. and skin : R36/37/38	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335	≥ 1 % ≥ 1 % ≥ 1 %
Index : N/A CAS : 112945-52-5	Silice	5-20	Irritant XI, eyes., skin. : R36/37	Irrit oc 2 : H319 Irrit cut 2 : H315	≥ 1 % ≥ 1 %
Index : N/A CAS : 94-36-0	BPO Benzoyl peroxide	0,1-1	R2; R7 Irrit, Xi, for eyes: R36 Skin sen.: R43	Organic Peroxid C : H242 Eye irrit.2: H319 Skin sens.1: H317	≥ 1 % ≥ 0,1 %

Additional information: For the wording of the listed H and R phrases, refer to section 16.

Section 4 - First aid measures

4.1 Description of first aid measures

Inhalation: N/A in normal conditions of use.

Swallowing: Rinse the mouth and drink a lot of water. If symptoms persist consult doctor.

Skin contact: Wash with soap and thoroughly rinse with water. Generally the product does not irritate the skin. In case of skin irritation or sensitization, seek for a medical advice

Eye contact: Rinse opened eye for several minutes under running water. Seek for a medical advice irritation persists.

Other measures to be taken: take off contaminated clothe if large quantities of products are involved.

4.2 Most important symptoms and effects, both acute and delayed: N/A.

4.3 Indication of any immediate medical attention and special treatment needed: N/A

Section 5 - Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, powder or water spray. Fight larger fires with water spray or alcohol-resistant foam.

5.2 Special hazards arising from the substance or mixture N/A

Advice for firefighters

Protective equipment: No special measures required.

Section 6 - Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Wash hands with soap and water in case on contact.

6.2 Environmental precautions: Big quantities, Dispose of in accordance to all federal, national and local regulations. Small quantities, polymerize and dispose of normally. Do not allow the product to enter sewers, surface and ground water.

6.3 Methods and material for containment and cleaning up: Wear gloves and protection goggles. Remove the spill with absorbent textile materials (paper towels, sand, sawdust). Wash the contaminated area with soap and water.

6.4 Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.
See Section 7 for a safe handling

Section 7 - Handling and storage

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Wash with soap and water in case on contact. A good ventilation of the workplace is necessary. For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities

Store in the original containers. Avoid exposure to temperature above 23 ° C. Store in a dry, cool place, away from light and moisture. Do not store near a source of heat or flame. Keep containers tightly closed.

S3, S9, S14 : keep in a cool, well-ventilated place. Avoid extreme temperatures, strong light sources, moisture and flames.

7.3 Specific end use(s): Dental professional use only.

Section 8 - Exposure controls/personal protection

8.1 Control parameters

Respiratory protection: Not required in normal conditions of use..

Personal protective equipment: Mask and protection clothe.

Protection of hands: 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 the 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 cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection: Safety glasses.

General protective and hygienic measures:

Usual hygienic measures for dental practice. Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin. Keep away from foodstuffs, beverages and feed. Wash with soap and water in case on contact.

Section 9 - Physical and chemical properties

Appearance: Beige (Part A) and white paste (Par B)

Odour: Characteristic

PH-value: 7

Melting point/Melting range: N/A

Boiling point/Boiling range: N/A

Flash point: N/A.

Flammability: N/A.

Danger of explosion: No explosion hazard.

Vapour pressure: Negligible at room temperature

Density at 20 °C: 1.094 g/cm³

Vapour density N/A

Solubility in / Miscibility with water: Nearly insoluble.

Oxidative properties: No

Specific gravity: ~ 2.2

Section 10 - Stability and reactivity

10.1 Reactivity: N/A

10.2 Chemical stability: Generally stable under normal handling and storage conditions.

10.3 Thermal decomposition / conditions to be avoided: N/A

10.4 Possibility of hazardous reactions: No dangerous reactions known.

10.5 Conditions to avoid: Avoid exposition to direct light and to high temperatures

10.6 Incompatible materials: Amines.

10.7 Hazardous decomposition products: Unknown

Section 11 - Toxicological information

11.1 Information on toxicological effects

Acute toxicity: Possibility of irritation or sensitization of the skin, if the product is not wash off rapidly (soap and water)

Chronical toxicity : Possibility of sensitization of the skin, in case of repeated contacts.

Signes and symptoms of exposure: Irritation of skin, eyes and respiratory tracks. Sensitization of skin.

11.2 Other Information : N/A

Section 12 - Ecological information

12.1 Toxicity

No ecological toxicity or impact on the environment have been identified for this product in the quantities present in the normal packaging. It is inert once polymerized.

Aquatic toxicity: N/A

12.2 Persistence and degradability: N/A

12.3 Bioaccumulative potential: N/A

12.4 Mobility in soil: N/A

12.5 Results of PBT and vPvB assessment: N/A

12.6 Other adverse effects: N/A

Aquatic toxicity : N/A

General indications : not a polluting agent according to the CLP classification.

Do not allow the product to enter sewers, surface and ground water.

Section 13 - Disposal considerations

13.1 Waste treatment methods

Big quantities, Dispose of in accordance to all federal, national and local regulations. Small quantities, polymerize and dispose of normally.

European catalog of wastes

18 01 06 - chemical products made of, or containing dangerous substances

13.2 Uncleaned packaging: Disposal must be in accordance to all federal, national and local regulations

Section 14 - Transport information

UN-Number

ADR, ADN, IMDG, IATA : Void

UN proper shipping name

ADR, ADN, IMDG, IATA: Void

Transport hazard class(es)

ADR, ADN, IMDG, IAT

Class:

Void

Packing group

ADR, IMDG, IATA: Void

Environmental hazards:

Marine pollutant: No

Special precautions for user: N/A

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code: N/A

Section 15 - Regulatory information

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

This product is a Class IIa medical device according to the amended EC-directive 93/42/EEC.

Chemical safety assessment: N/A or ot done

Section 16 - Other information

N/A : Non applicable

Symbols of potential hazards:

Xi : irritating

E : Explosive

O : Oxidizer

STOT SE 3 : Specific target organ toxicity - single exposure hazard category 3

R phrases

R 36: Irritating to eyes.

R 37: Irritating to respiratory system.

R 38: Irritating to skin.

S phrases

S3/9/14: Keep in a cool, well-ventilated place. Avoid extreme temperatures, strong light sources, moisture and flames.

H phrases

Catégorie 2, H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

STOT, SE 3, H335 : Specific target organ toxicity - single exposure hazard category 3. May cause respiratory irritation.

Catégorie 1, skin sensitization, H317: May cause an allergic skin reaction.

Organic peroxyd C : H242 :

P phrases

P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P233: Keep container tightly closed.

P235: Keep cool.

P261 : Avoid breathing dust/fume/gas/mist/vapours/spray.

P264: Wash hands thoroughly after handling.

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

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.

P304 + P340: If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P333 + P313 : If skin irritation or rash occurs: Get medical advice/attention.

P363 : Wash contaminated clothing before reuse.

P403: Store in a well-ventilated place.

P410: Protect from sunlight.

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in this MSDS was obtained from sources that we believe are reliable. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this MSDS information may not be applicable.