

MATERIAL SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Commercial name: HEALDENT

Relevant use of product: Anti-microbial and fluoride self curing liner

Product references: DES

Information concerning safety data sheet supplier:

G-PHARMA

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SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the mixture

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/ 45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP):

Eyes irrit. 2 : **H319**, Skin irrit. 2: **H315**; Skin sens. 1: **H317**

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

Xi : R36, R38. Skin sens. : R43

2.1.3 Additional Informations

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

2.2 Label elements

Labeling according to Regulation (EC) No 1272/2008 (CLP) and its exemptions from Article 17 (relating to labeling and packaging requirements) provided for products with a capacity of less than 125 ml (Annex I of Regulations section 1.5.2.1)

Pictogram (s)

SGH07



Signal word Warning

H statement H317: May cause an allergic skin reaction.

P statements 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

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 rules (CE) N° 1272/2008 (CLP)	Generic threshold
Index : N/A CAS : N/A	Mixture of methacrylates	40-50	Xi eyes, skin irr: R36/38 Skin sens. R43	Skin irrit 2: H315 Eyes irrit 2: H319 Skin Sens. : H317	≥ 1 % ≥ 1 % ≥ 0,1 %
Index : N/A CAS : 8001-54-5	Chlorure of benzalkonium	>1	Aquat. Tox. : R50	Acute aqua. tox. 1: H400	≥ 0,1%

Note: The full text of hazard H and R-phrases is specified in section 16.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

General information: IN CASE OF suspected or proved exposition. Seek medical advice.

Swallowing: Do not induce regurgitation. Always seek medical advice as fast as possible after the ingestion of a large amount of product or if digestive disorder persist.

Skin contact: Rinse abundantly with water, then wash with water and soap. Remove contaminated clothes.

Eye contact: Wash abundantly with water. Seek medical advice.

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

Potential health hazard: With this concentration and use in normal condition of use, the danger for the health is low.

Inhalation: N/A

Swallowing: Possible

Skin Contact: Can cause a light irritation. In case of an allergic reaction, seek medical advice.

Eyes contact: Irritation in case of contact

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

If you feel like seeking medical advice, see section 4.1

SECTION 5 - FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media: N/A

Explosion limits in air: N/A

Unsuitable extinguishing media: N/A

Melting Point: N/A

Specific protection gear: No

Self-ignition temperature: N/A

Inflammability: No

Flash Point: > 100°C

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

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes and skin. Make sure the room is well ventilated

6.2 Environmental precautions:

Don't remove the product in its pure form in the wastewater system

6.3 Methods and material for containment and cleaning up:

Removal method: Large amount: Dispose of material according to regional, provincial and federal regulations (In an adequate and authorize container incineration). Dispose of the containers like the product itself.

Cleaning method: Remove the product with absorbent textile. Then wash the contaminated area with water. Dispose of material according to regional, provincial and federal regulations (In an adequate and authorize container incineration).

6.4 Reference to other sections

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7 – HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid long term exposure to high temperature. This product is for professionals only.

7.2 Conditions for safe storage, including any incompatibilities

Keep the product locked. Avoid exposure to high temperature. Keep the product in a cool and dry place. Do not keep the product near a source of flame or heat. Take appropriate measure to avoid electrostatic forces. Keep containers tightly closed.

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

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Respiratory and ventilating protection: Not necessary in normal condition of use.

Personal protective equipment: Gloves, goggles and blouse

Specific hygiene measure: Avoid the contact with eyes. In case of an eye contact, rinse opened eye for several minutes under running water. Wash hands after use.

SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES

9.1 Information regarding the physicals and chemicals properties

Appearance: Slightly viscous liquid

Colour: Light or slightly yellow

Boiling point: Around 100°C

Density: N/A

Specific gravity (H₂O=1): ~1.03

Odour: Light smell

Solubility with solvents: Yes

Evaporation rate: > butyl acetate

Solubility in water : Soluble

SECTION 10 – STABILITY & REACTIVITY

10.1 Reactivity: N/A.

10.2 Chemical stability: Unstable

10.3 Possibility of hazardous reactions: No dangerous reactions known

10.4 Conditions to avoid: Avoid temperature above 30°C that induce evaporation of water.

10.5 Incompatible materials: Contact with acids liberates toxic gas. Alkalines substances (metals, heavy metals), alkaline oxides, free radicals initiators, intense UV radiations.

10.6 Hazardous decomposition products: Can occur with the substances mentioned above or with high temperature.

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity for health: May cause irritation if the product is not wash rapidly.

Chronical toxicit : Possibility of an allergy to HEMA because of a long term and repeated exposure to the product.

Signs and symptoms of exposure: Irritation of skin and eyes. If swallowed in a large amount, sickness can appear. Inflammatory aspect of the mucosa. Dermatitis

11.2 Other Information: Medical conditions aggravated by exposure: Allergies, pre-existent dermatitis.

SECTION 12 – ECOLOGICAL INFORMATION

12.1 Toxicity

No ecological toxicity or impacts on the environment have been identified for this product in small quantities present (as diluted as it is). In large quantity, has an impact on the water quality.

Hazardousness classification for water: WGK=1 (Substance slightly pollutant)

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

SECTION 13 - DISPOSAL MEASURES

13.1 Waste treatment methods

Large quantity:

Disposal must be made according to local, state and federal regulations.

Small quantity:

Dispose of the product in the sewage system after a high dilution in water.

SECTION 14 - TRANSPORT INFORMATION

The transportation requirements followed the international transportation requirements.

No restriction for the road, boat or plane transportation. Avoid high temperatures during transportation.

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture: Class IIa medical device according to the Directive 93/42 / EEC

15.2 Chemical safety assessment: N/A

SECTION 16 - OTHER INFORMATION

N/A : Non applicable

Symbol of potential danger:

Xi: irritating

R phrases

R 25: Toxic if swallowed

R 32: Contact with acids liberates toxic gas

R 36: Irritating to eyes.

R 38: Irritating to skin.

R 50: Really toxic for aquatics organism

S phrases

S3: Maintain in a well ventilated and fresh area

S9, S14: Avoid extremely high temperature, direct sunlight, flammable and humidity sources

H phrases

Category 2, H315: Causes skin irritation.

H319: Causes serious eye irritation.

H317, Category 1, skin sensitization: Can cause skin allergy

H301, Category 3: Toxic if swallowed

AUH032: Contact with acids liberates toxic gas

H400: High toxicity for the aquatic organisms, toxicity high 1

P phrases:

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.

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

P363: Wash clothes before re-use

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