

According to Regulation (EC) No.1907/2006, Art.31

Issue date: 20.05.2015

1. Identification of the substance/preparation and of the company/undertaking

Product details :

1.1. Trade name

EASYCEM HARD

1.2. Application of the substance / the preparation Filler/ Extender

Dental product

1.3. Manufacturer/Supplier

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1.4. Information in case of emergency

Ospedale Niguarda di Milano-Centro antiveneni numero di emergenza +39 02 66101029

2. Hazards identification

Classification of the substance or mixture:

Classification according to Regulation (EC) No 1272/2008:

Acute aquatic toxicity, Category 1, H400 Very toxic to aquatic life

Chronic aquatic toxicity, Category 1, H410 Very toxic to aquatic life with long lasting effects

Skin Irrit. 2, H315 Causes skin irritation

Eye Irritation, Category 2; H319 Causes serious eye irritation

STOT SE 3, H335 May cause respiratory irritation.

Information concerning particular hazards for human and environment:

The product has to be labeled due to calculation procedure for the "General Classification guideline for preparations of the EU" in the latest version.

Classification system:

The classification corresponds to actual EU-lists, and completed with details from technical literature and company data.

Label elements

Labeling according to Regulation (EC) 1272/2008:

Hazard pictograms

Signal word

Warning

Hazard statements

H400 Very toxic to aquatic life

H315 Causes skin irritation

H319 Causes serious eye irritation

H335 May cause respiratory irritation

Precautionary statements

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.

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

P273 Avoid release to the environment

Labeling according to EU guidelines:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body; are exempted from the provisions of Regulation (EC) No. 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable

vPvB: not applicable

3. Composition/information on ingredients

Chemical characterization:

Description:

Mixture of organic acids, zinc oxide and methacrylates

Hazardous components:

Cas-No.	EC-No.	Name
[CAS-No. 1314-13-2]	Zinc Oxide	GHS09, H410, H411
[Index-No. 607-134-00-4]	Methacrylates	GHS07, H315, H319, H335
	Mixture of organic acids	GHS07, H315, H319, H335

4. First aid measures

General informations: no special measures required

After skin contact: Wash off with plenty of water.

After eye contact: Rinse opened eye for several minutes under running water and consult an ophthalmologist.

After swallowing: Call a medical advice immediately.

5. Fire-fighting measures

Extinguishing media:

CO₂, powder, water spray

Use extinguishing method and media suitable to surrounding fire.

Special hazards arising from the substance or mixture :

No further relevant information available

Protective equipment :

Wear self-contained respiratory protective equipment

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Environmental precautions:

Do not allow to enter drains/surface water/ ground-water.

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Methods for cleaning up:

Take up mechanically. Clean up affected area.

Reference to other sections:

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment

See Section 13 for disposal information.

7. Handling and storage

Handling:

This product should only be supplied or handled to dentists or dental technicians or upon their instructions.

Precautions for safe handling:

Observe normal care for working with chemicals.

Information about fire and explosion protection:

No special measures required

Storage:

Requirements at storerooms and containers: Store only in the original containers

Further information on storage conditions:

Store at dry place, storage temperature 8 - 25°C. Store away from food stuffs.

Specific end uses: No further relevant information available

8. Exposure controls and personal protection

Components with limits of values to be supervised at the workplace:

The product contains no relevant quantities of components with limit values to be supervised at the workplace.

Additional information: The lists valid during the making were used as basis

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs and beverages.

Hand protection: Protective gloves. Due to missing tests no recommendation to the glove material can be given for the product.

Eye protection: Safety glasses

Respiratory protection: Required, when aerosols are generated .

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form: paste

Colour: white yellowish

Odour: odorless

Safety relevant basic data

Melting point/Melting range: n.a

Boiling point/Boiling range: n.a

Flash point: n.d

Ignition temperature: product is not selfigniting

Danger of explosion: none

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Density at 20°C: 1,71 g/cm³

Vapour pressure at 25°C: not applicable, non volatile

Ph: n.a

Solubility in / Miscibility with : slightly in toluene, organic solvent

Water: insoluble

Content of solvents: none

Organic solvents: none

10.Stability and reactivity

Thermal decomposition / conditions to be avoided

No decomposition if used according to specifications.

Possibility of hazardous reactions: No dangerous reaction known

Conditions to avoid: avoid heat, direct sunlight

Incompatible materials: Peroxides, metal powders, strong oxidizers, free radical initiators

Hazardous decomposition products: No dangerous decomposition products known.

11.Toxicological information

Allergic reactions to methacrylates by chronic exposure to the product are possible

Primary irritant effect

skin: slight irritant

eye:irritating effect

Sensitization: no sensitizing effect known

Additional toxicological information:

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12.Ecological information

Toxicity:

Aquatic toxicity:

May cause long term adverse effect in the aquatic environment

Persistence and degradability:

No further relevant information available

Behavior in environmental systems:

Bioaccumulative potential :

No further relevant information available

Mobility in soil :

No further relevant information available

General information:

Do not allow product into surface water or sanitary sewer system

13. Disposal considerations

Product

Recommendation:

Use proper landfill disposal or incineration in accordance with local, state and federal regulations.

Uncleaned packaging:

Handle contaminated packaging in the same way as the substance itself.

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Recommendation:

Disposal must be made according to official regulations.

14. Transport information

Land transport ADR/RID and GGVS/GGVE (EU):

ADR, RID

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S (Zinc oxide), III, 9

Sea transport IMDG

IMDG-Code

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

EmS: F-A S-F

Air transport ICAO-TI and IATA-DGR:

CAO, PAX

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

The transport regulations are cited according to international regulations and in the form applicable in EU. Possible national deviations in other countries are not considered.

15.Regulations

Classification according to EC-guidelines:

The product is a medical device according to EC-directive 93/42 EEC.

Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16.Other informations

Changes compared with the previous version:

Adaptation according to 1907/2006/EG, Article 31

The above information is based on our present day knowledge and relates solely to the safety requirements of the product. The data do not signify any warranty with regards to products properties. However users of the product should satisfy themselves that the information given is sufficient and correct for their specific circumstances of use.