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Printing date: 10.06.2015

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

Product Identifier

Trade name: DEFEND VINYL TRAY ADHESIVE (VP-8300)

Use of the preparation: Dental product

Details of the supplier of the safety data sheet:

Manufacturer/supplier: Mydent International 80 Suffolk Court

Hauppauge, NY 11788, Tel# 631-434-3190

sales@defend.com

Emergency telephone number: CHEMTREC (800) 424-9300

2. Hazards identification

Classification of the substance or mixture:

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

Flam. Liq. 2, H225 Higly flammable liquid and vapour

Aquatic acute 1, H400 Very toxic to aquatic life

Classification according to Directive 67/548/EEC or Directive 1999/45/EC:

F Highly flammable

N Dangerous for the environment

R11 Highly flammable

R50 Very toxic to aquatic organisms

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

Danger

P403 Store in a well ventilated place.

P210 Keep away from heat/sparks/openflames/hot surfaces. – No smoking.

P273 Avoid release to the environment

Labeling according to 67/548/EEC or 1999/45/EC:

F Highly flammable

N Dangerous for the environment

R11 Highly flammable

R50 Very toxic to aquatic organisms

S09 Keep container in a well ventilated place.

S16 Keep away from heat and ignition sources – No smoking.

S61 Avoid release to the environment. Refer to special instrucitons/ Safety data sheets.

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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 dangerous substance Directive 1999/45/EWG.

Other hazards

Results of PBT and vPvB assessment

PBT: not applicable **vPvB:** not applicable

3. Composition/Information on Ingredients

Chemical characterization:

Description of the mixture:

Solution of alkyl poly siloxane and red dye in alkyldisiloxane and xylene

Hazardous components:

CAS 107-46-0, EC 203-492-7 Alkyldisiloxane >65% F, N, R11, R50

GHS02, GHS09, H225, H400

GHS02, GHS07, H226, H332, H312, H315

4. First-aid measures

General information: Seek medical advice, if symptoms occur, which can be caused by the product

after skin contact: wash with plenty of water and soap

After inhalation: fresh air

after eye contact: Rinse opened eye for several minutes under running water and consult a doctor

after swallowing: Seek medical advice

5. Fire fighting measures

Extinguishing media:

Foam, CO₂, powder, water spray.

Extinguishing media should be selected according to the 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:

Do not breathe vapours/aerosols. Use it in well ventilated rooms.

Environmental precautions:

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

Methods for cleaning up:

Absorb with liquid binding material. Forward for disposal. 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

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Information about fire and explosion protection:

Keep away from heat and ignition sources, do not smoke.

Storage:

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

Further information on storage conditions:

Store in well ventilated place at 15 - 25 °C. Store away from food stuffs. Store tightly closed.

Specific end uses: No further relevant information available

8. Exposure controls/personal protection

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

CAS-No. name	art	value	unit
1330-20-7 Xylene (all isomers)	TRGS900	100	ml/m^3
	or	440	mg/m^3

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. Avoid contact with eyes or skin

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: Provide adequate ventilation

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance

Form: liquid Color: red

Odor: characteristic

Value Unit Method

Safety relevant basic data

Melting point/melting range: n.a. **Boiling point/boiling range:** n.a.

Flash point: $-6 \,^{\circ}\text{C}$ DIN 51755

Ignition temperature: n.a. **Danger of explosion:** n.a.

Density: $0.8 (20^{\circ}\text{C}) \text{ g/cm}^{3}$

Vapor pressure: n.d.

Solubility in/miscibility with: Ethanol, ketones

Water: insoluble

10. Stability and reactivity

Thermal decomposition / conditions to be avoided : heat

Possibility of hazardous reactions: no information available

Conditions to avoid: Avoid strong acids, strong alkalis, strong oxidizing agents.

Hazardous decomposition products: No information available.

11. Toxicological information

Acute toxicity: no data available

Primary irritation:

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skin: frequently or prolonged contact with skin may cause dermal irritation

eye: slight irritating effect

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: No further relevant information available

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 flush into surface water or sanitary sewer system

Do not allow uncontrolled leakage of product into the environment

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.

Recommendation: Disposal must be made according to official regulations

14. Transport information

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

UN 1993

ENTZUENDBARER FLUESSIGER STOFF, N.A.G., 3, II (Hexamethyldisiloxan)

Sea transport IMDG:

UN 1993,

FLAMMABLE LIQUID, N.O.S., 3, II (Hexamethyldisiloxane)

EmS: F-E S-D

Air transport ICAO-TI and IATA-DGR:

UN 1993

FLAMMABLE LIQUID, N.O.S., 3, II (Hexamethyldisiloxane)

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

15. Regulatory information

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 information:

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.

Preparation by

Mydent International