

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING INFORMATION ON THE PRODUCT 1.1 Product identifier Trade name Synthetic polymer teeth REF-LINE 1.2 Relevant identifier uses of the substance or mixture and uses advised against Recommended use Teeth are intended for replacing missing teeth by making total and partial dentures and by making implant supported dentures. Non-recommended use Non-dental use. 1.3 Details of the supplier of the Safety Data Sheet Manufacturer/supplier Polident d.o.o., Dental Products Industry Volčja Draga 42, 5293 Volčja Draga, Slovenija Tel.:00386 5 3304840, Fax: 00386 5 3304870 E-mail: polident@polident.si Information provided by 00386 5 3304859 Emergency telephone number 00386 5 3304840	
2. HAZARDS IDENTIFICATION 2.1 Classification of the substance or mixture Classification according to Regulation 1272/2008/EC: Not applicable 2.2 Label elements Labelling according to Regulation 1272/2008/EC: Not applicable. 2.3 Other hazards: Avoid breathing dust generated by final working. Results of PBT and vPvB assessment: Not applicable.	
3. COMPOSITION/INFORMATION ON INGREDIENTS 3.1 Chemical characterization: Mixtures Description Material is highly crosslinked polymethylmethacrylate containing inorganic filler and pigments. Hazardous ingredients according to Regulation 1272/2008/EC: Not applicable	
4. FIRST AID MEASURES 4.1 Description of first aid measures General information No special measures required. Inhalation Remove the casualty into fresh air. In case of complaints get medical advice. Skin contact Wash off with water and soap. Consult a physician if irritation persists. Eye contact Rinse eye with plenty of water if it is necessary seek medical attention: only mechanical effect. Ingestion	

4.2	Wash out mouth with water and drink water. In case of complaints get medical advice. Most important symptoms and effects, both acute and delayed None known.
4.3	Indication of any immediate medical attention and special treatment needed Treat symptomatically.
5.	FIRE – FIGHTING MEASURES
5.1	Extinguishing media Suitable extinguishing media Water, foam, dry powder, carbon dioxide. Unsuitable extinguishing media for safety reasons None.
5.2	Special hazards arising from the substance or mixture May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition.
5.3	Advice for firefighters Wear self-contained breathing apparatus.
6.	ACCIDENTAL RELEASE MEASURES
6.1	Personal precautions, protective equipment and emergency procedures Not required.
6.2	Environmental precautions No special measures required.
6.3	Methods and material for containment and cleaning up Pick up mechanically. Dispose of in accordance with regulations.
6.4	Reference to other sections For information on safe handling see Section 7. For information on personal protection equipment see Section 8. For information on disposal information see Section 13.
7.	HANDLING AND STORAGE
7.1	Precautions for safe handling Safe handling advice Only adequate trained persons may deal with product. For use in dentistry only. Keep away from children. Ensure the area is well ventilated. No eating, drinking or smoking during handling with product. Follow the usual good standards of occupational hygiene. Information on fire and explosion protection No special measures required.
7.2	Conditions for safe storage, including any incompatibilities Storage Requirements for storage areas Keep in dry storage.
7.3	Specific end use(s) None.
8.	EXPOSURE CONTROLS /PERSONAL PROTECTION
8.1	Control parameters Ingredients with limit values that require monitoring at the workplace The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
8.2	Exposure controls General protective measures Provide adequate ventilation. Hygiene measures Follow the usual good standards of occupational hygiene and dental practise. Respiratory protection

Avoid contact with powder/dust generated by final working.
Wear respiratory protective device in case of dust formation.

Hand protection

Not required.

Eye protection

Wear safety goggles during mechanical processing.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:

Form: solid

Colour: different colours

Odour: odourless

Changes in condition: /

Melting point: Undetermined

Boiling point: Undetermined

Flash point: >250°C

Ignition temperature: not applicable

Lower explosion limit: not determined

Upper explosion limit: not determined

Vapour pressure: not applicable

Density: 1,17 g/cm³

Viscosity (dynamic): not applicable

Solubility in water: insoluble

pH – value: not applicable

9.2 Other information

None.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No relevant information available.

10.2 Chemical stability

The product is stable under normal handling and storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Decompositions begins at appr. 250°C.

10.5 Incompatible materials

No relevant information available.

10.6 Hazardous decomposition products

None when used as prescribed.

May be released in case of fire: carbon monoxide, carbon dioxide, organic products of decomposition

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity

The product has been tested according to EN ISO 10993-5 (2009): Tests for in vitro cytotoxicity. The test article extract met the requirements of the EN ISO 10993-5 (2009).

Irritation

The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. An intracutaneous irritation test by intradermal injection in the rabbit has been performed and the test article extract met the requirements of the ISO 10993-10 (2010).

Sensitization

The similar product has been tested according to EN ISO 10993-10 (2010): Tests for irritation and skin sensitization. According to the EN ISO 10993-10 (2010) the product did not induce delayed sensitization and met the requirements of the standard.

12. ECOLOGICAL INFORMATION	
12.1 Toxicity	Hazardous to the aquatic environment: No further relevant information available, no evidence for hazardous properties
12.2 Persistence and degradability:	No further relevant information available, no evidence for hazardous properties
12.3 Bioaccumulative potential:	No further relevant information available, no evidence for hazardous properties
12.4 Mobility in soil:	No further relevant information available, no evidence for hazardous properties
12.5 Results of PBT and vPvB assessment	PBT: Not applicable. vPvB: Not applicable.
12.6 Other adverse effects:	No further relevant information available.
13. DISPOSAL CONSIDERATIONS	
13.1 Waste treatment methods	Product: Disposal should be made in accordance with local, state and national legislation. Uncleaned packaging: Disposal should be made in accordance with local, state and national legislation.
14. TRANSPORT INFORMATION	
14.1 UN Number:	see section 14.2
14.2 UN proper shipping name	Land transport ADR: Not dangerous according to transport regulations. Land transport RID: Not dangerous according to transport regulations. Inland waterway transport ADN: Not dangerous according to transport regulations. Shipment by sea IMDG: Not dangerous according to transport regulations. Air transport ICAO/IATA: Not dangerous according to transport regulations.
14.3 Transport hazard class(es):	see section 14.2
14.4 Packing group:	see section 14.2
14.5 Environmental hazards:	None.
14.6 Special precautions for user:	see section 14.2
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	None.
15. REGULATORY INFORMATION	
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	National regulations Other regulations, limitations and prohibitive regulations The product is Class IIa medical device according to the EC Directive 93/42/EEC.
16. OTHER INFORMATION	None
This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a guarantee of certain product's features.	

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