


01. Identification of the substance / preparation and of the company

Product:	alphasil® PERFECT ACTIVATOR PASTE DBTL -free
Registration number:	not applicable
Use / Method of operation:	see product information / instructions for use
Identified use:	Medical device, hardener for dental impression materials
Company:	Müller-Omicron GmbH & Co. KG Schlosserstraße 1 51789 Lindlar / GERMANY
Phone:	0049 (0) 2266-4742-0
Fax:	0049 (0) 2266-3417
eMail:	info@mueller-omicron.de
Homepage:	www.mueller-omicron.de
Emergency phone:	0049 (0) 2266-4742-0 (8:00 – 17:00)
Responsible:	vschr@omicron-dental.de

02. Hazards identification

Physico-chemical hazards:	See chapter 10
Human health dangers:	See chapter 11
Environmental hazards:	See chapter 12.
Other hazards:	none
Hazard symbols :	 Harmful Contains: organo tin compounds
R-phrases:	R38 Irritating to skin. R43 May cause sensitization by skin contact. R48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed. R62 Possible risk of impaired fertility R63 Possible risk of harm to the unborn child.

03. Composition / Information on ingredients

Tetraalkylsilicate	20 - < 50 %
Xi, R38 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:-	
Diorganotin-dicarboxylate	1 - < 10 %
Xn, R48/22-53 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:-	
Tetraorganotin compound	1 - < 10 %
Xn, R48/22-62-63-43-52/53 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:-	
Description:	Mixture: hardener for the base-component of dental impression materials based on condensation-curing 2-part silicones.
Hazardous Ingredients:	For the wording of the listed risk phrases refer to section 16.

04. First aid measures

General information:	Change soaked clothing.
Inhalation:	Ensure supply of fresh air. In the event of symptoms seek for medical treatment.
Skin contact:	In case of contact with skin wash off immediately with soap and water.

Eye contact:	In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice.
Ingestion:	Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Seek medical advice.
Advice to doctor:	Treat symptomatically.

05. Fire-fighting measures

Suitable extinguishing media:	Foam. Dry powder. Water spray jet. Carbon dioxide.
Extinguishing media that must not be used:	Full water jet.
Special exposure hazards arising from the substance or preparation itself or combustion products:	Unknown risk of formation of toxic pyrolysis products.
Special protective equipment for firefighters:	Use self-contained breathing apparatus.
Additional information:	Fire residues and contaminated firefighting water must be disposed of in accordance within the local regulations.

06. Accidental release measures

Personal precautions:	High risk of slipping due to leakage/spillage of product. Ensure adequate ventilation.
Environmental precautions:	Do not discharge into the drains / surface waters / groundwater.
Methods for cleaning up:	Take up mechanically. Take up residues with absorbent material (e.g. sand, sawdust, generalpurpose binder, diatomaceous earth). Dispose of absorbed material in accordance within the regulations.

07. Handling and storage

Advice on safe handling:	Use only in well-ventilated areas.
Advice on protection against fire and explosion:	Keep away from all sources of ignition - Refrain from smoking.
Requirements for storage rooms and vessels:	Keep only in original container. Prevent penetration into the ground.
Advice on storage compatibility:	Do not store together with oxidizing agents.
Further information on storage conditions:	Keep container tightly closed. Keep container in a well-ventilated place. Keep in a cool place.

08. Exposure controls / personal protection

Additional advice on system design:	Ensure adequate ventilation on workstation.
Ingredients with occupational exposure limits to be monitored:	not applicable
Respiratory protection:	Breathing apparatus in the event of high concentrations. Short term: filter apparatus, filter A.
Hand protection:	butyl rubber, > 120 min (EN 374)
Eye protection:	safety glasses
Skin protection:	Light protective clothing.
General protective measures:	Avoid contact with eyes and skin. Do not inhale gases/vapours.
Hygiene measures:	Do not eat, drink, smoke or take drugs at work. Wash hands before breaks and after work. Use barrier skin cream.

Delimitation and monitoring of the environment exposition:

not determined

09. Physical and chemical properties

Appearance:	pasty	Density at 23°C [g/ml]:	approx. 0,98
Color:	red	Evaporation speed:	not determined
Odor:	characteristic	Vapour pressure [kPa]:	not determined
pH-value:	not determined	Viscosity [mPas]:	not applicable
Boiling point [°C]:	not determined	Solubility in water:	immiscible
Flash point [°C]:	not applicable	Oxidizing properties:	no
Flammability:	not determined	Melting point [°C]:	not determined
Upper explosion limit:	not applicable	Autoignition temperature:	not applicable
Lower explosion limit:	not applicable	Decomposition temperature:	not applicable

10. Stability and reactivity

Hazardous reactions:	Reactions with oxidizing agents.
Hazardous decomposition products:	No hazardous decomposition products known.

11. Toxicological information

Acute toxicity oral / dermal / inhalational:	not determined
Irritant effect on eye:	not determined
Irritant effect on skin :	not determined
Sensitization:	not determined
Subacute / Chronic toxicity:	not determined
CMR-activity	not determined
Experiences made in practice:	none
General remarks:	Toxicological data are not available. The product was classified on the basis of the calculation procedure of the preparation directive.

12. Ecological information

Fish / Daphnia / Bacteria toxicity:	not determined
Behaviour in environment compartments:	not determined
Behaviour in sewage plant:	not determined
Biological degradability:	not determined
Chemical (COD) / Biochemical (BOD 5) oxygen demand:	not determined
AOX-advice:	not applicable
2006/11/EC:	not applicable
General information:	Ecological data are not available. Do not discharge product unmonitored into the environment or into the drainage.

13. Disposal considerations

Product:	Dispose of as hazardous waste. For recycling, consult manufacturer.
Waste no. (recommended):	070608*
Contaminated packaging:	Uncontaminated packaging may be taken for recycling. Packaging that cannot be cleaned should be disposed of as for product.
Waste no. (recommended):	150110*

14. Transport information

Classification according to ADR:

Classification according to ADR:	no dangerous goods
- Classification Code:	-
- Label:	-
- ADR LQ	-
- ADR 1.1.3.6 (8.6):	Transport category (tunnel restriction code): -

Classification according to IMDG:

Classification according to IMDG:	not classified as « Dangerous Goods »
- EMS:	-
- Label:	-
IMDG LQ:	-

Classification according to IATA:

Classification according to IATA:	not classified as « Dangerous Goods »
- Label:	-

15. Regulatory information

Exposure scenario:	not determined
Chemical safety report:	not determined
Labelling:	The product is classified and labelled in accordance within EC-directives. This preparation is excluded as medical device from the regulation 1999/45/EEC and TITEL IV of 1907/2006/EEC (REACH).
Special labelling:	not applicable
Authorisation, TITEL VII:	not applicable
Restrictions, TITEL VIII:	not applicable
EEC-REGULATIONS:	1967/548 (1999/45); 1991/689 (2001/118); 1999/13; 2004/42; 648/2004; 1907/2006 (Reach); 1272/2008; 75/324/EC (2008/47/EC); 453/2010/EC
TRANSPORT- REGULATIONS:	DOT-Classification, ADR (2011); IMDG-Code (2011, 35. Amdt.); IATA-DGR (2011).
NATIONAL REGULATIONS:	EH40/2005 Workplace exposure limits with amendments October 2007

16. Other informations

R-phrases (Chapter 03):	R 48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed.
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	R 53 May cause long-term adverse effects in the aquatic environment. R 62 Possible risk of impaired fertility R 63 Possible risk of harm to the unborn child. R 43 May cause sensitization by skin contact. R 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R 38 Irritating to skin.
Observe employment restrictions for people:	yes
VOC (1999/13/CE):	not determined
Customs tariff:	not determined

Disclaimer: This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.