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

Product: alphasil® PERFECT ACTIVATOR LIQUID 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

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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: organotin 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		50 - < 70 %
Xi, R38 CAS: -, EINECS/ELINCS: -	-, EU-INDEX: -, ECBnr:-	
Diorganotin-dicarboxylate		10 - < 25 %
Xn, R48/22-53 CAS: -, EINECS/ELI	NCS: -, EU-INDEX: -, ECBnr:-	
Tetraorganotin compound		10 - < 25 %
Xn, R48/22-62-63-43-52/53 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:-		
Alkanol 1 -		1 - < 5 %
Xn, R20/21/22-36/38 CAS: -, EINECS/ELINCS: -, EU-INDEX: -, ECBnr:-		
Tetraalkylsilicate		1 - < 5 %
Xn, R36/37-20-10 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.



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Skin contact:	When in contact with the skin, clean with soap and water. Consult a doctor if skin irritation persists.	
Eye contact:	In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice.	
Ingestion:	Supply with medical care. Do not induce vomiting. Rinse out mouth and give plenty of water to drink.	
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	Use self-contained breathing apparatus.
firefighters:	Do not inhale explosion and/or combustion gases.
Additional information:	Fire residues and contaminated firefighting water must be disposed of in accordance within the local regulations.

06. Accidental release measures

Personal precautions:	Some risk of slipping due to spillage of product. Ensure adequate ventillation. Keep away from all sources of ignition.
Environmental precautions:	Do not discharge into the drains / surface waters / groundwater. Prevent spread over a wide area (e.g. by containment or oil barriers).
Methods for cleaning up:	Take up with absorbent material (e.g. general-purpose binder). 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.	
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	



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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:	liquid	Density at 23°C [g/ml]:	approx. 1,0
Color:	colourless / red	Evaporation speed:	not determined
Odor:	characteristic	Vapour pressure [kPa]:	not determined
pH-value:	not determined	Viscosity [mPas]:	not determined
Boiling point [°C]:	not determined	Solubility in water:	immiscible
Flash point [°C]:	not determined	Oxidizing properties:	no
Flammability:	not determined	Melting point [°C]:	not determined
Upper explosion limit:	not applicable	Autoignition temperature:	not determined
Lower explosion limit:	not applicable	Decomposition temperature:	not determined

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. No classification 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.



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13. Disposal considerations

Product:	Dispose of as hazardous waste. For recycling, consult manufacturer.
Waste no. (recommended):	070704*
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

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16. Other informations

R-phrases (Chapter 03):	R 38 Irritating to skin. R 48/22 Harmful: danger of serious damage to health by prolonged exposure if swallowed. 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 20/21/22 Harmful by inhalation, in contact with skin and if swallowed.
	R 36/38 Irritating to eyes and skin. R 36/37 Irritating to eyes and respiratory system. R 20 Harmful by inhalation. R 10 Flammable.
Observe employment restrictions for people:	yes
VOC (1999/13/CE):	not applicable
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.