

Safety data sheet
according to 1907/2006/EC, Article 31

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Version number 3

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Product identifier**
- **Trade name: *alphasil® PERFECT ACTIVATOR PASTE DBTL-free***
- **Application of the substance / the mixture** Hardener for impression material, medical device.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Müller-Omicron GmbH & Co. KG
Schlosserstr. 1
D-51789 Lindlar
GERMANY
www.mueller-omicron.com
- **Further information obtainable from:**
Product safety department
sds@mueller-omicron.de
- **1.4 Emergency telephone number:**
Emergency CONTACT (24-Hour-Number): GBK GmbH +49 (0)6132-84463

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Repr. 1B H360D May damage the unborn child.
STOT RE 2 H373 May cause damage to the blood and the immune system through prolonged or repeated exposure. Route of exposure: Oral.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
dioctyltin dilaurate
Dioctylzinnbisacetylacetonat (CAS 54068-28-9)
Tetrakis(2-butoxyethoxy)silane (CAS 18765-38-3)
Aroma mixture

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- Hazard statements

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H360D May damage the unborn child.
- H373 May cause damage to the blood and the immune system through prolonged or repeated exposure.
Route of exposure: Oral.
- H412 Harmful to aquatic life with long lasting effects.

- Precautionary statements

- P101 If medical advice is needed, have product container or label at hand.
- P102 Keep out of reach of children.
- P103 Read carefully and follow all instructions.
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P405 Store locked up.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- Additional information: Restricted to professional users

- 2.3 Other hazards

- Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures

- Description: Mixture of substances listed below with nonhazardous additions.

- Dangerous components:

	Tetrakis(2-butoxyethoxy)silane (CAS 18765-38-3) ⚠ STOT RE 2, H373; ⚠ Skin Irrit. 2, H315	10-25%
CAS: 3648-18-8 EINECS: 222-883-3 Index number: 050-031-00-9	dioctyltin dilaurate ⚠ Repr. 1B, H360D; STOT RE 1, H372	≥2.5-<10%
	Dioctylzinnbisacetylacetonat (CAS 54068-28-9) ⚠ STOT SE 2, H371; ⚠ Skin Sens. 1, H317	≥2.5-<10%
CAS: 111-76-2 EINECS: 203-905-0 Index number: 603-014-00-0	2-butoxyethanol ⚠ Acute Tox. 3, H311; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.1-1%
	Aroma mixture ⚠ Flam. Liq. 3, H226; ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥0.25-<1%

- SVHC

3648-18-8 | dioctyltin dilaurate

- Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures

- General information:

Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- After skin contact: Immediately wash with water and soap and rinse thoroughly.

- After eye contact: Rinse opened eye for several minutes under running water.

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- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Mount respiratory protective device.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **6.4 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.

* SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

* SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Additional information about design of technical facilities:** No further data; see item 7.
- **Ingredients with limit values that require monitoring at the workplace:**

111-76-2 2-butoxyethanol

IOELV	Short-term value: 246 mg/m ³ , 50 ppm
	Long-term value: 98 mg/m ³ , 20 ppm
	Skin

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

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- 8.2 Exposure controls

- Personal protective equipment:

- General protective and hygienic measures:

- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Store protective clothing separately.
- Avoid contact with the skin.
- Avoid contact with the eyes and skin.

- Respiratory protection:

In case of intensive or longer exposure use self-contained respiratory protective device.

- Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties

- General Information

- Appearance:

Form: Pasty
Colour: According to product specification

- Odour: Characteristic

- Odour threshold: Not determined.

- pH-value: Not determined.

- Change in condition

Melting point/freezing point: Undetermined.
Initial boiling point and boiling range: Undetermined.

- Flash point: >70 °C

- Flammability (solid, gas): Not applicable.

- Ignition temperature: Not determined.

- Decomposition temperature: Not determined.

- Auto-ignition temperature: Product is not selfigniting.

- Explosive properties: Product does not present an explosion hazard.

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- Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
- Vapour pressure at 20 °C:	0.1 hPa
- Density:	Not determined.
- Relative density	Not determined.
- Vapour density	Not determined.
- Evaporation rate	Not determined.
- Solubility in / Miscibility with water:	Not miscible or difficult to mix.
- Partition coefficient: n-octanol/water:	Not determined.
- Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
- Solvent content:	
Organic solvents:	<0.7 %
VOC (EC)	<0.75 %
Solids content:	91.6 %
- 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

* SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- LD/LC50 values relevant for classification:

Vaseline

Oral	LD50	>5,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
May damage the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.

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- **STOT-repeated exposure**
May cause damage to the blood and the immune system through prolonged or repeated exposure. Route of exposure: Oral.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number - ADR, IMDG, IATA	Void
- 14.2 UN proper shipping name - ADR, IMDG, IATA	Void
- 14.3 Transport hazard class(es) - ADR, ADN, IMDG, IATA - Class	Void
- 14.4 Packing group - ADR, IMDG, IATA	Void
- 14.5 Environmental hazards:	Not applicable.
- 14.6 Special precautions for user	Not applicable.
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
- UN "Model Regulation":	Void

* SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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- Regulation (EU) No 649/2012	
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- DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II	
None of the ingredients is listed.	
- REGULATION (EU) 2019/1148	
- Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))	
None of the ingredients is listed.	
- Annex II - REPORTABLE EXPLOSIVES PRECURSORS	
None of the ingredients is listed.	
- Regulation (EC) No 273/2004 on drug precursors	
None of the ingredients is listed.	
- Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors	
None of the ingredients is listed.	

- **National regulations:**

- **Other regulations, limitations and prohibitive regulations**

- **Substances of very high concern (SVHC) according to REACH, Article 57**

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- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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.

- **Relevant phrases**

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H360D May damage the unborn child.

H371 May cause damage to organs.

H372 Causes damage to organs through prolonged or repeated exposure.

H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

- **Contact:** sds@mueller-omicron.de

- **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

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Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 1B: Reproductive toxicity – Category 1B
STOT SE 2: Specific target organ toxicity (single exposure) – Category 2
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

- Sources

The data for the hazardous ingredients were taken respectively from the last version of Safety Data Sheets of suppliers.

- * Data compared to the previous version altered.