



Trade name: Otoform Ak Comp. B in double cartridge

Substance number: 44692

Version: 2 / GB

Date revised: 23.05.2025

Replaces Version: 1 / GB

Print date: 23.05.2025

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

1.1. Product identifier

Otoform Ak Comp. B

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

Addition curing ear impression silicone

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Dreve Otoplastik GmbH

Max-Planck-Straße 31

DE-59423 Unna

Telephone no. +49 2303 8807-0

Fax no. +49 2303 8807-29

Information provided by / telephone Department Research & Development: Fax: +49 2303 8807-562

E-mail address of person responsible for this SDS sicherheitsdatenblatt@dreve.com

1.4. Emergency telephone number

Henkel Fire Department / 24h-Emergency-Contact-No.: +49 211 797-3350

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Supplemental information

EUH210

Safety data sheet available on request.

2.3. Other hazards

No special hazards have to be mentioned.

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

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Chemical characterization

Kneadable, addition-vulcanising 2-component silicone

Hazardous ingredients**White mineral oil**

CAS No. 8042-47-5

EINECS no. 232-455-8

Registration no. 01-2119487078-27

Concentration ≥ 1 < 10 %Classification (Regulation (EC) No. 1272/2008)
Asp. Tox. 1 H304**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

No special measures required

After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

After ingestion

Do NOT induce vomiting. Summon a doctor immediately.

Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

4.2. Most important symptoms and effects, both acute and delayed

Until now no symptoms known so far.

4.3. Indication of any immediate medical attention and special treatment needed**Hints for the physician / hazards**

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**Recommended: alcohol resistant foam, CO₂, powders, water spray/mist, Extinguishing measures to suit surroundings**5.3. Advice for firefighters****Special protective equipment for fire-fighting**

In case of combustion use a suitable breathing apparatus.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Do not allow to enter drains or waterways.

6.3. Methods and material for containment and cleaning up

Pick up mechanically. Clean contaminated floors and objects thoroughly, observing environmental regulations.

6.4. Reference to other sections

Refer to protective measures listed in Sections 7 and 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Observe the usual precautions for handling chemicals. For personal protection see Section 8.

Advice on protection against fire and explosion

No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store product in closed containers.

Hints on storage assembly

Do not store together with foodstuffs.

Further information on storage conditions

Keep container tightly closed and dry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Derived No/Minimal Effect Levels (DNEL/DMEL)

White mineral oil

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Repeated exposure	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	164,6	mg/m ³

Type of value	Derived No Effect Level (DNEL)
Reference group	Worker
Duration of exposure	Repeated exposure

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Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	217,1	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Repeated exposure	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	34,78	mg/m ³
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Repeated exposure	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	93,02	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Repeated exposure	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	25	mg/kg/d

8.2. Exposure controls

General protective and hygiene measures

Observe the usual precautions for handling chemicals. Do not eat, drink or smoke during work time.
Wash hands before breaks and after work. Avoid contact with eyes.

Respiratory protection

Not necessary.

Hand protection

Not necessary.

Eye protection

Not necessary.

Body protection

Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Kneadable
Colour	green
Odour	characteristic
Melting point	
Remarks	not determined
Freezing point	
Remarks	not determined
Boiling point or initial boiling point and boiling range	

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Value	> 200	°C
Flammability		
evaluation	not determined	
Upper and lower explosive limits		
Remarks	not determined	
Flash point		
Value	> 130	°C
Method	closed cup	
Auto-ignition temperature		
Remarks	not determined	
Decomposition temperature		
Remarks	not determined	
pH value		
Remarks	not determined	
Viscosity		
Remarks	not determined	
Solubility(ies)		
Remarks	not determined	
Partition coefficient n-octanol/water (log value)		
Remarks	not determined	
Vapour pressure		
Remarks	not determined	
Density and/or relative density		
Value	1,44	g/cm ³
Temperature	20	°C
Relative vapour density		
Remarks	not determined	
9.2. Other information		
Odour threshold		
Remarks	not determined	
Evaporation rate (ether = 1) :		
Remarks	not determined	
Solubility in water		
Remarks	virtually insoluble	
Explosive properties		
evaluation	not determined	
Oxidising properties		
Remarks	not determined	
Other information		
None known		

SECTION 10: Stability and reactivity

10.1. Reactivity

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No hazardous reactions when stored and handled according to prescribed instructions.

10.2. Chemical stability

No hazardous reactions known.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No hazardous reactions known.

10.5. Incompatible materials

None known

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**Acute oral toxicity**

Remarks Based on available data, the classification criteria are not met.

Acute oral toxicity (Components)**White mineral oil**

Species	rat	
LD50	> 5000	mg/kg
Method	OECD 401	

Acute dermal toxicity

Remarks Based on available data, the classification criteria are not met.

Acute dermal toxicity (Components)**White mineral oil**

Species	rabbit	
LD50	> 2000	mg/kg
Method	OECD 402	

Acute inhalational toxicity

Remarks Based on available data, the classification criteria are not met.

Acute inhalative toxicity (Components)**White mineral oil**

Species	rat	
LC50	> 5,2	mg/l
Duration of exposure	4	h
Administration/Form	Dust/Mist	
Method	OECD 403	

Skin corrosion/irritation

Remarks Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Remarks Based on available data, the classification criteria are not met.

Sensitization

Remarks Based on available data, the classification criteria are not met.

Subacute, subchronic, chronic toxicity

Remarks not determined

Mutagenicity

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Remarks Based on available data, the classification criteria are not met.

Reproductive toxicity

Remarks Based on available data, the classification criteria are not met.

Carcinogenicity

Remarks Based on available data, the classification criteria are not met.

Specific Target Organ Toxicity (STOT)**Single exposure**

Remarks Based on available data, the classification criteria are not met.

Repeated exposure

Remarks Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Aspiration hazard (Components)**White mineral oil**

Harmful: may cause lung damage if swallowed.

11.2. Information on other hazards**Endocrine disrupting properties with respect to humans**

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

Other information

No toxicological data are available.

SECTION 12: Ecological information

12.1. Toxicity**General information**

not determined

Fish toxicity (Components)**White mineral oil**

Species	golden orfe (<i>Leuciscus idus</i>)	
LC50	> 10000	mg/l
Duration of exposure	96 h	
Method	OECD 203	

Daphnia toxicity (Components)**White mineral oil**

Species	Daphnia magna	
LL50	> 100	mg/l
Duration of exposure	48 h	
Method	OECD 202	

White mineral oil

Species	Daphnia magna	
NOEL	>= 1000	mg/l
Duration of exposure	21 d	
Method	OECD 211	

Algae toxicity (Components)**White mineral oil**

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Species	Pseudokirchneriella subcapitata	
LOEC	>= 100	mg/l
Duration of exposure	72	h
Method	OECD 201	

12.2. Persistence and degradability**General information**

not determined

Biodegradability (Components)**White mineral oil**

Value	31	%
Duration of test evaluation	28	d
Method	Moderately/partially biodegradable	
	OECD 301 F	

12.3. Bioaccumulative potential**General information**

not determined

Partition coefficient n-octanol/water (log value)

Remarks not determined

Octanol/water partition coefficient (log Pow) (Components)**White mineral oil**

log Pow	4,3	to	18,02
Temperature	20	°C	
Source	ECHA		

12.4. Mobility in soil**General information**

not determined

12.5. Results of PBT and vPvB assessment**General information**

not determined

Results of PBT and vPvB assessment

The product contains no PBT substances

The product contains no vPvB substances.

12.6 Endocrine disrupting properties**Endocrine disrupting properties with respect to the environment**

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects**General information**

not determined

General information / ecology

Do not discharge product unmonitored into the environment.

SECTION 13: Disposal considerations

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13.1. Waste treatment methods**Disposal recommendations for the product**

Must not be disposed together with household garbage.

Dispose of waste according to applicable legislation.

Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off in agreement with the regional waste disposal company.

SECTION 14: Transport information ***

	Land transport ADR/RID ***	Marine transport IMDG/GGVSee ***	Air transport ICAO/IATA ***
14.1. UN number or ID number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.2. UN proper shipping name	-	-	-
14.3. Transport hazard class(es)		-	-
Label			
14.4. Packing group		-	-

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Other information**

All components are contained in the TSCA inventory or exempted.

15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

SECTION 16: Other information**Hazard statements listed in Chapter 2/3**

H304

May be fatal if swallowed and enters airways.

CLP categories listed in Chapter 2/3

Asp. Tox. 1

Aspiration hazard, Category 1

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: ***

This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.



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