



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

## 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

59423 Unna

Telephone no. +49 2303 8807-0

Fax no. +49 2303 8807-29

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

E-mail address of person responsible sicherheitsdatenblatt@dreve.de

for this SDS

### 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



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

**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, CO<sub>2</sub>, 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.



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

## 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

#### Exposure limit values

##### White mineral oil

List TRGS 900

Type AGW

A

Value 5 mg/m<sup>3</sup>

Short term exposure limit 20 mg/m<sup>3</sup>

Maximum limit value: 4(II) Pregnancy group: Y; Status: Sept 2015; Remarks: DGF

#### Other information

Contains no substances with occupational exposure limit values.

#### Derived No/Minimal Effect Levels (DNEL/DMEL)



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

**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 <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Repeated exposure	
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 <sup>3</sup>
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**



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

**9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	Kneadable		
<b>Colour</b>	green		
<b>Odour</b>	characteristic		
<b>Melting point</b>			
Remarks	not determined		
<b>Freezing point</b>			
Remarks	not determined		
<b>Boiling point or initial boiling point and boiling range</b>			
Value	> 200		°C
<b>Flammability</b>			
evaluation	not determined		
<b>Upper and lower explosive limits</b>			
Remarks	not determined		
<b>Flash point</b>			
Value	> 130		°C
Method	closed cup		
<b>Ignition temperature</b>			
Remarks	not determined		
<b>Decomposition temperature</b>			
Remarks	not determined		
<b>pH value</b>			
Remarks	not determined		
<b>Viscosity</b>			
Remarks	not determined		
<b>Solubility(ies)</b>			
Remarks	not determined		
<b>Partition coefficient n-octanol/water (log value)</b>			
Remarks	not determined		
<b>Vapour pressure</b>			
Remarks	not determined		
<b>Density and/or relative density</b>			
Value	1,44		g/cm <sup>3</sup>
Temperature	20	°C	
<b>Relative vapour density</b>			
Remarks	not determined		
<b>9.2. Other information</b>			
<b>Odour threshold</b>			
Remarks	not determined		
<b>Evaporation rate (ether = 1) :</b>			
Remarks	not determined		
<b>Solubility in water</b>			
Remarks	virtually insoluble		
<b>Explosive properties</b>			
evaluation	not determined		



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

**Oxidising properties**

Remarks not determined

**Other information**

None known

**SECTION 10: Stability and reactivity****10.1. Reactivity**

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**

ATE	16,4359	mg/l
Administration/Form	Dust/Mist	
Method	calculated value (Regulation (EC) No. 1272/2008)	
Remarks	Based on available data, the classification criteria are not met.	

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

Species	rat		
LC50	>	5	mg/l



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

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**

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 (*Leuciscus idus*)  
LC50 > 10000 mg/l  
Duration of exposure 96 h  
Method OECD 203



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

**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		
NOEC	10		mg/l
Duration of exposure	21	d	
Method	OECD 211		

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

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	
	biodegradable		

**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 18.2
Temperature	20	°C
Source	calculated value	

**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**





Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Date revised: 06.10.2023

Replaces Version: - / GB

Print date: 06.10.2023

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

### 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		-	-
14.5. Environmental hazards	-	no	-

## SECTION 15: Regulatory information

### 15.2. Chemical safety assessment

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



Trade name: Otoform Ak Comp. B

Substance number: 44692

Version: 1 / GB

Replaces Version: - / GB

Date revised: 06.10.2023

Print date: 06.10.2023

## 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.