

Trade name: Otoform Ak Comp. A in double cartridge

Substance number: F44691

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. A

### 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](mailto: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	>= 5	<	15	%
Classification (Regulation (EC) No. 1272/2008)	Asp. Tox. 1		H304	

**Kieselguhr, soda ash flux-calcined**

CAS No.	68855-54-9			
EINECS no.	272-489-0			
Registration no.	01-2119488518-22			
Concentration	>= 1	<	10	%

**Further ingredients****Starch**

CAS No.	9005-25-8			
EINECS no.	232-679-6			
Concentration	>= 10	<	25	%
Advice: [3]				

**Talc**

CAS No.	14807-96-6			
EINECS no.	238-877-9			
Registration no.	01-2120140278-58			
Concentration	>= 10	<	25	%
Advice: [3]				

**Note**

[3] Substance with occupational exposure limits

**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**

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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.

**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**

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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****Kieselguhr, soda ash flux-calcined**

List	TRGS 900
Type	AGW
A	
Value	0,3 mg/m <sup>3</sup>
Pregnancy group: Y; Status: 05/10; Remarks: DGF	

**Talc**

respirable fraction	
Value	1 mg/m <sup>3</sup>

**Starch**

List	OSHA
inhalable fraction	
Value	15 mg/m <sup>3</sup>

**Starch**

List	OSHA
respirable fraction	
Value	5 mg/m <sup>3</sup>

**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 <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	

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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

**Kieselguhr, soda ash flux-calcined**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Industrial use	
Duration of exposure	Long term	
Route of exposure	inhalative	
Concentration	0,05	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	0,05	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	18,7	mg/kg

**Talc**

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	0,434	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Short term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	2,16	mg/m <sup>3</sup>

Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	3,6	mg/m <sup>3</sup>

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



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Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	3,6	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	0,0375	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	Worker	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Local effects	
Concentration	4,54	mg/cm <sup>2</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	77,1	µg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Short term	
Route of exposure	inhalative	
Mode of action	Systemic effects	
Concentration	1,08	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	1,8	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Short term	
Route of exposure	inhalative	
Mode of action	Local effects	
Concentration	1,8	mg/m <sup>3</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	dermal	
Mode of action	Systemic effects	
Concentration	0,0045	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	dermal	

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Mode of action	Local effects	
Concentration	2,27	mg/cm <sup>2</sup>
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Long term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	1	mg/kg/d
Type of value	Derived No Effect Level (DNEL)	
Reference group	Consumer	
Duration of exposure	Short term	
Route of exposure	oral	
Mode of action	Systemic effects	
Concentration	160	mg/kg/d

**Predicted No Effect Concentration (PNEC)****Kieselguhr, soda ash flux-calcined**

Type of value	PNEC	
Type	Sewage treatment plant (STP)	
Concentration	10	mg/l

**Talc**

Type of value	PNEC	
Type	Freshwater	
Concentration	91,8	mg/l
Type of value	PNEC	
Type	Saltwater	
Concentration	0,918	mg/l
Type of value	PNEC	
Type	Freshwater sediment	
Concentration	0,627	mg/kg
Type of value	PNEC	
Type	Marine sediment	
Concentration	0,063	mg/kg
Type of value	PNEC	
Type	Air	
Concentration	10	mg/m <sup>3</sup>
Type of value	PNEC	
Type	Soil	
Concentration	70,6	mg/kg

**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.

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**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**

Value

&gt; 200

**Flammability**

evaluation

not determined

**Upper and lower explosive limits**

Remarks

not determined

**Flash point**

Value

&gt; 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

1,43

g/cm<sup>3</sup>

Temperature

20

°C

**Relative vapour density**



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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**

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	

**Kieselguhr, soda ash flux-calcined**

Species	rat (female)	
LD50	> 2000	mg/kg
Method	OECD 401	

**Talc**

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Species	rat (male)	
LD50	> 5000	mg/kg
Method	OECD 423	

**Acute dermal toxicity**

Remarks	Based on available data, the classification criteria are not met.
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**Acute dermal toxicity (Components)****White mineral oil**

Species	rabbit	
LD50	> 2000	mg/kg
Method	OECD 402	

**Talc**

Species	rat	
LD50	> 2000	mg/kg
Method	OECD 402	

**Acute inhalational toxicity**

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

**Kieselguhr, soda ash flux-calcined**

Species	rat	
LC50	> 2,6	mg/l
Method	OECD 403	

**Talc**

Species	rat	
LC50	> 2,1	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.
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**Skin corrosion/irritation (Components)****Kieselguhr, soda ash flux-calcined**

Remarks	Frequent persistent contact with the skin can cause skin irritation.
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**Starch**

Remarks	Longer or repeated exposure with the product may cause dermatitis
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**Serious eye damage/irritation**

Remarks	Based on available data, the classification criteria are not met.
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**Serious eye damage/irritation (Components)****Kieselguhr, soda ash flux-calcined**

Remarks	Eye contact with the product may lead to irritation.
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**Starch**

Remarks	Eye contact with the product may lead to irritation.
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**Sensitization**

Remarks	Based on available data, the classification criteria are not met.
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**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 ( <i>Leuciscus idus</i> )		
LC50	>	10000	mg/l
Duration of exposure	96	h	
Method	OECD 203		

**Kieselguhr, soda ash flux-calcined**

Species	rainbow trout ( <i>Oncorhynchus mykiss</i> )		
LC50	>	100	mg/l
Duration of exposure	96	h	
Method	OECD 203		
Remarks	No demonstrable toxic effect in saturated solution.		

**Talc**

Remarks Slightly water-soluble inorganic product. It can be removed to a large extent in a chemical purification plant.

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**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	

**Kieselguhr, soda ash flux-calcined**

Species	Daphnia magna	
EC50	> 100	mg/l
Duration of exposure	48	h
Method	OECD 202	
Remarks	No demonstrable toxic effect in saturated solution.	

**Talc**

Remarks	Slightly water-soluble inorganic product. It can be removed to a large extent in a chemical purification plant.
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**Algae toxicity (Components)****White mineral oil**

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

**Kieselguhr, soda ash flux-calcined**

Species	Desmodesmus subspicatus	
EC50	> 100	mg/l
Duration of exposure	72	h
Method	OECD 201	
Remarks	No demonstrable toxic effect in saturated solution.	

**Talc**

Remarks	Slightly water-soluble inorganic product. It can be removed to a large extent in a chemical purification plant.
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**Bacteria toxicity (Components)****Kieselguhr, soda ash flux-calcined**

Species	activated sludge	
	> 1000	mg/l
Duration of exposure	3	h

**Talc**

Remarks	Slightly water-soluble inorganic product. It can be removed to a large extent in a chemical purification plant.
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**12.2. Persistence and degradability****General information**

not determined

**Biodegradability (Components)****White mineral oil**

Value	31	%
Duration of test evaluation	28	d
	Moderately/partially biodegradable	

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Method OECD 301 F

**Kieselguhr, soda ash flux-calcined**

Remarks Slightly water-soluble inorganic product. It can be removed to a large extent in a chemical purification plant.

**Talc**

Remarks Inorganic product, cannot be eliminated from the water by biological purification processes.

**Starch**

evaluation 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	18,02
Temperature	20	°C	
Source	ECHA		

**Kieselguhr, soda ash flux-calcined**

Remarks Not applicable

**Talc**

Remarks Not applicable

**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

**13.1. Waste treatment methods**



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**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 \*\*\***

	<b>Land transport ADR/RID ***</b>	<b>Marine transport IMDG/GGVSee ***</b>	<b>Air transport ICAO/IATA ***</b>
<b>14.1. UN number or ID number</b>	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.
<b>14.2. UN proper shipping name</b>	-	-	-
<b>14.3. Transport hazard class(es)</b>		-	-
Label			
<b>14.4. Packing group</b>		-	-

**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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