



Trade name: Otoform Ak X Comp. A

Substance number: 41041

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 X 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

59423 Unna

Telephone no.

+49 2303 8807-0

Fax no.

+49 2303 8807-29

Information provided

Department Research & Development: Fax: +49 2303 8807-562

by / telephone

E-mail address of

sicherheitsdatenblatt@dreve.de

person responsible

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



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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

Exposure limit values

White mineral oil

List TRGS 900

Type AGW

A

Value 5 mg/m³

Short term exposure limit 20 mg/m³

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)



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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	
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



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9.1. Information on basic physical and chemical properties

Physical state	Kneadable		
Colour	white		
Odour	characteristic		
Melting point			
Remarks	not determined		
Freezing point			
Remarks	not determined		
Boiling point or initial boiling point and boiling range			
Value	>	300	°C
Flammability			
evaluation	not determined		
Upper and lower explosive limits			
Remarks	not determined		
Flash point			
Value	>	130	°C
Method	closed cup		
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		1,19	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		



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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

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

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

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



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

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

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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**

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



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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.



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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.