



Trade name: Otoform A softX with color indicator Comp. B

Substance number: 45182

Version: 1 / GB

Date revised: 27.09.2023

Replaces Version: - / GB

Print date: 27.09.2023

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

1.1. Product identifier

Otoform A softX with color indicator 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 & Development: Fax: +49 2303 8807-562

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

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

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	

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

EINECS no.	920-114-2			
Registration no.	01-2119459347-30			
Concentration	>= 1	<	10	%
Classification (Regulation (EC) No. 1272/2008)				
	Asp. Tox. 1		H304	

Cristobalite

CAS No.	14464-46-1			
EINECS no.	238-455-4			
Concentration	>= 1	<	10	%
Classification (Regulation (EC) No. 1272/2008)				
	STOT RE 1		H372	

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 - aspiration hazard. 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

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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

Non suitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of combustion evolution of dangerous gases possible.

5.3. Advice for firefighters

Special protective equipment for fire-fighting

In case of combustion use a suitable breathing apparatus.

Other information

Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

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.

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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 ³
Short term exposure limit	20	mg/m ³
Maximum limit value: 4(II) Pregnancy group: Y; Status: Sept 2015; Remarks: DGF		

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

List	TRGS 900	
Type	AGW	
Value	300	mg/m ³
Short term exposure limit	600	mg/m ³

Other information

Contains no substances with occupational exposure limit values.

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	
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	

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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	liquid, viscous	
Colour	Color change from violet to pink	
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		

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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 densityValue 1,21 g/cm³

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

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

10.6. Hazardous decomposition products

No hazardous decomposition products known.

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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	

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

Species	rat	
LD50	> 5000	mg/kg
Method	OECD 401	
Remarks	Test conducted with a similar formulation.	

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	

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

Species	rabbit	
LD50	> 3160	mg/kg
Method	OECD 402	

Acute inhalational toxicity

ATE	> 20	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
Duration of exposure	4	h
Administration/Form	Dust/Mist	
Method	OECD 403	

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

Species	rat	
LC50	> 5266	mg/m ³
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.



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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.

Specific Target Organ Toxicity (STOT) (Components)**Cristobalite****Repeated exposure**evaluation Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative**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.

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

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	

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Method OECD 203

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromaticsSpecies rainbow trout (*Oncorhynchus mykiss*)

NOELR > 1000 mg/l

Duration of exposure 28 d

Remarks The details of the toxic effect relate to the nominal concentration.

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

LL50 > 100 mg/l

Duration of exposure 48 h

Method OECD 202

White mineral oilSpecies *Daphnia magna*

NOEC 10 mg/l

Duration of exposure 21 d

Method OECD 211

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromaticsSpecies *Acartia tonsa*

LL50 > 3193 mg/l

Duration of exposure 48 h

Remarks The details of the toxic effect relate to the nominal concentration.

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromaticsSpecies *Daphnia magna*

NOELR 5 mg/l

Duration of exposure 21 d

Remarks The details of the toxic effect relate to the nominal concentration.

Algae toxicity (Components)**White mineral oil**Species *Pseudokirchneriella subcapitata*

LOEC >= 100 mg/l

Duration of exposure 72 h

Method OECD 201

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromaticsSpecies *Skeletonema costatum*

EL50 > 3200 mg/l

Duration of exposure 72 h

Remarks The details of the toxic effect relate to the nominal concentration.

Bacteria toxicity (Components)**Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics**

Species activated sludge

EC50 > 100 mg/l

Duration of exposure 3 h

Method OECD 209

12.2. Persistence and degradability**General information**

not determined

Biodegradability (Components)**White mineral oil**

Value 31 %

Duration of test 28 d

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evaluation

biodegradable

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

Value 74 %

Duration of test 28 d

evaluation Readily biodegradable (according to OECD criteria)

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

Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics

log Pow 5,22 to 9,67

Temperature 20 °C

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 allow to enter soil, waterways or waste water canal. Avoid release into the atmosphere.

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



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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

15.2. 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.
H372 Causes damage to organs through prolonged or repeated exposure.

CLP categories listed in Chapter 2/3

Asp. Tox. 1 Aspiration hazard, Category 1
STOT RE 1 Specific target organ toxicity - repeated exposure, 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.