



Trade name: Otoform Ak Comp. A

Substance number: F44691

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

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

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

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.

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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.

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



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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

Kieselguhr, soda ash flux-calcined

List TRGS 900
 Type AGW
 A
 Value 0,3 mg/m³
 Pregnancy group: Y; Status: 05/10; Remarks: DGF

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/m³

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/m³

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

Kieselguhr, soda ash flux-calcined

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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 ³

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 ³

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

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

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

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

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Boiling point or initial boiling point and boiling range

Value > 200

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 densityValue 1,43 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



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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		

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	16,3865	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		

Kieselguhr, soda ash flux-calcined

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

Skin corrosion/irritation

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

Skin corrosion/irritation (Components)**Kieselguhr, soda ash flux-calcined**

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

Serious eye damage/irritation

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

Serious eye damage/irritation (Components)**Kieselguhr, soda ash flux-calcined**

Remarks Eye contact with the product may lead to irritation.

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

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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.	

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

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

White mineral oil

Species	<i>Daphnia magna</i>	
NOEC	10	mg/l
Duration of exposure	21	d
Method	OECD 211	

Kieselguhr, soda ash flux-calcined

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

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

Species	<i>Pseudokirchneriella subcapitata</i>	
LOEC	\geq 100	mg/l
Duration of exposure	72	h
Method	OECD 201	

Kieselguhr, soda ash flux-calcined

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

Bacteria toxicity (Components)**Kieselguhr, soda ash flux-calcined**

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

12.2. Persistence and degradability**General information**

not determined

Biodegradability (Components)



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White mineral oil

Value	31	%
Duration of test evaluation	28	d
	biodegradable	

Kieselguhr, soda ash flux-calcined

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

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		

Kieselguhr, soda ash flux-calcined

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****Disposal recommendations for the product**

Must not be disposed together with household garbage.
Dispose of waste according to applicable legislation.



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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.

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.