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

1.1. Product identifier

Otopren Comp. B

This substance/mixture contains components in nanoform

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/preparation

A-silicone for the production of earmolds

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

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

Chemical characterization

Addition-vulcanising 2-component silicone

Hazardous ingredients ***

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

CAS No.	68909-20-6			
EINECS no.	272-697-1			
Registration no.	01-2119379499-16			
Concentration	>=	10	<	25 %

Classification (Regulation (EC) No. 1272/2008)

STOT RE 2 H373

Name of set of nanoform	Nanoagglomerate	
Particle size distribution	d50 60-300	nm
	Method	Transmission Electron Microscopy (TEM)
Shape and aspect ratio of particles	amorphous	
	Nano particles	
Particle size distribution	d50 6-50	nm
	Method	Transmission Electron Microscopy (TEM)
Shape and aspect ratio of particles	amorphous	

40 to 350 m²/g

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 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.

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

Other information

Contains no substances with occupational exposure limit values.

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	reddish transparent		
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		
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	1,08		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.

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)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

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)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	rabbit		
LD50	>	2000	mg/kg
Remarks	Test conducted with a similar formulation.		

Acute inhalational toxicity

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

Acute inhalative toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	rat		
LC50	>	5,01	mg/l
Duration of exposure	4	h	
Administration/Form	Dust/Mist		
Remarks	Test conducted with a similar formulation.		

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.

Specific Target Organ Toxicity (STOT) (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Repeated exposure

evaluation: May cause damage to organs through prolonged or repeated exposure
Route of exposure inhalative
Organs: Lungs

Aspiration hazard

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

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)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	zebra fish (Brachydanio rerio)			
LC50	>	10000		mg/l
Duration of exposure		96	h	
Source	Analogous			

Daphnia toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	Daphnia magna			
EC50	>	1000		mg/l
Duration of exposure		48	h	
Source	Analogous			

Algae toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	Desmodesmus subspicatus			
EC50	>	173		mg/l
Duration of exposure		72	h	
Source	Analogous			

Bacteria toxicity (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

Species	activated sludge			
EC50	>	2500		mg/l
Duration of exposure		3	h	
Method	OECD 209			
Source	Analogous			

12.2. Persistence and degradability

General information

not determined

Biodegradability (Components)

Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

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

12.3. Bioaccumulative potential

General information

not determined

Partition coefficient n-octanol/water (log value)

Remarks	not determined

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 envrionment

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

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

15.1. 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

H373 May cause damage to organs through prolonged or repeated exposure.

CLP categories listed in Chapter 2/3

STOT RE 2 Specific target organ toxicity - repeated exposure, Category 2

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.