

# Safety Data Sheet

## acc. to OSHA HCS

Printing date 06/03/2020

Reviewed on 06/03/2020

### 1 Identification

- **Product identifier**
- **Trade name: BioTec**
- **Application of the substance / the mixture**  
Silicone acrylate material for generative manufacturing of soft, flexible earmolds with DLP technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Dreve Otoplastik GmbH  
Max-Planck-Straße 31  
59423 Unna / Germany  
Tel.: ++49 2303 / 8807-0  
Fax.: ++49 2303 / 8807-29
- **Information department:**  
Department Research & Development  
Fax.: +49 2303 8807-562  
Email: sicherheitsdatenblatt@dreve.de
- **Emergency telephone number:**  
+49 211 797-3350  
Plant Fire Department Henkel

### 2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

Flam. Liq. 4 H227 Combustible liquid.

- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Warning
- **Hazard-determining components of labeling:**  
3,3,5-Trimethylcyclohexylacrylat  
Diphenyl(2,4,6-trimethylbenzoyl)phosphinoxide  
2-ethylhexyl acrylate

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Dimethylethylcyclohexylacrylate

- **Hazard statements**

Combustible liquid.  
 Causes skin irritation.  
 Causes serious eye irritation.  
 May cause an allergic skin reaction.  
 Suspected of damaging fertility or the unborn child.  
 May cause respiratory irritation.

- **Precautionary statements**

Keep away from flames and hot surfaces. – No smoking.  
 Avoid breathing dust/fume/gas/mist/vapors/spray  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 Store locked up.  
 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 2  
 Fire = 2  
 Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



HEALTH 2 Health = 2  
 FIRE 2 Fire = 2  
 REACTIVITY 0 Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

### 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

86178-38-3	3,3,5-Trimethylcyclohexylacrylat	10-25%
84100-23-2	Dimethylethylcyclohexylacrylate	2.5-10%
103-11-7	2-ethylhexyl acrylate	2.5-10%
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphinoxide	≤2.5%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First-aid measures

- **Description of first aid measures**

- **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.  
 In case of unconsciousness place patient stably in side position for transportation.

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- **After skin contact:**  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation continues, consult a doctor.
- **After eye contact:**  
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**  
Do not induce vomiting.  
Call a doctor immediately.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.  
Use fire fighting measures that suit the environment.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**  
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Avoid contact with skin and eyes.
- **Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

· <b>PAC-1:</b>	
Polydimethylsiloxan	65 mg/m <sup>3</sup>
· <b>PAC-2:</b>	
Polydimethylsiloxan	720 mg/m <sup>3</sup>

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<b>· PAC-3:</b>	
Polydimethylsiloxan	4,300 mg/m <sup>3</sup>

### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Avoid contact with skin and eyes.  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Protect from heat and direct sunlight.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

### 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing.  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Breathing equipment:**  
Do not inhale fumes.  
Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:**



Protective gloves

Protective gloves should be changed regularly, especially after intensive contact with the product. For every workplace a suitable type of protective gloves must be selected. The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves**

Nitrile rubber, NBR

As there are many different conditions in every day work these indications can only serve as an aid to orientation for the selection of suitable gloves for the handling of chemical products. By no means they can replace qualifying examinations by the end-user.

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Diese Empfehlung gilt nur für das im Sicherheitsdatenblatt genannte Produkt. Bei Vermischung mit anderen Substanzen und bei von der EN 374 abweichenden Bedingungen müssen Sie sich an den Hersteller von CE-genehmigten Handschuhen wenden.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

The determined penetration times according to EN 16523-1:2015 are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form:	Fluid
Color:	Clear transparent
· Odor:	Characteristic
· Odor threshold:	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	229 °C (444.2 °F)

- **Flash point:** 82 °C (179.6 °F)

- **Flammability (solid, gaseous):** Not applicable.

- **Ignition temperature:** 36 °C (96.8 °F)

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

- **Oxidizing properties** Not determined  
Not applicable.

- **Vapor pressure:** Not determined.

- **Density at 20 °C (68 °F):** 1.1 g/cm<sup>3</sup> (9.1795 lbs/gal)

- **Relative density** Not determined.

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· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Not miscible or difficult to mix.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
<b>Dynamic:</b>	Not determined.
<b>Kinematic:</b>	Not determined.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No dangerous reactions if used according to specifications
- **Chemical stability** Stable if used according to specifications
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.  
Protect from heat and direct sunlight.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**  
The product shows the following dangers according to internally approved calculation methods for preparations:  
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.  
Also poisonous for fish and plankton in water bodies.  
Toxic for aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.  
Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

<ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADR, IMDG, IATA</b></li> </ul>	UN3082
<ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT</b></li> <li>· <b>ADR</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul>	Environmentally hazardous substance, liquid, n.o.s. (3,3,5-Trimethylcyclohexylacrylat, Dimethylethylcyclohexylacrylate) 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (3,3,5-Trimethylcyclohexylacrylat, Dimethylethylcyclohexylacrylate) ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (3,3,5-Trimethylcyclohexylacrylat, Dimethylethylcyclohexylacrylate), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (3,3,5-Trimethylcyclohexylacrylat, Dimethylethylcyclohexylacrylate)

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- **Transport hazard class(es)**

- **DOT, ADR, IMDG, IATA**



- **Class**

9 Miscellaneous dangerous substances and articles

- **Label**

9

- **Packing group**

- **DOT, ADR, IMDG, IATA**

III

- **Environmental hazards:**

Product contains environmentally hazardous substances: 3,3,5-Trimethylcyclohexylacrylat

- **Marine pollutant:**

Yes (DOT)

- **Special marking (ADR):**

Symbol (fish and tree)

- **Special marking (IATA):**

Symbol (fish and tree)

- **Special precautions for user**

Warning: Miscellaneous dangerous substances and articles

- **Danger code (Kemler):**

90

- **EMS Number:**

F-A,S-F

- **Stowage Category**

A

- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

- **Transport/Additional information:**

According to special provision no 375 (ADR chapter 3.3), according to special provision no 969 (IMDG chapter 3.3 in conjunction with IMDG chapter 2.10.2.7) and according to special provision no A197 (IATA chapter 4.4) single - respectively inner packagings with a net quantity < 5 l / 5 kg aren't liable to the regulations, meaning those don't need to be sent as hazardous goods. Labelling with pictogram GHS09 is not necessary.

- **DOT**

- **Remarks:**

Special marking with the symbol (fish and tree).

- **ADR**

- **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

- **IMDG**

- **Limited quantities (LQ)**

5L

- **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

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- |                               |   |
|-------------------------------|---|
| <b>UN "Model Regulation":</b> | UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (3,3,5-TRIMETHYLCYCLOHEXYLACRYLAT, DIMETHYLETHYLCYCLOHEXYLACRYLATE), 9, III |
|-------------------------------|---|

### 15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara

<b>Section 355 (extremely hazardous substances):</b>
--

None of the ingredient is listed.

<b>Section 313 (Specific toxic chemical listings):</b>
--

None of the ingredients is listed.

- TSCA (Toxic Substances Control Act): All ingredients are listed.

<b>Hazardous Air Pollutants</b>
---------------------------------

None of the ingredients is listed.

<b>Proposition 65</b>
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<b>Chemicals known to cause cancer:</b>
---

None of the ingredients is listed.

<b>Chemicals known to cause reproductive toxicity for females:</b>
--

None of the ingredients is listed.

<b>Chemicals known to cause reproductive toxicity for males:</b>
--

None of the ingredients is listed.

<b>Chemicals known to cause developmental toxicity:</b>
---

None of the ingredients is listed.

- Cancerogenity categories

<b>EPA (Environmental Protection Agency)</b>
--

None of the ingredients is listed.

<b>TLV (Threshold Limit Value established by ACGIH)</b>
---

None of the ingredients is listed.

<b>MAK (German Maximum Workplace Concentration)</b>
---

None of the ingredients is listed.

<b>NIOSH-Ca (National Institute for Occupational Safety and Health)</b>
---

None of the ingredients is listed.

- GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- Hazard pictograms



GHS07 GHS08

- Signal word Warning

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- **Hazard-determining components of labeling:**

3,3,5-Trimethylcyclohexylacrylat  
Diphenyl(2,4,6-trimethylbenzoyl)phosphinoxide  
2-ethylhexyl acrylate  
Dimethylethylcyclohexylacrylate

- **Hazard statements**

Combustible liquid.  
Causes skin irritation.  
Causes serious eye irritation.  
May cause an allergic skin reaction.  
Suspected of damaging fertility or the unborn child.  
May cause respiratory irritation.

- **Precautionary statements**

Keep away from flames and hot surfaces. – No smoking.  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Wear protective gloves/protective clothing/eye protection/face protection.  
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
Store locked up.  
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Department Research & Development

- **Contact:** Dr. Thomas Veit, Lothar Sutor

- **Date of preparation / last revision** 06/03/2020 / -

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
DOT: US Department of Transportation  
IATA: International Air Transport Association  
ACGIH: American Conference of Governmental Industrial Hygienists  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
NIOSH: National Institute for Occupational Safety  
OSHA: Occupational Safety & Health  
TLV: Threshold Limit Value  
PEL: Permissible Exposure Limit  
REL: Recommended Exposure Limit  
Flam. Liq. 4: Flammable liquids – Category 4  
Skin Irrit. 2: Skin corrosion/irritation – Category 2  
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A  
Skin Sens. 1: Skin sensitisation – Category 1  
Repr. 2: Reproductive toxicity – Category 2  
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- **\* Data compared to the previous version altered.**