

MedEco IPI, MedEco IPI C1, MedEco IPI C5

Technical safety information

following the format of the safety data sheet according to 1907/2006/EC (REACH), Annex II

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Section 1: Identification of the substance/preparation and of the company/undertaking

1.1 Identification of the substance or preparation

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1.2 Use of the substance/preparation

Identified use

Industrial use

Uses advised against

Unknown

1.3 Company/undertaking identification

| | |
|-----------|---|
| Company | BIOVOX GmbH |
| Address | Bunsenstr. 15, 64293 Darmstadt, Germany |
| Telephone | +49 6151 7869330 |
| E-mail | be-green@biovox.systems |
| Website | https://www.biovox.systems/ |

1.4 Emergency telephone

+49 6151 7869330 BIOVOX GmbH (normal business hours)

Section 2: Hazards identification

2.1 Classification of the substance or mixture

European Regulation (EG) No.: 1272/2008 (CLP): Not classified as hazardous substance or mixture.

2.2 Label elements

European Regulation (EG) Nr.: 1272/2008: no hazard warning label required.

Hazard warnings Not classified

Unknown acute toxicity

> 99% of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

> 99% of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Additional information

The synthetic polymer microparticles supplied is subject to conditions laid down by entry 78 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

2.3 Other hazards

There is a risk of slipping due to spilt product. Even with proper earthing and connection, electrostatic charging may occur during handling. If a sufficient charge is allowed to build up, electrostatic discharges and the ignition of flammable air/vapour mixtures can occur.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Section 3: Composition /information on ingredients

3.1 Substances

Not applicable

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3.2 Mixtures

Chemical characterization

Preparation based on 1-Butene, polymer with ethene, contains additives

| | |
|---|--|
| Chemical name and CAS-No | 1-Butene, polymer with ethene 25087-34-7 |
| Weight-% | > 99% |
| REACH registration number | No data available |
| EC No (EU Index No) | No information available |
| Classification according to Regulation (EC) No. 1272/2008 [CLP] | [F] - Although non-hazardous, the manufacturer chooses to disclose the composition |
| Specific concentration limit (SCL) | - |
| M-Factor | - |
| M-Factor (long-term) | - |

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components.

| Chemical name and CAS-No | Oral LD 50 mg/kg | Dermal LD50 mg/kg | Inhalation LC50 - 4 hour - dust/mist - mg/L | Inhalation LC50 - 4h our - vapour - mg/L | Inhalation LC50 - 4 hour - gas - ppm |
|---|------------------|-------------------|---|--|--------------------------------------|
| 1-Butene, polymer with ethene 25087-34-7 | > 4000 g/kg | No data available | No data available | No data available | No data available |

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

This product contains one or more synthetic polymer microparticles as defined by entry 78 of Annex XVII to Regulation (EC) No. 1907/2006.

| Chemical name and CAS-No | Weight-% | Synthetic polymer microparticles |
|---|----------|----------------------------------|
| 1-Butene, polymer with ethene, 25087-34-7 | > 99% | x |

Section 4: First aid measures

4.1 Description of first aid measures

General information

Remove contaminated clothing. In case of accident or if feeling unwell, seek medical advice immediately.

After inhalation

After inhalation of decomposition products, remove affected person to fresh air and keep at rest. Seek medical treatment. In case of complaints after inhalation of dust: Remove to fresh air and seek medical attention.

After Skin contact

After contact with molten product: immediately cool affected skin with cold water. For removal of solidified molten material adhered to the skin, consult a physician. Burns caused by molten material must be treated medically. After contact with product or dust: wash skin thoroughly with water and soap. If irritation occurs and persists, seek medical advice.

After eye contact

In case of contact with eyes, rinse immediately with plenty of water, including under the eyelids. If irritation occurs, consult a physician.

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After swallowing

Rinse mouth and drink water. Seek medical attention if symptoms occur. Never induce vomiting or give anything by mouth if the injured person is unconscious or suffering from convulsions.

4.2 Most important symptoms and effects, both acute and delayed

Product dust may be irritating to eyes, skin and respiratory system.

4.3 Indication of any immediate medical attention and special treatment needed

Symptomatic treatment.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO₂), alcohol-resisting foam, dry chemical powder, dry sand, water spray.

Unsuitable extinguishing media

Do not use a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance or mixture

During combustion, irritating and toxic fumes may be released, including aldehydes, carbon monoxide (CO), and carbon dioxide (CO₂). The formation of additional decomposition and oxidation products depends on fire conditions. Do not inhale vapors or smoke.

Avoid dust formation. Fine dust dispersed in air may ignite. Powders, dusts, shavings, drillings, turnings, or cutting waste may explode or burn explosively.

5.3 Protective Equipment for Firefighters

Wear self-contained breathing apparatus and full protective clothing. Use appropriate personal protective equipment.

Additional information

Hazard depends on the burning substances and the fire conditions. Formation of toxic gases/vapors possible in case of fire. Accumulations of dust may be flammable. In case of fire in the vicinity, remove bags. Dispose of fire residues and contaminated extinguishing water in accordance with official regulations.

Section 6: Accidental release measures

6.1 Precautions, protective equipment and emergency procedures

Use personal protective equipment as required. Avoid contact with skin and eyes. Avoid inhalation. Ensure adequate ventilation. Prevent dust formation. Keep away from sources of ignition. Wipe up or sweep to avoid slipping hazard caused by spilled/leaked product. Take measures against electrostatic charging.

6.2 Environmental precautions

Use suitable containers. Do not allow product to enter drains or watercourses. Prevent release into the environment. Refer to Section 12 for additional ecological information.

6.3 Methods and materials for containment and cleaning up

Avoid further leakage or spillage if safe to do so. Collect mechanically with inert, damp, non-combustible material using clean, non-sparking tools and place into loosely covered plastic containers for later disposal. Avoid dust formation. Provide adequate ventilation. Dispose of collected material in accordance with regulations. Clean contaminated objects and surfaces thoroughly in compliance with environmental requirements.

6.4 Reference to other sections

Personal protective equipment (see section 8). Disposal (see section 13).

Section 7: Handling and storage

7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practices. Avoid contact with molten material. Prevent dust formation and static charge accumulation. Ensure suitable local exhaust ventilation/air extraction at processing machines. When grinding or milling, observe regulations regarding dust explosion hazards. This product has low electrical conductivity and may accumulate electrostatic charges. If sufficient charge is accumulated, ignition of

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flammable mixtures may occur. To minimize the risk of static discharge, containers should be properly closed and grounded. Dust suspended in air may be explosive. Avoid significant accumulation of material, especially on flat surfaces, as this may become airborne, form combustible dust clouds, and contribute to secondary explosions.

General occupational hygiene measures

Handle in accordance with good industrial hygiene and safety practices. Do not inhale dust. Do not eat, drink, or smoke while using this product. Remove contaminated clothing and wash before reuse. Regular cleaning of equipment, work area, and clothing is recommended

7.2 Conditions for safe storage, including any incompatibilities

Storage requirements for facilities and containers

Protect from moisture, excessive heat, and direct sunlight. Store away from potential sources of heat, open flames, direct sunlight, or incompatible chemicals. Avoid all sources of ignition.

Combined storage instructions

No special restrictions on storage with other products.

Storage class according to TRGS 510: LGK 11

7.3 Specific use(s)

No additional information available.

Section 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

No information available.

Derived No Effect Level (DNEL) – General Public

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2 Exposure controls

Appropriate engineering controls

Provide safety showers and eyewash stations. Ensure adequate ventilation and local exhaust at critical points during transfer and handling. Additional information: see Section 7. No further measures are required.

General hygiene measures

Handle in accordance with good industrial hygiene and safety practices. Avoid skin contact with molten material. Avoid inhalation of dust, fumes, or vapors. Do not eat, drink, or smoke when using this product. Remove contaminated clothing and wash before reuse. Regular cleaning of equipment, work area, and clothing is recommended.



a) Eye-/Face protection

Safety glasses with side shields (frame goggles) (e.g., EN 166). For hot processing, wear tightly sealed safety goggles. If risk of contact exists, wear a face shield.

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b) Skin protection

(i) Hand protection:

Wear suitable protective gloves (EN 374). When handling hot melts, additionally wear heat-resistant gloves (EN 407), e.g., made of fabric or leather.

(ii) Other protective measures:

Wear long-sleeved protective clothing. Additional body protection may be required depending on activity and potential exposure, e.g., apron, protective boots.

c) Respiratory protection

Under normal conditions of use, no respiratory protection is required. If exposure limits are exceeded or irritation occurs, use appropriate respiratory protection, e.g., a dust mask with particle filter FFP2 (EN 149). Ventilation and evacuation may be required. The filter class must be suitable for the maximum contaminant concentration (gas/vapor/aerosol/particles) that may occur during handling of the product.

d) Thermal hazards

No additional data available.

Environmental exposure controls

Do not discharge into surface waters or drains. Do not allow material to enter the groundwater system.

Section 9: Physical and chemical properties

9.1 Information on Basic Physical and Chemical Properties

| | |
|---|-----------------------------|
| Physical state: | Solid |
| Appearance: | Granules |
| Color: | White to off-white |
| Odor: | No data available |
| Melting point: | No data available |
| Boiling point: | No data available |
| Flammability: | No data available |
| Flash point: | No data available |
| Autoignition temperature | 350°C |
| pH value: | No data available |
| Viscosity: | No data available |
| Water solubility: | not soluble in water |
| Vapor pressure: | No data available |
| Partition coefficient: n-octanol/water: | No data available |
| Density: | 0,9 – 1,0 g/cm ³ |
| Particle characteristics: | No data available |

9.2 Other Information

Information on physical hazard classes

No additional data available.

Other safety-related parameters

No additional data available.

Section 10: Stability and reactivity

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical stability

Stable under normal conditions.

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10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Avoid moisture, heat, prolonged UV exposure, and sources of ignition. Avoid prolonged exposure to heat above 230 °C. Prolonged exposure above 230 °C leads to degradation. Prevent dust formation and dispersion of powder into airborne dust, which may create an explosion hazard.

Protect from moisture.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Combustion may produce irritating and toxic fumes. Carbon monoxide (CO), carbon dioxide (CO₂), and nitrogen oxides (NO_x) may be released.

Section 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Inhalation: Specific test data for the substance or mixture is not available. Inhalation of dust in high concentration may cause irritation of respiratory system.

Eye contact: Specific test data for the substance or mixture is not available. Dust contact with the eyes can lead to mechanical irritation.

Skin contact: Specific test data for the substance or mixture is not available. Contact with dust can cause mechanical irritation or drying of the skin.

Ingestion: Specific test data for the substance or mixture is not available. Specific test data for the substance or mixture is not available. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

None known.

Acute toxicity:

Numerical measures of toxicity: Based on available data, the classification criteria are not met.

The following values are calculated based on chapter 3.1 of the GHS document:

ATEmix (oral) > 4000mg/kg

Unknown acute toxicity:

> 99 percent of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

> 99 percent of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Component information:

| Chemical name and CAS-No | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|---|--------------------|-------------|-----------------|
| 1-Butene, polymer with ethene 25087-34-7 | > 4000 mg/kg (Rat) | - | - |

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: No information available.

Serious eye damage/irritation: No information available.

Respiratory or skin sensitization: No information available.

Germ cell mutagenicity: No information available.

Carcinogenicity: no ingredients above reportable quantities listed as a carcinogen.

Reproductive toxicity: No information available.

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| | |
|--|---------------------------|
| Specific target organ toxicity - single exposure: | No information available. |
| Specific target organ toxicity with repeated exposure: | No information available. |
| Aspiration hazard: | No information available. |

11.2 Information on other hazards

Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors.

Other information

No information available.

Section 12: Ecological information

12.1 Toxicity

There are no comprehensive studies on the environmental compatibility of the product. Material in pellet or bead form may have adverse mechanical effects if ingested by waterfowl or aquatic life. The plastic is not soluble in water. None of its components exhibit aquatic toxicity within the solubility limit. Avoid release to the environment.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The components of this mixture do not meet the criteria for classification as PBT or vPvB.

12.6 Endocrine disrupting properties

This product does not contain any known or suspected endocrine disruptors.

12.7 Other adverse effects

No data available.

PMT or vPvM properties

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

Section 13: Disposal considerations

13.1 Waste treatment methods

Product:

Minimize product waste generation wherever possible. Consider possibilities for recycling. Dispose of product in accordance with local regulations.

Contaminated packaging:

Empty containers completely and dispose of in compliance with official regulations. Do not reuse contaminated packaging.

Waste codes / waste designations according to EWC / AVV

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

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Section 14: Transport information

The product is not classified as dangerous goods under transport regulations ADR/RID, ADN, IMDG, or IATA/ICAO.

| ADR/RID | ADN | IMDG | IATA/ICAO |
|---|----------------|----------------|----------------|
| 14.1. UN-number or ID-number | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.2. UN proper shipping name | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.6. Special precautions for user | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |
| 14.7. Transport in bulk according to IMO instruments | | | |
| Not applicable | Not applicable | Not applicable | Not applicable |

Section 15: Regulatory information

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

National regulations:

France: Occupational Illnesses (R-463-3, France)

| Chemical name and CAS-No | French RG number |
|---|------------------|
| 1-Butene, polymer with ethene 25087-34-7 | - |

Germany:

Water hazard class

,nwg', not hazardous to water (self-classification according to Annex 1 of VwVwS) .

Netherlands: Water contaminating class

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should

European Union: Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV).

This product contains one or more substance(s) subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

Persistent Organic Pollutants:

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009:

Not applicable

15.2. Chemical safety assessment

The product is not classified as hazardous. A Safety Data Sheet for this product is not legally required and is provided voluntarily for customer information.

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A chemical safety assessment is not required.

Section 16: Other information

Use in medical devices only with prior approval by BIOVOX GmbH.

The above information is believed to be accurate but does not claim to be complete and is intended as a guide only. The above information is based on our current knowledge. It characterizes the product with regard to the corresponding safety precautions. It does not constitute a guarantee of the product's properties.