

MedEco IGH, MedEco XGB

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 GHS labelling required.

Signal word: -

Pictograms: -

Hazard warning: -

Safety instructions: -

2.3 Other hazards

No data available.

Section 3: Composition /information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical characterization

Preparation based on: Biobased Polylactid, contains additives

CAS-No.: 9051-89-2 (PLA)

n/a (Additives)

BIOVOX GmbH | Bunsenstraße 15 | 64293 Darmstadt

be-green@biovox.systems | +49 6151 7869330

Geschäftsführer: Dr.-Ing. Julian Lotz, Dr.-Ing. Vinzenz Nienhaus, Carmen Rommel

Registergericht: Amtsgericht Darmstadt, HRB 101494

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Additional notes: does not contain any hazardous ingredients affecting health.

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..

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

No information available.

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

None known.

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.

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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

Collect mechanically. Avoid the generation of dust. Ensure proper ventilation. Dispose of the collected material in accordance with applicable regulations.

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 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

Protect from moisture, extreme heat and UV radiation. Store in a cool and closed place. Avoid ignition sources of any kind.

Combined storage instructions

No special restrictions on storage with other products.

7.3 Specific use(s)

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Section 8: Exposure controls/personal protection

8.1 Control parameters

Exposure limits

No known occupational exposure limits to be monitored.

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.

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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.

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
Odor:	Odourless
Melting point:	150-230 °C
Boiling point:	n/a
Flammability:	Not flammable
Flash point:	n/a
Auto-ignition temperature:	n/a
pH value:	n/a
viscosity:	n/a

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Water solubility:	not soluble in water
Vapor pressure:	No data available
Partition coefficient: n-octanol/water:	No data available
Density:	1,3 – 1,4 g/cm ³

9.2 Other Information

Information on physical hazard classes

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.

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

Acute toxicity:	Not classified
Skin corrosion/irritation:	Not classified
Serious eye damage/irritation:	Not classified
Respiratory or skin sensitization:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
Specific target organ toxicity - single exposure:	Not classified
Specific target organ toxicity with repeated exposure:	Not classified
Aspiration hazard:	Not classified

11.2 Information on other hazards

Endocrine disrupting properties

Contains no known or suspected endocrine disruptors.

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Other information

No additional data available.

Section 12: Ecological information

12.1 Toxicity

The product is not considered harmful to aquatic organisms and is not expected to cause long-term adverse effects in the environment.

12.2 Persistence and degradability

The product is biodegradable.

12.3 Bioaccumulative potential

Based on its consistency and insolubility in water, bioaccumulation is not expected.

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

No data available.

12.7 Other adverse effects

No data available.

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.

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

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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

EG-Regulations:

The product is not subject to labeling requirements under EU regulations.

Water exposure class (Germany):

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

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.

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.