

Regulatory Information Sheet

Product: MedEco® ICB-C1

BIOVOX

Product Information

Manufacturer/Supplier: BIOVOX GmbH
Date of Declaration: 2025-08-14

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Absence Declaration

The substances listed below are not included as raw materials, processing aids, or formulation ingredients in the production of the above product:

- 1,3-benzenediol (Resorcinol) (CAS-Nr. 108-46-3)
- 1,4-butanediol (CAS-Nr. 110-63-4)
- 1,4-Dioxane (CAS-Nr. 123-91-1)
- 2,2dimethoxy--2-phenylacetophenone (CAS-Nr. 24650-42-8)
- 2,4-pentanedione (acetylacetone) (CAS-Nr. 123-54-6)
- 2,4-xylydine (CAS-Nr. 95-68-1)
- 2,6-xylydine (CAS-Nr. 87-62-7)
- 3,4-diacetoxy-1-butene (CAS-Nr. 18085-02-4)
- 3-hydroxybenzophenone (CAS-Nr. 13020-57-0)
- 3-monochloro-propanediol (3-MCPD) (CAS-Nr. 96-24-2)
- 4-amino-3-fluorophenol (CAS-Nr. 399-95-1)
- 4-hydroxybenzophenone (CAS-Nr. 1137-42-4)
- 4-methylbenzophenone (CAS-Nr. 134-84-9)
- 6-amino-2-ethoxynaphthaline (CAS-Nr. 293733-21-8)
- Acrylamide (CAS-Nr. 79-06-1)
- Adsorbable organically combined halogens (AOX)
- Alkylphenols and alkylphenol ethoxylates
- Aluminum
- Anthraquinone (CAS-Nr. 84-65-1)
- Aromatic amines (as listed in Regulation 1907/2006/EC Annex XVII Appendix 8)
- Asbestos (CAS-Nr. 1332-21-4)
- Azocolorants
- Azodicarbonamides (ADA)
- Benzene (CAS-Nr. 71-43-2)
- Benzophenone (CAS-Nr. 119-61-9)
- Benzophenone and derivatives
- BHA (CAS-Nr. 121-00-6)
- BHT (CAS-Nr. 128-37-0)
- Bisphenol A and its derivatives (CAS-Nr. 9980-07-6)
- Bisphenol B and its derivatives (CAS-Nr. 77-40-7)
- Bisphenol F and its derivatives (CAS-Nr. 620-92-8)
- Bisphenol S and its derivatives (CAS-Nr. 80-09-1)
- Carbon Black (CAS-Nr. 1333-86-4)
- Chlorinated solvents
- Chlorobenzenes
- Chlorophenols (CAS-Nr. 67-97-0)
- Cobalt(II)-chloride (CAS-Nr. 7469-79-9)
- Conflict minerals as defined by Section 1502 of the Dodd-Frank Act
- Cyanuric acid (CAS-Nr. 108-80-5)
- DEAB (CAS-Nr. 90-93-7)
- Derivatives from palm tree

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- Di-isopropylnaphthalenes (DIPN)
- Diarylide pigments or dyes
- Dichloro-propanediol (DCP)
- Diethanolamine (CAS-Nr. 111-42-2)
- Dimethyl Fumarate (CAS-Nr. 624-49-7)
- Dioxins and Furans
- Diphenyl-2ethylhexylphosphate -(DPO) (CAS-Nr. 1241-987-2)
- Elastomers or rubbers from which n-nitrosamines may be released
- Epichlorohydrin (CAS-Nr. 106-89-8)
- Erucamide (CAS-Nr. 112-84-5)
- ESBO (Epoxidized Soybean Oil) (CAS-Nr. 8013-07-8)
- Ethyl-4dimethylaminobenzoate (CAS-Nr. 10287-53-3)
- Ethylbenzene (CAS-Nr. 100-41-4)
- Ethyleneimine (aziridine) (CAS-Nr. 151-56-4)
- Flame retardants
- Fluorescent optical brightening agents
- Fluorinated organic compounds or polymers
- Fluorinated surfactants
- Formaldehyde (CAS-Nr. 50-00-0)
- Formaldehyde cyanohydrin (CAS-Nr. 107-16-4)
- Fungicides (according to EEA definition)
- Hydrazines (azodicarbonamides)
- Hydroquinone (CAS-Nr. 123-31-9)
- Irgafos 126 (CAS-Nr. 26741-53-7)
- Irgafos 168 (CAS-Nr. 31570-04-4)
- ITX (CAS-Nr. 83846-86-0)
- Latex (Natural rubber latex or natural rubber)
- Linear Alkylbenzenes (CAS-Nr. 67774-74-7)
- Maleic acid di-(2-ethylhexyl)-ester (CAS-Nr. 142-16-5)
- MEK (Methyl Ethyl Ketone or 2-butanone)
- Melamine (CAS-Nr. 108-78-1)
- MIBK (Methyl Isobutyl Ketone)
- Michler's ketone (CAS-Nr. 90-94-8)
- Nonylphenol and nonylphenol ethoxylate (1907/2006/EC Annex XVII)
- o-phenylphenol and sodium o-phenylphenate
- Para-phenylenediamine (PPD) (CAS-Nr. 106-50-3)
- Parabens
- Perchlorates
- Phenols and polyphenoles
- Phenylphenol (CAS-Nr. 90-43-7)
- Polybrominated biphenylether (PBDE)
- Polybrominated biphenyls (PBB)
- Polychlorinated biphenyls (PCB)
- Polychlorinated n-alkanes

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- Polystyrene (CAS-Nr. 9003-53-6)
- Polyvinyl chloride (PVC), PVDC and Vinyl chloride monomer
- Priority Pollutants as listed in Appendix A of 40 CFR 423 of the US EPA
- Rhodamine-based pigments
- Short-Chain Chlorinated Paraffins (SCCPs)
- Styrene (CAS-Nr. 100-42-5)
- Talc (CAS-Nr. 14807-96-6)
- Tetrahydrofuran (CAS-Nr. 109-99-9)
- Titan-acetylacetonate (TAA) (CAS-Nr. 14024-64-7)
- Titanium dioxide (TiO₂)
- Toluene (CAS-Nr. 108-88-3)
- Tributyltin (TBT)
- Tributyltin oxide (TBO) (CAS-Nr. 56-35-9)
- Triclosan (CAS-Nr. 3380-34-5)
- Tris-Nonylphenol Phosphite (TNPP) (CAS-Nr. 26523-78-4)
- Vinylchloride (CAS-Nr. 75-01-4)

Absence of Epoxy Compounds

We confirm that our product are not manufactured using the following substances:

- 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE)

- BADGE derivatives, including:
- BADGE.H₂O
- BADGE.HCl
- BADGE.2HCl
- BADGE.H₂O.HCl

- bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE)

- BFDGE derivatives, including:
- BFDGE.H₂O
- BFDGE.HCl
- BFDGE.2HCl
- BFDGE.H₂O.HCl

- novolac glycidyl ethers (NOGE)

To the best of our knowledge, these chemicals are not present in any of the raw materials used to manufacture this/these polymer(s). Therefore, Commission Regulation 1895/2005 does not apply to BIOVOX GmbH polymer grades.

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Allergens

No substances listed in Annex II of Regulation (EU) No 1169/2011, as amended by Commission Delegated Regulation (EU) No 78/2014, are used in the production of the mentioned product.

The product is free from allergens such as milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame, in compliance with the US Food Allergen Labeling and Consumer Protection Act of 2004 and the Food Allergy Safety, Treatment, Education, and Research Act of 2021.

It also conforms to Regulation (EC) No 1223/2009 Annex III, ensuring it does not contain substances causing allergies or intolerances.

Animal derived substances

We confirm that no animal-derived substances are used as additives or ingredients in the manufacturing process of the above product.

Biocides

BIOVOX GmbH confirms that no substances intended to act as biocides, including pesticides, herbicides, insecticides, fungicides, bactericides, or fumigants (such as Kathon CG or Kepone), are intentionally added or used in the manufacture of this product.

We also wish to inform you that none of the ingredients is either a biocidal active substance or a product intentionally added to the aforementioned product to function as a biocide. Therefore, Regulation (EU) No 528/2012 does not apply to our product.

Brominated Flame Retardants

We confirm that the brominated flame retardants specified in Commission Recommendation 2014/118/EU are not utilized as additives or ingredients in the mentioned product.

BSE/TSE

Our products do not contain any animal ingredients, nor are any used in the manufacturing process. Therefore, there is no risk of Transmissible Spongiform Encephalopathy (TSE) or Bovine Spongiform Encephalopathy (BSE) contamination.

We have obtained assurances from our suppliers that all raw materials currently used in the manufacture of these products are either not derived from animal substances or, if animal-derived, originate from Category 3 materials. These materials undergo a rigorous production process involving high temperatures (>200°C) and pressure for more than 20 minutes, as described in Annex XIII, Chapter XI of Commission Regulation (EU) No 142/2011, which implements Regulation (EC) No 1069/2009 and fulfills the requirements of EMA/410/01 Rev.3 (2011/C 73/01), Chapter 6.4. Tallow derivatives produced under these conditions are unlikely to present any TSE risk and are exempt from the requirements of Commission Regulation (EU) No 722/2012 as defined in Article 1(4) and Annex I 3.

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California Proposition 65

Based on a review of the manufacturing process and information from our raw material suppliers, we confirm that, to the best of our knowledge, none of our products contain Proposition 65 chemicals at levels requiring a warning under the California Safe Drinking Water and Toxic Enforcement Act.

We do not utilize any substances listed in California Proposition 65 as components or auxiliary agents in the manufacture of our products, nor are these substances intentionally added. However, we do not test for these substances as part of our quality control, and therefore cannot guarantee their complete absence.

Our products may contain low levels of naturally occurring impurities such as crystalline silica (quartz) and trace metals like lead, cadmium, and arsenic, which are listed under Proposition 65. These substances are not intentionally added, and the potential exposure is limited to airborne particles of respirable size.

Conflict minerals

BIOVOX GmbH does not source raw materials from conflict areas like the Democratic Republic of the Congo or adjoining countries. Our products do not intentionally contain cassiterite, wolframite, coltan, or gold.

According to Section 1502 of the Dodd-Frank Act and U.S. SEC regulations, "Conflict Minerals" include cassiterite, columbite-tantalite (coltan), gold, wolframite, and their derivatives. These are not used in our products.

All our products are "DRC conflict free," as defined by the Dodd-Frank Act and U.S. SEC regulations.

CMR and Hazardous Substances in Compliance with Regulation 1272/2008

Based on an evaluation of the product formulation, manufacturing procedures, and data provided by raw material suppliers, the product mentioned above do not contain CMR (Carcinogenic, Mutagenic, or Toxic to Reproduction) substances classified under Category 1A or 1B, as defined in Part 3 of Annex VI of Regulation (EC) No 1272/2008, at concentrations exceeding 0.1% by weight.

End-of-Life Vehicles Directive

Based on the information available from our raw material suppliers, our current products do not contain the four heavy metals—lead, cadmium, chromium (VI), and mercury—and their compounds as intentional additives or ingredients. This compliance is in accordance with the EU Directive 2000/53/EC (End-of-Life Vehicles Directive) and its amendments, up to and including Commission Delegated Directive (EU) 2020/362 and 2020/363 of 17 December 2019.

Therefore, our products meet the requirements of EU Directive 2000/53/EC and its amendments.

Endocrine disruptor list - List I: Substances identified as endocrine disruptors at EU level

The Endocrine Disruptor List I (latest update November 2023, [link](#)) includes substances that have been evaluated for endocrine-disrupting properties as regulated in the EU under REACH (EC 1907/2006), BPR (EU 528/2012, and EU 2017/2100), PPPR (EC 1107/2009, and EU 2018/605), and identified as endocrine disruptors.

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We wish to inform you that during the manufacturing of the aforementioned product(s), no substances listed in ""List I: Substances Identified as Endocrine Disruptors at EU Level"" (updated November 2023) are intentionally used as additives or ingredients

European Standard EN71 - Safety of Toys

BIOVOX GmbH hereby certifies that our products, as supplied by BIOVOX GmbH, are suitable for use in toy production as per European Commission Regulation EC 2009/48.

European standard EN 71 specifies safety requirements for toys, which are legally required for all toys sold in the European Union. BIOVOX GmbH supplies products that can be classified as Category III toy material. The following migration limits have been established for certain elements for Category III toy materials as included in Annex II, Section III Sub 13 of EC 2009/48.

Directive 2009/48/EC of 18 June 2009 and its amendments on the safety of toys do not apply to our product. Nevertheless, according to Annex II Part III chemical properties, our product:

- Is not a hazardous substance or mixture under Regulation 1272/2008/EC (CLP),
- Is not a CMR of category 1A, 1B, or 2 under CLP,
- Does not intentionally contain nitrosamines or nitrosable substances,
- Does not intentionally contain any allergenic fragrance listed in point 11 of Annex II.

Concerning nitrosamines, nitrosable substances, and allergenic fragrances: these products have not been tested for these chemical substances as they are not expected to be present in our products.

Glycol ethers

The following substances are not utilized as additives or ingredients in the production of the specified product:

- (2-Methoxymethylethoxy)propanol (DPGME, CAS No. 34590-94-8)
- [2-(2-Methoxymethylethoxy)methylethoxy]propanol (CAS No. 25498-49-1)
- 1-Butoxypropan-2-ol (CAS No. 5131-66-8)
- 1-Methoxypropan-2-ol (CAS No. 107-98-2)
- 1-Phenoxypropan-2-ol (CAS No. 770-35-4)
- 2-Ethoxy-1-methylethyl acetate (CAS No. 54839-24-6)
- 2-Ethoxyethanol (EGEE, CAS No. 110-80-5)
- 2-Ethoxyethylacetate (EGEEA, CAS No. 111-15-9)
- 2-Methoxy-1-methylethyl acetate (PGMEA, CAS No. 108-65-6)
- 2-Methoxyethanol (EGME, CAS No. 109-86-4)
- 2-Methoxypropanol (CAS No. 1589-47-5)

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Genetically-Modified Organisms (GMOs)

BIOVOX GmbH confirms that our products are non-GMO and comply with Regulation (EC) No. 1829/2003 and Council Regulation (EC) No. 834/2007. No genetically modified organisms or substances derived from GMOs are used or added in our products.

Our products are GMO-free and do not require GMO labeling as per Regulations (EC) No. 1829/2003 and (EC) No. 1830/2003.

Halogens

Based on information from our raw material suppliers, we confirm that our products do not contain any halogenated compounds as intentional additives or ingredients.

Heavy metals

Our products comply with:

- The CONEG model Toxics in Packaging Legislation
- California Toxics in Packaging Prevention Act
- European Directive 94/62/EC and subsequent amendments
- European Commission Regulation 10/2011, Annex II

Our ground limestone and calcium carbonate materials, derived from natural limestone ore, may contain trace amounts of metals. These concentrations are consistently below 100 ppm, ensuring compliance with CONEG and EU Directive 94/62/EC.

This product does not intentionally contain any heavy metals and meets the standards of Regulation (EU) 94/62/EC and US CONEG.

We formulate our products without the intentional addition of metals such as aluminum, antimony, arsenic, beryllium, bismuth, boron, cadmium, chromium (and its hexavalent forms), cobalt, copper, gold, iridium, lead, manganese, mercury, molybdenum, nickel, osmium, palladium, platinum, rhodium, ruthenium, selenium, silver, strontium, tantalum, tellurium, thallium, titanium, tungsten, or vanadium. Any incidental traces of lead, mercury, cadmium, and hexavalent chromium are well below the 100 parts per million (ppm) threshold.

Human Samples

In the manufacture of the above mentioned product human samples or their derivatives are not used as additives or ingredients.

Microplastic

We confirm that the aforementioned product(s) comply with the requirements of Regulation (EC) No. 2023/2055, which amends Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and Council concerning the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) with respect to synthetic polymer microparticles.

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Ozone Depleting Substances

Our product is not manufactured with any Class I or Class II Ozone Depleting Chemicals (ODCs) listed by the US EPA, the Montreal Protocol, or the Ozone Depleting Substances listed in Annexes I & II of EU Directive 1005/2009/EC and its amendments up to April 19th, 2017.

We confirm that the aforementioned product(s) comply with the requirements of Regulation (EC) No. 1005/2009, last amended by Commission Regulation (EU) 2017/605 of 29 March 2017, as well as the US labelling requirements of Section 611 of the Clean Air Act Amendments of 1990 (CAA), §602 and §611.

Polycyclic Aromatic Hydrocarbons (PAH)

In the manufacture of the above mentioned grade polycyclic aromatic hydrocarbons (PAHs) are not used as additives or ingredients.

Per- and Polyfluorinated substances (PFAS)

BIOVOX GmbH does not intentionally add or use per- and polyfluoroalkyl substances (PFAS), including PFOA (perfluorooctanoic acid, CAS 335-67-1) and PFOS (perfluorooctane sulfonates, CAS 1763-23-1), in the manufacture of its products. Additionally, BIOVOX GmbH confirms that our product formulations do not contain intentionally added organic fluorinated chemicals, such as PFAS or PFC.

No PFAS are used in or on any equipment that comes into contact with these products. The entire manufacturing process is dedicated to ensuring no PFAS or fluorinated chemicals are present.

Phthalates

In the manufacture of the above product/s phthalates are not used as additives or ingredients.

Plant derived substances

This product may contain additives and/or monomers derived from plants and/or its parts.

Plasticizers

BIOVOX GmbH does not intentionally add plasticizers during the manufacture of this product. However, trace levels may be present as a result of the polymerization process.

Please note that these substances are not routinely tested for in our products.

Radioactivity

BIOVOX GmbH assures that there are no concerns regarding radioactivity in the raw materials used for our products, or in the finished products themselves. Based on our thorough assessments, we have no reason to believe that any issues related to radioactivity are present.

REACH Declaration

The above-mentioned product line complies with the requirements of Regulation (EC) No. 1907/2006 (REACH) concerning the registration of chemical substances.

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All substances that we manufacture or import, and which require registration, have either been registered by ourselves or are covered by registrations submitted by appointed EU Only Representatives (OR) on behalf of our non-EU raw material suppliers.

RoHS Declaration – Directive 2011/65/EU

The above-mentioned product line complies with the provisions of Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS Directive"), including its latest amendment by Commission Delegated Directive (EU) 2015/863.

We have reviewed Annex II of the RoHS Directive, which sets the maximum allowable concentrations of certain restricted substances. Based on information provided by our raw material suppliers, the above-mentioned product(s) do not contain, as intentionally added substances, any of the restricted materials listed below. To the best of our knowledge, these substances are also not generated during the production process.

Accordingly, the requirements regarding the absence of substances listed in Annex II of Directive 2011/65/EU are fulfilled. The restricted substances include:

- Cadmium and its compounds
- Lead and its compounds
- Mercury and its compounds
- Hexavalent chromium compounds
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

Therefore, we confirm that the above-mentioned product(s) do not contain these substances above the defined threshold limits of 0.01% by weight for cadmium and 0.1% by weight for all other listed substances.

Silicone and Siloxane

Silicone is not used as an additive or ingredient in the production of the specified product.

VOC content

Swiss law "Ordonnance sur la taxe d'incitation sur les composés organiques volatils (OCOV)" 814.018 mandates a tax on VOCs in chemicals, mixtures, and articles. Products with less than 3% VOC content are exempt.

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The VOC content in the mentioned product(s) is well below the 3% limit, allowing import into Switzerland without VOC tax.

Our products, when used as packaging components, comply with:

- US EPA 40 CFR 59 National VOC Emission Standards
- EU Directive 2004/42/EC on VOC emissions in paints, varnishes, and vehicle refinishing products

They contain less than 3% VOCs by weight, typically much less.

This statement excludes:

- Modifications by adding other products
- Changes from processing
- Improper use or storage

Important Notice

Many substances are prevalent in various environments. To our best knowledge, the supplied products do not contain the aforementioned substances in concentrations exceeding 0.01%. However, monitoring these substances is not part of our continuous production control. Given the numerous variables that can influence the processing and application of our products, this information does not relieve the processor from conducting their own tests and investigations. This information does not imply any guarantee regarding specific properties or the suitability of the product for particular applications. It remains the responsibility of the recipient of our products to ensure compliance with proprietary rights and existing laws and regulations.

Sincerely,

BIOVOX GmbH

This document is valid without signature.