

Regulatory Information Sheet



Product: MedEco XPI C4

Product Information

Manufacturer/Supplier: BIOVOX GmbH
Date of Declaration: 2026-02-13

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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-xylidine (CAS-Nr. 95-68-1)
- 2,6-xylidine (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 derivates (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
- Di-isopropylnaphthalenes (DIPN)

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- Diarlide 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
- 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

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- 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 (TBTO) (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.

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.

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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 Kepona), 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

To the best of our knowledge, BIOVOX GmbH does not intentionally add or use any animal-derived raw materials in the manufacturing process of the aforementioned product. Consequently, we can confirm the absence of agents responsible for Transmissible Spongiform Encephalopathy (TSE) and Bovine Spongiform Encephalopathy (BSE), which could potentially arise from animal-based contaminants.

Since these substances are not intentionally included, they are not tested for during our production processes.

California Proposition 65

With regard to the presence of substances on the California Proposition 65 list (Safe Drinking Water and Toxic Enforcement Act of 1986) in the following products: IPI, IPI C1, XPI C2, BIOVOX GmbH informs that the following impurities might be present:

- Ethylene oxide (CAS# 75-21-8), at levels less than 10 ppb
- 1,4-Dioxane (CAS# 123-91-1), at levels less than 10 ppb

These components are encapsulated within a polymer matrix in the product supplied by BIOVOX GmbH. It should be noted that BIOVOX GmbH has not conducted safe harbor calculations nor analyzed for these specific substances. Each company selling products in California is responsible for determining their own products' compliance with Proposition 65 and developing appropriate regulatory plans. BIOVOX GmbH does not provide any warranties or representations in this regard.

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.

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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.

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

This product has not been assessed under Directive 2009/48/EC – Safety of Toys.

It has not been tested and assessed according to the European Standard EN 71-3:2019+A1:2021, which specifies requirements and test methods for the migration of elements such as aluminum, antimony, arsenic, barium, boron, cadmium, chromium (III), chromium (VI), cobalt, copper, lead, manganese, mercury, nickel, selenium, strontium, tin, organic tin, and zinc from toy materials and parts of toys.

Additionally, this product has not been tested and assessed according to the European Standard EN71-9: Safety Of Toys - Part 9: Organic chemical compounds - Requirements.

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)

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- 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)

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.

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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.

MOSH and MOAH

BIOVOX GmbH does not intentionally add or use Mineral Oil Aromatic Hydrocarbons (MOAH) in the manufacture of this product.

However, Mineral Oil Saturated Hydrocarbons (MOSH) are used during production. These MOSH are in compliance with Regulation (EU) No 10/2011 on food contact materials, either as FCM Substance No. 95 or based on a completed safety assessment in accordance with Article 19 of the regulation.

Please note that GmbH does not perform specific analytical testing for these substances.

Nanomaterials

According to the definition provided in EC Recommendation 2022/C 229/01, nanomaterials are considered to be natural, incidental, or manufactured materials consisting of solid particles present as such or as identifiable constituent particles in aggregates or agglomerates, where:

- 50% or more of the particles have one or more external dimensions in the size range of 1 nm to 100 nm; or
- the particles have an elongated shape (e.g., rod, fiber, or tube) with two external dimensions smaller than 1 nm and the other larger than 100 nm; or
- the particles have a plate-like shape with one dimension smaller than 1 nm and the others larger than 100 nm.

Based on this definition, BIOVOX does not intentionally add nanomaterials to this product.

Please note that BIOVOX does not conduct specific analytical testing for the presence of nanomaterials.

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

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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.

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.

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

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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.