



Gulbrandsen, Inc.

183 Gulbrandsen Rd.
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Date: April 11, 2026

G-COAT H110 – Monobutyltin Trichloride Statement of Compliance

Chemical Inventory Status

Country	Inventory	Status
Australia	AICS	Listed
Canada	DSL	Listed
China	IECES	Listed
Europe	EINECS	Listed
Japan	ENCS	Listed
South Korea	KECI	Listed
New Zealand	NZIOC	Listed
Philippines	PICCS	Listed
United States	TSCA	Listed

Regulation (EC) No. 1907/2006 - REACH

The above-mentioned product has been REACH registered in accordance with Article 23 of European Regulation (EC) No. 1907/2006 (the REACH regulation). Gulbrandsen's registration number is 01-2119484854-24-0007. Our only representative is REACHLaw Ltd.

<https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/14718>

Substances of Very High Concern

The above-mentioned product contains one impurity at a level of <0.1% – Dibutyltin Dichloride (DBTC) CAS No. 683-18-1 - that is on the Candidate List of Substances of Very High Concern (SVHC) because the substance is potentially toxic to reproduction.

<http://echa.europa.eu/web/guest/candidate-list-table>





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Regulation (EC) No. 1907/2006 – Annex XVII and as amended by COMMISSION REGULATION (EU) 2021/2204 of 13 December 2021

This information is available in Chapter 15, “Regulatory Information,” of this product's SDS.

Organostannic compounds as listed in European Regulation (EC) No. 1907/2006 Annex XVII and amendments are used in the manufacture of Monobutyltin Trichloride; however, the concentration of tributyltin (TBT) and dibutyltin (DBT) compounds found in the final product is less than the acceptable limit of 0.1% by weight of tin. All other components listed in EC 1907/2006 are not intentionally added in the manufacturing process of the above-mentioned product. Their presence is therefore not expected in this product.

Warranty concerning material for Food Contact Application – European Union

Article 3 of the European Regulation (EC) No. 1935/2004 concerning materials and articles intended to come into contact with food, lays down that the materials shall be manufactured in compliance with the Good Manufacturing Practices so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- Endanger human health
- Bring about an unacceptable change in the composition of the food
- Bring about deterioration in the organoleptic characteristics of the food

EU Directive (EU) 2023/915 establishes the following maximum levels of inorganic tin in foods:

- For canned food except products listed below, the maximum level of Sn = 200 mg/kg of food (wet weight)
- For canned beverages except products listed below, the maximum level of Sn = 100 mg/kg of food (wet weight)
- For canned infant formulae, canned follow-on formulae, and canned young-child formulae, the maximum level of Sn = 50 mg/kg of food (The maximum level applies to the product as placed on the market.)
- For canned baby food and canned processed cereal-based food for infants and young children, the maximum level of Sn = 50 mg/kg of food (The maximum level applies to the product as placed on the market.)
- For canned food for special medical purposes intended for infants and young children, the maximum level of Sn = 50 mg/kg of food (The maximum level applies to the product as placed on the market.)



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To be in compliance with European Regulation (EC) No. 1935/2004 as amended and EU Directive (EU) 2023/915 as amended, all appropriate technical measures must be taken in the Monobutyltin Trichloride (G-Coat H110) application process in order to minimize the quantity of SnO₂ deposited on the mouth of the glass bottle and also on the inner surface of the glass container, which are in contact with food.

Assuming 100% migration (worst case calculation) of the SnO₂ amount applied on the inner surface of a glass jar having a surface area of 130cm² (100ml tall jar), **the maximum thickness of tin oxide expressed in CTU** (Coating Thickness Units – 1 CTU is approximately 0.24 nm or 1.7 mg of SnO₂/m² or 1.35 mg of Sn/m²) **to comply with** the requirements of EU Directive (EU) 2023/915 (to 50 mg/kg of Sn or 63.48 mg/kg of SnO₂ into baby food) **must be smaller than 285 CTU.**

Assuming 100% migration (worst case calculation) of the amount of SnO₂ applied on the inner surface of a glass jar having a surface area of 130cm² (100ml tall jar), one CTU is equivalent to 0.1755 mg of Tin per kilogram of food (density of food = 1 g/cm³)

We remind you that it is the responsibility of the manufacturer that brings the glass containers to market to check for compliance of the finished article with the essential safety and health requirements as mentioned in European Regulations (EC) No. 1935/2004, No 333/2007 and EU Directive (EU) 2023/915.

Warranty concerning material for Food Contact Application – United States FDA

When the above-mentioned product is used to apply a hot-end coating to the exterior surface of glass containers, a complete thermal breakdown of monobutyltin trichloride occurs, depositing a stannic oxide (tin oxide) coating on the exterior surface.

According to the Institute of Surface Science and Technology (ISST), a division of the internationally recognized Institute of Polymer Technology and Materials Engineering (IPTME), Loughborough University, UK, the examinations that they conducted on glass containers that had been commercially coated using the above mentioned product showed amounts of stannic oxide consistent with commercial levels of hot end coating on the outer surface, but they found no detectable amount of stannic oxide on the internal surfaces. This indicates that the stannic oxide coating produced on the exterior of the glass container surface is separated from contact with the packaged food by the functional barrier created by the wall of the container.

As a result, the above-mentioned product is not subject to the US FDA's indirect food additive regulation 21 CFR 174.5.





When applied to the exterior surface and below the threads on the neck of a glass container according to the technical advice provided by Gulbrandsen and with suitable application equipment, the tin oxide coating produced using the above mentioned product does not constitute an indirect food additive and the aforementioned product may be used as a glass coating

Statement on Heavy Metals

Article 11 of EU Directive 94/62/EC and the US CONEG Standard address the concentration of heavy metals present in packaging materials, requiring that the sum of the concentration levels of lead, cadmium, mercury, and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight.

Lead, cadmium, mercury, and hexavalent chromium are not used for the manufacture of the above-mentioned product. Their presence is therefore not expected in this product, except at extremely low trace levels.

This is confirmed by analysis carried out on this product, for which the levels of the above-mentioned heavy metals were found to be lower than 1 ppm.

Therefore, this product conforms to the US CONEG Standard and to the requirements of Article 11 of EU Directive 94/62/EC.

RoHS

Article 4 EU Directive 2015/863 (RoHS-3), specifies the maximum concentration tolerated (by weight) in homogeneous materials for the following restricted substances:

- | | |
|---|---------|
| ● Lead | < 0.1% |
| ● Mercury | < 0.1% |
| ● Hexavalent Chromium | < 0.1% |
| ● Cadmium | < 0.01% |
| ● Polybrominated biphenyls (PBB) | < 0.1% |
| ● Polyprominated diphenyl ethers (PBDE) | < 0.1% |
| ● Bis(2-Ethylhexyl) phthalate (DEHP) | < 0.1% |
| ● Benzyl butyl phthalate (BBP) | < 0.1% |
| ● Dibutyl phthalate (DBP) | < 0.1% |
| ● Diisobutyl phthalate (DIBP) | < 0.1% |

Lead, cadmium, mercury, and hexavalent chromium are not intentionally used in the manufacturing process;





therefore, their presence is not expected, except at extremely low trace levels.

This is confirmed by analysis carried out on this product, for which the levels of the above-mentioned heavy metals were found to be lower than 1 ppm.

Moreover, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Bis(2-Ethylhexyl) phthalate (DEHP), Benzyl butyl phthalate (BBP), Dibutyl phthalate (DBP), and Diisobutyl phthalate (DIBP) are not intentionally introduced in the manufacturing process; therefore, their presence is not expected.

Therefore, this product meets the criteria of the first article of Directive 2011/65/EU relative to the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Ozone Layer Depleting Substances

The product mentioned above has not been manufactured from any of the listed hydrochlorofluorocarbons (HCFCs) or Chlorofluorocarbons (CFCs) as specified under the Clean Air Act Amendments of 1999 and Regulation 2037/2000 recast as Regulation 1005/2009 of the EU.

Volatile Organic Compounds

EU Directive No. 2004/42/EC has the purpose to limit the total content of VOCs in certain paints and varnishes and vehicle refinishing products in order to prevent or reduce air pollution resulting from the contribution of VOC's to the formation of tropospheric ozone. This regulation does not apply to the above-mentioned product as it is not used in these applications.

Biocides

The following preservatives are not used during the manufacturing process of the above-mentioned product:

- 5-Chloro-2-Methyl-2H-Isothiazol-3-one/2-Methyl-2H-Isothiazol-3-one (CMIT/MIT mixture) (CAS Registry No. 55965-84-9)
- 5-Chloro-2-methyl-Isothiazolin-3-one solution (CAS Registry No. 26172-55-4)
- 2-Methyl-2H-Isothiazol-3-one (MIT) (CAS Registry No. 2682-20-4)
- 1,2-benzisothiazol-3(2H)-one (BIT) (CAS Registry No. 2634-33-5)
- Bronopol (CAS Registry No. 52-51-7)
- Ortho-phenylpehnol and its salts

Therefore, their presence is not expected. However, systematic testing is not performed to verify the absence of these substances.





CMR

The above-mentioned product is not classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) as defined by Regulation No. 1272/2008. Monobutyltin Trichloride (n-butyltin trichloride – CAS Registry No. 1118-46-34) has been included in the *Draft Community Rolling Action Plan (CoRAP) update for the years 2018-2020*. However, as of the date of this communication, the evaluation process is listed as suspended.

<https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807eb434>

Endocrine Disruptor

The above-mentioned product is not classified as an Endocrine Disrupter as referenced in Article 57(f) of Regulation No. 1907/2006.

Allergens

The allergens listed in Annex II of EU Regulation No 1169/2011, as well as those defined under the US Food Allergen Labeling and Consumer Protection Act, as amended, and the positive list of allergens specified in RDC No. 26/2015 issued by ANVISA, are not used during the manufacturing process of the above-mentioned product nor used within the production area where the above-mentioned product is produced; therefore, their presence is not expected. However, systematic testing is not performed to verify the absence of these substances. The above-mentioned product is not intended, nor suitable, for human consumption

Statement on Radiological Contamination

The above-mentioned product is not intentionally exposed to ionizing radiation and is not manufactured using irradiated raw materials; therefore, radiological contamination is not expected. However, systematic testing is not performed to verify the absence of radioactive substances.

Epoxy Derivatives

As listed in Annex 1 of EU Regulation (EC) 1895/2005

- BADGE (CAS Registry No. 1675-54-3)
- BADGE.H₂O (CAS Registry No. 76002-91-0)
- BADGE.2H₂O (CAS Registry No. 5581-32-8)
- BADGE.HCl (CAS Registry No. 1836-48-1)
- BADGE.2HCl (CAS Registry No. 4809-35-2)
- BADGE.HCl.H₂O (CAS Registry No. 227947-06-0)

are not used in the manufacturing process. However, systematic testing is not performed to verify the absence





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of these substances.

Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE)

No animal-derived substances are intentionally added in the manufacturing process; therefore, their presence is not expected.

Nanomaterial and Nanotechnology

Nanotechnology is an important technology of the 21st century. Gulbrandsen is aware that these new materials might raise new Product Stewardship questions. We are committed to managing them responsibly and, in particular, in full compliance with relevant legislation and guidelines.

Having regard to the definition of nanomaterials recommended on 10 June 2022 by the European Commission in its Recommendation 2022/C229/01, nano-form substances are not used during the manufacturing process and the final product delivered to the customer is not a nano-form material.

Per-and Poly Fluorinated Substances (PFAS)

The substances listed below are not intentionally added and are not used as raw materials, catalysts, or stabilizers in the manufacturing process; therefore, they are not anticipated to be present. ;

- Per-and poly-fluoro alkyl substances (PFAS)
- Per fluoro octanoic acid (PFOA, CAS 335-67-1)
- Per fluoro octane sulfonates (PFOS, CAS 1763-23-1)
- Undecafluorohexanoic acid (PFHxA, CAS 307-24-4) and PFHxA-related substances.

Analytical testing performed in accordance with EN ISO 23702-1:2023, using solvent extraction followed by LC-MS/MS, did not detect these substances above the specified detection limits. The detection limits were 1 µg/m² for PFOA and PFOS, and 0.1 mg/kg for all other substances.

G-Coat H110 is not routinely tested for these substances on a batch-by-batch basis.

Bisphenol

Bisphenols, including Bisphenol A (BPA), are not intentionally added during the manufacturing process. Analytical testing performed using solvent extraction followed by LC-MS/MS did not detect these substances above the specified detection limits. The detection limits were 0.1 ppm.

G-Coat H110 is not routinely tested for these substances on a batch-by-batch basis.



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Persistent Organic Pollutants

The above-mentioned product is not a persistent organic pollutant (POP) as defined by Regulation EU 2019/1021.

Silicone

The above-mentioned product does not contain silicone

List of Substances not intentionally added

The candidate list of Substances of Very High Concern defines the substances published by the European Chemicals Agency (ECHA) that may have serious health and environmental effects. As of the date of this communication, according to ECHA communications, there are currently 235 substances on the REACH Candidate List. Gulbrandsen does not intentionally add any of the listed products; therefore, their presence is not expected. However, systematic testing is not performed to verify the presence or absence of these substances.

Dibutyltin dichloride is a substance contained in the ECHA's SVHC candidate list. Although not intentionally added, this substance is present in monobutyltin trichloride (MBTC) hot end coatings as a byproduct of the manufacturing process at a level of <0.1%.

The Candidate List of Substances of Very High Concern is available on the ECHA website at the following web address: <http://echa.europa.eu/web/guest/candidate-list-table>

Disclaimer

This statement is limited to the material in the condition in which it is supplied by Gulbrandsen and does not extend to any modification, formulation change, treatment, or substance added thereafter by the converter or any downstream user.

