

Regulatories, food contact and chemical inventories Lucofin®X1008

Product Manufacturer

This product is manufactured by

LUCOBIT AG
Brühler Str. 60 • Basell Polyolefine GmbH • B 100 •
D-50389 Wesseling

REACH Regulation 1907/2006/EC

According to the EC Regulation REACH, this product is classified as a preparation. We confirm that all substances of this preparation comply with the registration requirements of REACH. We source materials exclusively from suppliers who have confirmed that the suppliers are aware of their REACH requirements, that they have registered their substances, and that they provide the relevant Material Safety Data Sheets (SDS) with REACH registration numbers. Under no circumstances will LUCOBIT AG be liable for violations based on false or incorrect information provided by its suppliers.

Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern (SVHC) above the 0.1% threshold

- determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing – as stated in REACH (Article 57, Regulation 1907/2006/EC and its amendments) and published at the current website link of ECHA :

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

This product is not subjected to restriction of using (conc. Annex XVII, latest version). This product does not contain substances that have to be authorized (conc. Annex XIV, latest version).

Global Chemical Control Regulations

All ingredients in this product are in compliance with the following chemical inventories:

United States: Toxics Substances Control Act Inventory (TSCA)

Canada: Domestic Substances List (DSL)

Europe: REACH

Australia: Australian Inventory of Chemical Substances (AICS)

Korea: Korean Existing Chemicals List (KECL)

Japan: Japanese Inventory of Existing and New Chemical Substances (ENCS)

The Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)

China: Inventory of Existing Chemical Substances Manufactured or Imported in China (IECSC)

New Zealand: New Zealand Inventory of Chemicals (NZIoC)

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

Global Food Contact Status

European Union

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

EU Regulation 10/2011/EC specifies 10 mg/dm² as the maximum overall migration (OML) from the finished plastic food contact material or article.

The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. The organoleptic/sensory suitability must be verified by the end user.

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Dual use additives subject to restrictions in food as defined in Regulation 10/2011/EC are not intentionally used in the manufacture or formulation of this product.

There is a SML specified for a monomer in this resin. The monomer subject to migration in this resin is nBA: n- Butylacrylate CAS 000141-32-2 – Ref 10780 with SML (T) = 6mg/kg (expressed as acrylic acid)

EU National Legislations

The composition of this product complies with the following National Legislations, Recommendations or Communications for the production of food packaging.

Austria: “K.V.O.” N.476/2003 as amended at last by BGBl - Teil II - N.140/2009

Belgium: “Arrete royal du 5 Juliet 2006 (amending Arrete royal du 11 Mai 1992 and modifying “Arrete royal du 3 Juliet 2005”)

Denmark: Bekendtgørelse N.579 (01/06/2011)

Finland: “KTM”, Paatos 953/2002 of 2.11.2002 (amended by 107/2009 of 03/03/2009)

France: “Materiaux au contact des aliments et de denre destine a l'alimentation humaine” Brochure n.1227 edition Janvier 1994 as updated. Arrete du 02 Janvier 2003 (as modified at last by Arrete 03/09/2010)

Germany: Bedarfsgegenstaendeverordnung – in der Fassung vom 23. Dezember 1997 (BGBl I 1998 S.5), zuletzt geändert durch Art. 1 der Verordnung vom 24. Juni 2013 (BGBl I S.1682)

Greece: AXE Decision n.458/2003 modified by Decision no. 6/2011

Ireland: S.I. No. 587 of 2007, as amended by S.I. No. 301 of 2010

Italy: “Decreto Ministeriale del 21/03/1973” amended on 26/4/1993 : D.M. N.220 and following updates (last update: 16/02/2011)

Luxembourg: “Reglement Grand-Ducal” n. 163 du 05/11/2008

Norway: Regulations 21 December 1993 No 1381 on materials and articles intended to come into contact with foodstuffs Chapter I General regulations, as amended.

Portugal: Decreto-Lei no. 62/2008 of 31/03/2008 and Amend. Decreto-Lei no. 29/2009, of 02/02/2009

Spain: Real Decreto N.118 31/01/2003 modified by

Real Decreto N.103/2009 of 06/02/2009

Sweden: Ordinance of the National Food Administration on materials and articles intended to come into contact with foodstuffs LIVSFS 2011:7.

The Netherlands: Staatscourant n.6861 of 06.05.2010.

England: “The Plastic Materials and Articles in Contact with Food (England) Regulations 2009”, Statutory Instrument 2009 n.205

Switzerland: BGVO 817.023.21 of 23 November 2005, as amended

Czech Republic: Regulation of the Ministry of Health N.551/2006 modifying N.38/2001

United States

Information according to FDA compliance on request.

Allergen Statements

The food ingredients listed in the Annex II of Regulation 1169/2011/EU, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

Biomedical Policy

This product may not be used in

(i) any U.S. FDA Class I, Health Canada Class I, and/or European Union Class I Medical Devices, without prior notification to Seller for each specific product and application; or

(ii) the manufacture of any of the following, without prior written approval by Seller for each specific product and application: (1) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (2) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; (3) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration; (4) tobacco related products and applications; (5) electronic cigarettes and similar devices.

(iii) Additionally, the product(s) may not be used in: (1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; (2) applications involving permanent implantation into the body; (3) life-sustaining medical applications.

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All references to the U.S. FDA, Health Canada and European Union regulations include all other country's equivalent regulatory classifications.

Animal Based Raw-Materials (BSE/TSE)

Components derived from animal sources are not used in the manufacture or formulation of this product.

Epoxy Derivatives

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

Conflict Minerals

So called conflict minerals (Columbite-tantalite, cassiterite, wolframite, gold) are not intentionally used in the manufacture of or formulation of this product.

Halal Certification

This product is not certified as Halal.

Kosher Certification

This product is not certified as Kosher.

Latex

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

Metals Content

US CONEG

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

EU Packaging and Packaging Waste

Based on the available documentation from raw materials suppliers, this product complies with the directive 94/62/EC and its following amendments concerning the defined limit(s) of heavy metals.

End of Life Vehicle

To the best of our knowledge, based on the available documentation from raw materials suppliers, we deem that this product complies with the directive 2000/53/EC and its following amendments as concerns the defined limit(s) of heavy metals.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC, as amended, and 2011/65/EU concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE).

Nanomaterials

Nanomaterials (insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm) are not used in the manufacture of or the formulation of this grade.

However, this product has not been tested for these chemical substances.

Ozone Depleting Substances European Union

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation 1005/2009/EC of 16 September 2009, are not intentionally used in the manufacture of or formulation of this product.

United States

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFC's and Class II, HCFC's, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

VOC Content - Switzerland

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland „VOC-LENKUNGSABGABE“.

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Toys

This product complies with the requirements in CEN Standard EN 71.3 and those in Directive 2009/48/EC.

Phthalates

The phthalates listed in Annex of Directive 2005/84/EC (Annex I of Directive 76/769/EEC) are not intentionally added in the manufacture of or the formulation of this product in a concentration above the given limits.

Energy Recovery - CEN Standard prEN 13431

The calorific gain from polyethylene in an energy recovery process is 22 MJ/Kg.

Composting - CEN Standard prEN 13432

This product is not suitable for composting.

Disclaimer

The information in this document is, to our knowledge true and accurate at the time and date of issue. However, information in this document may be updated periodically due to changes in the laws and regulations, or for other reasons, therefore we cannot guarantee that the status of this product will remain unchanged.

Ultimately customers must make their own independent determination that the product is suitable for the intended use and can be used safely and legally.

Seller makes no warranty; express or implied (including any warranty of merchantability or fitness for a particular purpose or any warranty) other than as separately agreed to by the parties in a contract.

Users should review the applicable Safety Information before handling the product.

In addition to the above, LUCOBIT AG may further prohibit or restrict the use of this product in certain applications. For further information please contact a LUCOBIT AG representative.