Polyethylene
Bormed™ LE6609-PH

We confirm that this product fulfils the applicable requirements on substances used for the manufacturing of materials and articles or components of articles intended to come into contact with food as described in the below cited legislation and standards.

EU

The below listed regulations represent harmonised EU legislation and are directly applicable in all EU-member states. National legislation implementing such regulations is therefore not separately cited in this document.

We would like to stress that this product is a **Plastic Intermediate Material** as defined in the former *Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain*. Therefore this confirmation is restricted to the requirements as applicable for **Plastic Intermediate Materials** used for the manufacturing of materials and articles or components of articles intended to come into contact with food.

- Commission Regulation (EC) No. 1935/2004. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore, compliance with article 3 §1,c must be verified and tested by the producer of the final packaging material.
- Commission Regulation (EU) No. 10/2011 as amended. All used monomers and additives are listed in Annex I of this regulation. For any relevant restriction as set by the Annexes I and/or II see chapter “migration testing”.
- Commission Regulation (EC) No. 2023/2006 as amended. This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the "Quality information document" on Borealis' homepage.
- Commission Regulation (EU) No. 2024/3190 as amended. BPA, other hazardous bisphenols or hazardous bisphenol derivates falling withing the scope of the regulation are not used in the production of this grade.
- Commission Regulation (EU) No. 2022/1616 as amended. Not applicable.
- Commission Regulation (EC) No. 1895/2005. BADGE, NOGE and BFDGE are not used in the production of this grade.
- Commission regulation (EC) No. 450/2009 on active and intelligent materials and articles is not applicable to Borealis' polymer resins.

Additional national legislation in EU-member states (as amended to date)

Polymerisation production aids, aids to polymerisation, colorants and solvents, if not already listed in Annex I of Regulation (EU) No. 10/2011 can be used based on their national approval and are subject to mutual recognition. The process chemicals used for the manufacturing of this grade are permitted by at least one of the following national regulations/recommendations, or are to be deemed safe based on a risk assessment conducted in accordance with article 19 of Regulation (EU) No. 10/2011.

France	Décret No. 2007-766 du 10 mai 2007 portant application du code de la consommation en ce qui concerne les matériaux et les objets destinés à entrer en contact avec les denrées alimentaires, as amended and the French DGCCRF guidelines on food contact plastics.
Germany	BfR-Empfehlung

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The Netherlands	III Polyethylen, Stand 01.04.2021 Verpakkingen- en Gebruiksartikelenbesluit, 2014 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amended (last update from 01.07.2022

Europe (Non-EU-countries)

Norway	Sosial- og helsedepartementets forskrift 1993-12-21-1381 - as amended (referring to Regulation EU No. 10/2011)
Switzerland	Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21); Stand 01.01.2026, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff
Türkiye	Notification No. 2019/44 from 25.12.2019 - referring to Regulation EU No. 10/2011 and subsequent amendments
United Kingdom	The Materials and Articles in Contact with Food SI 2019 No. 704 - (England) (Amendment) (EU Exit) Regulations 2019 SI 2018 No. 186 - (Nothern Ireland) (Amendment) Regulations 2018 SI 2019 No. 32 - (Scotland) (Amendment) Regulations 2019 SI 2018 No. 913 - (Wales) (Amendment) Regulations 2018 (referring to EU legislation)

World

Brazil	ANVISA RDC nº 56 /2012 as amended - Lista positiva de monômeros (Brazilian implementation of Mercosur RES 02/12 and amendments) ANVISA RDC nº 326/2019 as amended - Lista positiva de aditivos (Brazilian implementation of Mercosur RES 39/19 and amendments)
China	GB 4806.1-2016 - National standard on general safety requirements for materials and articles in food contact - so far applicable to polymer resins. GB 31603-2015 - General Hygienic Standard for Production of Food Contact Materials and Articles - This material has been manufactured in accordance with the relevant requirements of good manufacturing practice for materials articles intended to come into contact with food, as described in more detail in the "Quality information document" on Borealis homepage. GB4806.7-2023 - National Food Safety Standard on Food Contact Plastic Materials and Articles - so far applicable to "Resin" as described in chapter 2.1. Appendix A.1 - 139 Ethylene homopolymer; Polyethylene GB9685-2016 as amended - National standard on the use of additives in food containers and packaging materials, Appendix A - Table A1
Japan	Positive list for food utensils, containers and packaging - Notification No. 324 as published on November 30, 2023 by MHLW (Japan Ministry of Health, Labour and Welfare) and subsequent amendments. Appendix 1, Table 1 - Polymer group 2 - polymer composed of alkenes as the main monomer Appendix 1, Table 2 - Additives All used additives are permitted and - so far applicable - below the defined concentration limits.
Mercosur	MERCOSUR/GMC/RES. Nº 03/92 & MERCOSUR/GMC/RES. Nº 56/92 as amended by GMC/RES. Nº20/21 - so far applicable to polymer resins MERCOSUR/GMC/RES. Nº 02/12 as amended by GMC/RES. Nº 19/21 and 28/24 - Lista positiva de monomeros MERCOSUR/GMC/RES. Nº 39/19 as amended by GMC/RES. Nº 22/24 - Lista positiva de aditivos
USA	FDA, CFR, Title 21, 177.1520 (a)(2)(i), (b) and (c) 2.2 Olefin polymers

Limits of use (FDA)	Test samples made from this product fulfilled the extraction requirements according to FDA CFR 21 §177.1520 (c), as defined for the type of polymer described above.

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Therefore this product may be used in contact with all food types as described in table 1 of CFR 21 §176.170(c), under conditions of use B through H as described in table 2 of CFR 21 §176.170(c). **The product is not intended for use in packing or articles holding food during high temperature heat sterilisation. It is the responsibility of the converter or food packer to control that the final packaging complies with the requirements of the intended and foreseeable conditions of use.**

Migration testing

Migration limits

Monomers and additives used for the manufacturing of this grade are not regulated with specific migration limits.

Substances also authorised as direct food additives ("Dual use additives") are either not used for the manufacturing of this product, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceed of the limits as set in the applicable food legislation.

Migration testing

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21, article 2.12 of Chinese standard GB4806.1 and Mercosur GMC Res No. 56/92 as amended by Res 20/2021, the overall migration shall not exceed 10 mg/dm² from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg).

Compliance with the overall and specific migration limits, as described above, must be measured from the final packaging intended to come into contact with foodstuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 10/2011; Annex 4 of Swiss Ordinance 817.023.21; Chinese standard GB31604.8-2021; Mercosur GMC Res No. 32/2010. It is the responsibility of the converter or food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

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Non-intentionally added substances - NIAS

Commission Regulation (EU) 10/2011 notes that not all contaminants and reaction products of authorised monomers and additives can be listed in its Annex I. The identification of non-listed migrants may therefore not be an exclusion criterion in itself. However, a toxicological evaluation of these migrants needs to be performed.

The major fractions of NIAS in Polyolefins are the oligomers, which are unavoidably formed during polymerisation and cannot be removed. A joint study of polyolefin producers demonstrated that oligomers migrating from all types of polyolefins only consist of linear and branched alkanes (POSH) and alkenes (POMH), no cyclic or aromatic compounds were found. The toxicological assessment of such migrants concluded that they are sufficiently characterised by the existing overall migration limit.

Further a variety of representative Borealis products, covering the whole Borealis product spectrum, was assessed in relation to migrating NIAS by renowned test institutes. Beside oligomers the typical NIAS are reaction- and decomposition products from antioxidants, many of them known as “Arvin-substances”. Another joint industry study confirmed that none of these Arvin-substances are genotoxic and can therefore be rated at least as “Cramer-class III”, allowing a daily consumption of 90 µg/person/day.

However, we wish to stress that a NIAS-assessment is subject to the finished food contact article and the formation of NIAS is influenced by thermal and mechanical treatment during conversion, mixture with other substances and the applied test conditions. A raw material screening therefore can never monitor all potential criteria. Further information on potential NIAS can be requested.

Annex IV of Commission Regulation (EU) 10/2011 (Declaration of compliance) requires to inform the downstream user about substances in the intermediate material, *for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant.* **To our present day knowledge, this product does not contain any intentionally added or known non-intentionally added substances for which genotoxicity has not been ruled out.**

Prepared by Borealis, Group Product Stewardship

Disclaimer

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication.

The legislation cited above applies to the final packaging which is intended to come or is brought into contact with foodstuff. This statement however is restricted to the Borealis product as it leaves production. It is the customers responsibility to verify compliance with applicable legislation of the final packaging under actual and foreseeable conditions of use.

Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

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