Polyethylene
OE5515

DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS

This document is confidential and may not be distributed

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 chapter 4.3.1. of *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, from 28.11.2013*. 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 applicable restrictions see chapter “migration testing”.
- Commission Regulation (EC) No. 2023/2006. 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 "Borealis AG responses to customer inquiries" on Borealis' homepage.
- Commission Regulation (EC) No. 1895/2005 - BADGE, NOGE and BFDGE are not used for 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

Borealis AG | Wagramer Strasse 17-19 | 1220 Vienna | Austria
Telephone +43 1 224 00 0 | Fax +43 1 22 400 333
FN 269858a | CCC Commercial Court of Vienna | Website www.borealisgroup.com

Polyethylene
OE5515

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 XXXV Mischpolymerisate aus Ethylen, Propylen, Butylen, Vinylestern und ungesättigten aliphatischen Säuren sowie deren Salzen und Estern; Stand 01.06.2019
The Netherlands	Verpakkingen- en Gebruiksartikelenbesluit, 2014 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amended (last update from 14.12.2019)

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 01.12.2019, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff
Turkey	Notification No. 2019/44 from 25.12.2019 - referring to Regulation EU No. 10/2011

World

Brazil	ANVISA RDC nº 56 /2012 - lista positiva de monômeros (Brazilian implementation of Mercosur RES 02/12) ANVISA RDC nº 326/2019 - Lista Positiva de Aditivos (Brazilian implementation of Mercosur RES 39/19)
China	GB9685-2016 - National standard on the use of additives in food containers and packaging materials 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 "Borealis AG responses to customer inquiries" on Borealis' homepage. GB 4806.6-2016 - National standard on plastic resins for food contact use - Appendix A - 101 Ethylene-copolymer - for detailed information on the SML of the co-monomer see chapter "Migration limits"
Japan	Notification No. 196 of 2020 as published on April 28, 2020 by MHLW (Japan Ministry of Health, Labour and Welfare) - and subsequent amendments Appendix 1, Table 1 (1) Basic polymer & Table 1(3) monomers Resin class: 2; all food types; max. temperature: III (> 100 °C)

Polyethylene
OE5515

	Appendix 1, Table 2 Additives All used additives are listed and below the permitted concentration limits
Mercosur	MERCOSUR/GMC/RES. Nº 02/12 - Lista positiva de monomeros MERCOSUR/GMC/RES. Nº 39/19 - Lista positiva de aditivos
USA	FDA, CFR, Title 21, 177.1350 Ethylene-vinyl acetate copolymers

Limits of use (FDA)

According to FDA the finished food-contact articles made from this product, are subject to specific extraction tests, which are in the responsibility of the converter or final user (see FDA CFR 21 § 177.1350)

Migration limits and testing

Migration limits

The product contains 2.6-di-tert-butyl-p-cresol (= BHT) (EU-FCM 315; CH-No. 721; CHN-FCA 1135; Mercosur MCA 315 / CAS No.128-37-0), which is regulated with a specific migration limit in China, EU, Mercosur and Switzerland (3 mg/kg) and with a maximum concentration limit in food of 0,005% in the USA (FDA, CFR Title 21; §181.24).

The product contains acetic acid, vinyl ester (EU-FCM 231; CH-No. 434 / CAS No. 108-05-4) which is regulated with a specific migration limit (12 mg/kg) in China (GB4806.6-101), EU, Mercosur (Res 02/2012) and Switzerland.

Other used monomers and additives are not regulated with specific migration limits.

Migration testing

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21 and article 2.12 of Chinese standard GB4806.1 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);(Mercosur GMC Res No. 56/92 - 8 mg/dm2 and 50 mg/kg food).

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 GB31604.8-2016; 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.

Borealis AG | Wagramer Strasse 17-19 | 1220 Vienna | Austria
Telephone +43 1 224 00 0 | Fax +43 1 22 400 333
FN 269858a | CCC Commercial Court of Vienna | Website www.borealisgroup.com

Polyethylene
OE5515

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 recent 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.

Prepared by

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.

Borealis AG | Wagramer Strasse 17-19 | 1220 Vienna | Austria
Telephone +43 1 224 00 0 | Fax +43 1 22 400 333
FN 269858a | CCC Commercial Court of Vienna | Website www.borealisgroup.com