

# COMPLIANCE STATEMENT POLYETHYLENE Borstar® FB2230

## DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS – FB2230

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 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 Material** 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) 10/2011 as amended (Latest amendment is Commission Regulation (EU) 2023/1442 of 11 July 2023). All used monomers and additives are listed in Annex I of this regulation. For any applicable restrictions as set by the Annexes I and/or II 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 “Borouge Position on Food Hygiene Demands and Standards” on Borouge’s homepage.
- Commission Regulation (EC) 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 Borouge’s polymer resins.

### ADDITIONAL NATIONAL LEGISLATION IN EU-MEMBER STATES

Polymerisation production aids, aids to polymerisation, colorants and solvents, if not already listed in Annex I of Regulation (EU) No. 10/2011 can be 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 regulations/recommendations, or are to be deemed safe based on a risk assessment conducted in accordance with Article 19 of Regulation (EU) 10/2011.

<b>France</b>	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
<b>Germany</b>	BfR-Empfehlung III Polyethylen, Stand 01.04.2021
<b>The Netherlands</b>	Verpakkingen- en Gebruiksartikelenbesluit, 2014 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amended (last update from 01.07.2022)

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## EUROPE (NON-EU-COUNTRIES)

<b>Norway</b>	Sosial-og helsedepartementets forskrift 1993-12-21-1381 as amended (referring to Regulation EU 10/2011)
<b>Switzerland</b>	Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21) ; Stand 15.10.2022, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff
<b>Türkiye</b>	Notification No. 2019/44 from 25.12.2019 - referring to Regulation EU No. 10/2011 The Materials and Articles in Contact with Food
<b>United Kingdom</b>	SI 2019 No. 704 - (England) (Amendment) (EU Exit) Regulations 2019 SI 2018 No. 186 - (Northern 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

<b>China</b>	GB 9685-2016 - 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 4806.6-2016 - National standard on plastic resins for food contact use Appendix A - 101 Ethylene - copolymer (Poly[ethene-co-(1-butene)] CAS#25087-34-7). For any applicable restrictions see chapter "migration testing." 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 "Borouge Position on Food Hygiene Demands and Standards" on Borouge's homepage.
<b>India</b>	IS 16738: 2018 Positive list of constituents for polypropylene polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals IS 16621: 2017 Positive list of constituents of polyethylene and polypropylene in contact with foodstuffs pharmaceuticals and drinking water 3.1 & 3.2 of IS 10146: 1982 "Specification for Polyethylene for its Safe Use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water"
<b>Indonesia</b>	Badan Pengawas Obat dan Makanan (BPOM) Regulation 20/2019 on Food Packaging.
<b>Brazil</b>	All used additives are listed and below the permitted concentration limits ANVISA RDC n° 56 /2012 - lista positiva de monômeros (Brazilian implementation of RES 02/12 and amendments) ANVISA RDC n° 326/2019 - Lista Positiva de Aditivos (Brazilian implementation of RES 39/19)
<b>Mercosur</b>	All used additives are listed and below the permitted concentration limits MERCOSUR/GMC/RES. N° 02/12 as amended: Lista positiva de monomeros MERCOSUR/GMC/RES. N° 39/19 - Lista positiva de aditivos
<b>Japan</b>	Notification No. 196 of 2020 as published on April 28, 2020 by MHLW (Japan Ministry of Health, Labour and Welfare) - and Notification No.370 of MHLW as amended Appendix 1, Table 1 Polymer group 2b - polymer composed of alkenes as the main monomer; all food types; max. temperature: III (> 100°C) Appendix 1, Table 2 Additives
<b>USA</b>	All used additives are listed and below the permitted concentration limits FDA, CFR, Title 21, 177.1520 (a)(3)(i)(c)(1), (b) and (c)3.2a Olefin polymers
<b>Limits of use</b>	Test samples made from this product fulfilled the extraction requirements according

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**(FDA)**

to FDA CFR 21 §177.1520(c), as defined for the type of polymer described above. 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 A through H as described in table 2 of CFR 21 §176.170(c) (including articles used for packing or holding food during cooking). **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 LIMITS AND TESTING**

**Migration limits**

The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Article 6.3.a and Annex II), Mercosur (Res. 39/2019 Anexo 4.3.b and Res. 02/2012 chapter 4b) and Switzerland (Bedarfsgegenständeverordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al). Representative worst case tests (3% acetic acid; 4h/100°C) did not show any migration above 0,04 mg/kg.

Other used 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 and article 2.12 of Chinese standard GB4806.1 the overall migration shall not exceed 10 mg/dm<sup>2</sup> 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. 20/21 amending Mercosur GMC Res No. 56/92 - 8 mg/dm<sup>2</sup> and 50 mg/kg food).

In accordance with requirement 3.4 of Indian Standard IS 10146 : 1982, the overall migration shall not exceed 60 mg/kg from plastic materials and articles, with the exception for plastic materials and articles described in 3.4 a)i) and ii) (10 mg/dm<sup>2</sup>). A representative sample from this or a comparable material, tested for 2d at 20°C in isooctane (1 mm plate / total immersion) did not exceed the limit of 10 mg/dm<sup>2</sup> for overall migration. This test result is only valid for orientation purposes but must not be used to confirm legal compliance of the finished article.

**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 and Indian Standard IS 9845. 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.**

**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.

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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 Borouge products, covering the whole Borouge 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.

Annex IV of Commission Regulation (EU) 10/2011 (Declaration of compliance), as revised by Commission Regulation (EU) 2020/1245, 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: Product Stewardship Specialist  
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#### 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 Borouge 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.

This statement is not intended and should not be construed as a warranty or representation of any kind for which Borouge would assume legal responsibility. Without anyway limiting the abovementioned, Borouge gives no warranties and makes no representations which extend beyond the description contained herein. Nothing herein shall constitute any warranty as to the merchantability or fitness for a particular purpose or application of Borouge products.

No liability can be accepted in respect of the use of Borouge's 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.

All terms and conditions regarding the supply of Borouge products shall be subject to Borouge General Sales Terms.

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