COMPLIANCE STATEMENT

POLYETHYLENE

Borstar® FB5600

DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS – Borstar FB5600

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**. 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) No. 10/2011 as amended including Commission Regulation (EU) No. 2025/351 and Commission Regulation (EU) No. 2026/245.
  All substances used in the manufacture of this product meet the high purity degree criteria set out in Article 3.a. and Article 8 of this regulation. 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.” For any known Non-Intentionally Added Substances (NIAS), see chapter “NIAS".
- 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 (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 “Borouge Position on Food Hygiene Demands and Standards” on Borouge’s 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 Borouge’s 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 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) 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 III Polyethylen, Stand 01.04.2021
The Netherlands	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 10/2011)
Switzerland	Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21); Stand am 1. Januar 2025, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff
Türkiye	Notification No. 2019/44 from 25.12.2019 - referring to Regulation EU No. 10/2011
United Kingdom	The Materials and Articles in Contact with Food 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

Brazil	ANVISA RDC nº 56 /2012 - Lista positiva de monômeros (Brazilian implementation of RES 02/12 and amendments) ANVISA RDC nº 326/2019 - Lista positiva de aditivos (Brazilian implementation of RES 39/19 and amendments)
China	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 4806.7-2023 - National Food Safety Standard on Food Contact Plastic Materials and Articles: Appendix A Table A.1 – 146: 1-Butene, polymer with ethene, CAS# 25087-34-7 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.
India	IS 16738 : 2018 Positive list of constituents for polypropylene polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals 3.1 & 3.2 of IS 10146 : 1982 Specification for Polyethylene for its Safe Use in Contact with Foodstuffs, Pharmaceuticals and Drinking Water
Indonesia	Badan Pengawas Obat dan Makanan (BPOM) Regulation 20/2019 on Food Packaging.
Japan	Specifications and Standards for Foods, Food Additives, Etc. (Notification No. 370 of 1959 by Japan Ministry of Health, Labour and Welfare (MHLW)) as amended (Latest amendment is Notification No. 324 of 2023 as promulgated on November 30, 2023 by MHLW and amended by Cabinet Office Notification No. 128 on September 27, 2024 Appended Table 1, Table 1 (Base materials) Polymer group 2: Polymer composed of alkenes as the main monomer; Appended Table 1, Table 2 (Additives) All used additives are listed and below the permitted concentration limits
Mercosur	MERCOSUR/GMC/RES. Nº 03/92 & MERCOSUR/GMC/RES. Nº 56/92 as amended by GMC/RES. Nº 20/21 - so far applicable to polymer resins MERCOSUR/GMC/RES. Nº 02/12 as amended by GMC/RES. Nº 19/21 and Nº 28/24 - Lista positiva de monomeros

	MERCOSUR/GMC/RES. Nº 39/19 as amended by GMC/RES. Nº 22/24 - Lista positiva de aditivos
MIDDLE EAST: GCC countries	All used monomers, starting substances and additives are listed as authorised for materials in Table 1 of Gulf Technical Regulation GSO 1863:2021 Food Packages - Part 2: Plastic Package – General Requirements Gulf Technical Regulation GSO 2231:2012 General requirements for materials intended to come into contact with food Gulf Technical Regulation GSO 839:2021 Food packages – Part 1: General requirements and Gulf Technical Regulation GSO 1863:2021 Food packages – Part 2 Plastic package – General Requirements cover those materials and articles that, in their finished state, are intended or reasonably expected to contact food, or to transfer their constituents to food under normal or foreseeable conditions of use. This product is a **Plastic Intermediate Material**, in pellets, to be converted into final articles. We don't manufacture final articles. It is the responsibility of the converter or food packer to verify that the final articles made out of Borouge products comply with all the applicable regulations and requirements.
USA	FDA, CFR, Title 21, 177.1520 (a)(3)(i)(c)(1), (b) and (c)3.2a 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. 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

This product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation (EU) No. 10/2011; Article 6.3.a and Annex II), Mercosur (Res. 39/2019 Annexo 4.3.b) and Switzerland (Bedarfsgegenstände-verordnung 817.023.21, Anhang 2.3.1); (1 mg/kg expressed as Al). Representative worst case tests (3% acetic acid; 4h/100°C; S/V-ratio 6) did not show any migration above 0.04 mg/kg.

Other used monomers and additives used for the manufacturing of this product 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) No. 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 20/21 amending MERCOSUR/GMC/RES Nº 56/92 - 8 mg/dm^2 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/dm2).

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/dm² 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) No. 10/2011; Annex 4 of Swiss Ordinance 817.023.21; Chinese standard GB31604.8-2021; Mercosur GMC Res No. 32/2010 and Indian Standard IS 9845 : 1988. 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) No. 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.

Annex IV of Commission Regulation (EU) No. 10/2011 (Declaration of Compliance), as revised by Commission Regulation (EU) No. 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.**

This product may contain minor trace levels of other metals or ammonium substances, which are regulated with a specific migration limit in EU (Commission Regulation 10/2011 as amended; Annex II). Based on our knowledge, these metals are not intentionally added except Calcium and Aluminium but may be present as impurity of the raw material used. The product does not release metal/ammonium substances in quantities exceeding the specific migration limits. This was determined by migration estimates following a worst-case calculation, assuming 100% migration, using a S/V ratio of 6 dm²/kg and final plastic article thickness 2mm. We should emphasize that it is the responsibility of the converter or food packer to verify that the final packaging complies with the specific migration limits as set out by the Annex II.

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 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/degradation products from antioxidants, many of them known as “Arvin-substances”. These Arvin-substances in the product are scientifically risk-assessed in accordance with Article 19 of the Plastics Regulation (EU) No. 10/2011 and comply with the safety limit and the relevant requirements of the Framework Regulation (EU) No. 1935/2004.

We’d like to stress that the formation of NIAS is influenced by thermal and mechanical treatment during downstream processing such as conversion, mixture with other substances and the applied test conditions. A raw material screening can never monitor all potential criteria. Therefore, the final responsibility for evaluating NIAS migration during downstream processing lies with the food contact article manufacturer.

Note:
Table 1. Potential known NIAS: reaction/degradation products that may form during downstream processing of the polymer containing antioxidants.

Chemical Name	CAS No.	Common Name	Genotoxicity Status	Safety Limit (sTDI/SML)
3-(3,5-di-tert-butyl-4-hydroxyphenyl) methylpropanoate	6386-38-5	Arvin 9	Negative	0.2 mg/kg b.w./day
3-(3,5-di-tert-butyl-4-hydroxyphenyl) propanoic acid	20170-32-5	Arvin 10	Negative	0.25 mg/kg b.w./day
7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione	82304-66-3	Arvin 8	Negative	0.1 mg/kg b.w./day
Pentaerythritol 3,5-di-tert-butyl-4-hydroxyhydrocinnamate	26347-98-8	Tri-ester	Negative	0.8 µg/kg b.w./day
2,6-di-tert-butyl-p-benzoquinone	719-22-2	Arvin 3	Negative	0.24 mg/kg b.w./day
3,5-di-tert-butyl-4-hydroxybenzaldehyde	1620-98-0	Arvin 6	Negative	0.083 mg/kg b.w./day
2,6-di-tert-butyl-4-hydroxy acetophenone	14035-33-7	Arvin 7	Negative	0.083 mg/kg b.w./day
Pentaerythritol bis(3,5-di-tert-butyl-4-hydroxyhydrocinnamate) (Diester)	36913-60-7	Diester	Negative	0.06 mg/kg b.w./day
2,6-di-tert-butyl-4-ethylphenol	4130-42-1	FCM 477	Positive listed in Union list	4.8 mg/kg food
2,4-di-tert-butylphenol	96-76-4	Arvin 4	Negative	0.75 mg/kg b.w./day
Tris(2,4-di-tert-butylphenyl)phosphate	95906-11-9		Negative	1.86 mg/kg b.w./day
p-tert-Butylphenol	98-54-4	Arvin 2 FCM 186	Positive listed in Union list	0.05 mg/kg food

A 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.

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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.

Borstar is a registered trademark of the Borealis group

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