COMPLIANCE STATEMENT

POLYETHYLENE
BorPure™ MB6562

STATEMENT ON COMPLIANCE TO FOOD CONTACT REGULATIONS – MB6562

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 an **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 contat 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. All used monomers and additives are listed in Annex of this regulation. For any applicable restrictons see chapter “migration testing.”
- 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 reuglations/recommendations, or are to be deemed safe based on a risk assessment conducted in accordance with Aricle 19 of Regulation (EU) 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 01.06.2019
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 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

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 4806.6-2016 - National standard on plastic resins for food contact use Appendix A - 101 Ethylene - copolymer (Poly[ethene-co-(1-butene)] CAS#25087-34-7) for detailed information on the SML of the co-monomer see chapter "Migration limits".
India	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
Indonesia	Badan Pengawas Obat dan Makanan (BPOM) Regulation 20/2019 on Food Packaging.
Brazil	ANVISA RDC nº 56 /2012 - lista positiva de monômeros (Brazilian implementation of RES 02/12) ANVISA RDC nº 326/2019 - Lista Positiva de Aditivos (Brazilian implementation of RES 39/19)
Mercosur	MERCOSUR/GMC/RES. Nº 02/12 - Lista positiva de monomeros MERCOSUR/GMC/RES. Nº 39/19 - Lista positiva de aditivos
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: 5; all food types; max. temperature: III (> 100°C) Appendix 1, Table 2 Additives All used additives are listed and below the permitted concentration limits
USA	FDA, CFR, Title 21, 177.1520 (a)(3)(i)(c)(1), (b) and (c)3.1a 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 C through G 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 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) 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/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).

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) 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.

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.

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It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose.

The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

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