



# Polypropylene BorPure™ RJ377MO

## DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS

We confirm that this product fulfils the 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:

<b>Austria</b>	Kunststoffverordnung Nr. 476/2003 und Änderungen 242/2005, 452/2006, 325/2007, 140/2009, 196/2010 und 45/2011
<b>Belgium</b>	Koninklijk Besluit - Arrêté Royal van/du 03.07.2005 and subsequent amendmends incl. Koninklijk Besluit - Arrêté Royal van/du 11.02.2011
<b>China</b>	GB9685-2008 "Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials" September 09, 2008
<b>Czech Republic</b>	Vyhlaska Ministerstva zdravotnictvi c. 38/2001 Sb - as amended (last update c. 111/2011 Sb)
<b>Denmark</b>	Bekendtgørelse om fødevarekontaktmaterialer nr. 872 af 27.08.2013 (referring to Regulation EU 2011/10)
<b>EU</b>	Commission Regulation (EC) No 1935/2004 - so far applicable to polymer pellets. 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 must be verified and tested by the producer of the final packaging material. Commission Regulation (EU) 2011/10 as amended. Commission Regulation (EC) 1895/2005 - BADGE, NOGE and BFDGE are not used for the production of this grade. Commission Regulation (EC) 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 statement "Food hygiene demands and standards"
<b>Finland</b>	Maa- ja metsätalousministeriön asetus 497/2011 (referring to Regulation EU 2011/10)
<b>France</b>	Brochure N°1227 (2002), et Arrêté du 02.01.2003 tel que modifié incl. Arrêté du 19.12.2013
<b>Germany</b>	Bedarfgegenständeverordnung vom 23.12.1997 in der Fassung vom 24.06.2013 (referring to Regulation EU 2011/10), sowie BfR-Empfehlungen A VII Polypropylen, Stand 01.01.2012
<b>Great Britain</b>	Regulation (EU) 2011/10 implemented by England: Statutory Instrument 2012 No. 2619; Northern-Ireland: Statutory Rule 2012 No. 384; Scotland: Statutory Instrument 2012 No. 318; Wales: Statutory Instrument 2012 No. 2705
<b>Italy</b>	Decreto Ministeriale n.220, 26.04.1993 and subsequent amendmends (last update: Decreto del 04.02.2013) and D.M. n.34, 21.03.1973
<b>The Netherlands</b>	Verpakkingen- en Gebruiksartikelenbesluit, 1979 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amendmended (last update from 27.03.2014)
<b>Norway</b>	Sosial- og helsedepartementets forskrift 1993-12-21-1381 (referring to Regulation EU 2011/10)
<b>Portugal</b>	Decreto-Lei n° 62/2008 as amended by DL n° 29/2009 and DL n° 55/2011
<b>Spain</b>	Real Decreto 866/2008 as amended (referring to Regulation EU 2011/10)

BorPure is a trademark of the Borealis group.

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**Sweden**

and Real Decreto 847/2011  
Statens Livsmedelsverks kungörelse LIVSFS 2011:7 (referring to Regulation EU 2011/10)

**Switzerland**

Verordnung der EDI über Bedarfsgegenstände vom 23.11.2005 (817.023.21); Stand 01.04.2013, 3. Abschnitt Bedarfsgegenstände aus Kunststoff

**USA**

FDA, CFR, Title 21,  
177.1520 (a)(3)(i)(c)(1), (b) and (c)3.1a Olefin polymers

**Migration limits**

The product contains traces of Aluminium, which is regulated with a specific migration limit in EU (Commission Regulation 2011/10; Article 6.3.a and Annex II, 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.

The product may contain a residual component from the catalyst system which is regulated with a specific migration limit in EU. Migration tests in 95% Ethanol for 10 days at 60°C showed a migration level significantly below the SML, so when applying a standard surface volume ratio of 6, this SML cannot be exceeded under any foreseeable conditions of use. For more details pls. ask your Borealis sales contact.

Other used monomers and additives 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 (EU)**

In accordance with Article 12 of Commission Regulation (EU) 2011/10, 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).

**A representative sample from this or a comparable material, tested for 2d at 20°C in isoctane (1 mm plate / total immersion) did not exceed the limit of 10mg/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) 2011/10. 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**



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## legislation.

### Non-intentionally added substances - NIAS (EU)

Commission Regulation (EU) 2011/10 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, so Borealis cannot provide a final answer in this regard.

### 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.**

**Polypropylene****BorPure RJ377MO****Prepared by**

Borealis, Group Product Stewardship / Jürgen Emig

**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.