



# Polypropylene Beta (β)-PP™ BE60-7032

## STATEMENT ON COMPLIANCE TO FOOD CONTACT REGULATIONS

**This document is confidential and may not be distributed**

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>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. 579 af 01.06.2011 (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 08.12.2011
<b>Germany</b>	Bedarfgegenständeverordnung vom 23.12.1997 in der Fassung vom 13.12.2011, 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 16.04.2012) 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 14.02.2011)
<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)

Beta (β)-PP is a trademark of Borealis group.



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<b>Sweden</b>	and Real Decreto 847/2011 Statens Livsmedelsverks kungörelse LIVSFS 2011:7 (referring to Regulation EU 2011/10)
<b>Switzerland</b>	Verordnung der EDI über Bedarfsgegenstände vom 23.11.2005 (817.023.21); Stand 01.05.2011, 3. Abschnitt Bedarfsgegenstände aus Kunststoff
<b>USA</b>	FDA, CFR, Title 21 (2013), 177.1520 (a)(1)(i), (b) and (c)1.1a Olefin polymers
<b>Migration limits</b>	<p>The product contains Thiodipropionic acid, dioctadecyl ester (FCM-substance No. 368 / PM-Ref. No. 93280 / CAS No. 693-36-7), which is regulated with a specific migration limit in EU and Switzerland (5 mg/kg) and with a maximum concentration limit in food of 0,005% in the USA (FDA, CFR Title 21; §181.24).</p> <p>Other used monomers and additives are not regulated with specific migration limits.</p> <p>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.</p>
<b>Migration testing</b>	<p>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).</p> <p>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 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.</p> <p>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 Directive 82/711/EEC (as amended) and 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 legislation.</p>

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**Limits of use**

According to FDA this product can be used in contact with all food types as described in table 1 of CFR 21 §176.170(c), under conditions of use B through H as described in table 2 of CFR 21 §176.170(c).

**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.