

3rd of December 2014

Declaration of compliance, food contact status Regulation EC no 10/2011

This statement is applicable for the Product: Dryflex 800701

We confirm that our mentioned products are manufactured using good manufacturing practices (GMP) recommended by Regulation EC 2023/2006 and that our quality management system ensure the traceability required by the framework regulation EC 1935/2004.

The raw materials used in production for this product comply by composition with the union list of authorised substances 10/2011 Annex I.

It is the supplier of the finished article who is obliged to ensure that his product complies with the overall and specific migration limits.

The following restrictions for end product are relevant:

- a. Overall migration: The material is not suitable for fatty food, and will not pass migration tests with simulant D2 (vegetable oil).
- b. Specific migration: Recommended food simulants are A, B,C and D1. Additives present with SML limits mentioned in the directive:
CAS 26741-84-5 SML 0,6 mg/kg
- c. Dual use additives: The material contains amorphous silica CAS nr 7631-86-9, talc CAS 14807-96-6 and calcium stearate.

Best regards,

Anniké Andreasson

Quality and EHS manager

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Dryflex® | Mediprene® | Flexible TPE Solutions



UNRO Dispenser System AB

Er ref.
Your ref.

Vår ref. Anders Lundbäck
Our ref.

Datum 2015-11-06
Date

VARUINFORMATIONSBLAD UNRO DISPENSER, artikel 210

UNRO DISPENSER uppfyller kraven på ämnen som används för tillverkning av produkter avsedda att komma i kontakt med livsmedel, med undantag för feta livsmedel.

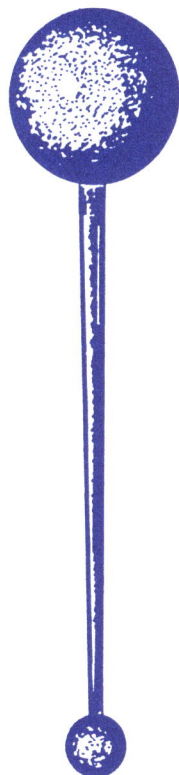
Följande materiel ingår i produkten
Klämkropp - Termoplastisk Elastomer (VTC Elastoteknik, Dryflex 800701)
Skruvdel - PP Copolymer (Borealis, BD310MO)
Ventil - PP Copolymer (Polykemi, POLYfill PPC B8060 FA)

Förpackning 1 st/ ask
Mått: 190*63*63 mm
Vikt: 126 gram

Ytterkartong 108 st ask/kartong
Mått: 570*380*380 mm
Vikt: 14,3 kg

Gävle 2015-11-06

Anders Lundbäck





Polypropylene BD310MO

STATEMENT ON 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:

Austria	Kunststoffverordnung Nr. 476/2003 und Änderungen 242/2005, 452/2006, 325/2007, 140/2009, 196/2010 und 45/2011
Belgium	Koninklijk Besluit - Arrêté Royal van/du 03.07.2005 and subsequent amendmends incl. Koninklijk Besluit - Arrêté Royal van/du 11.02.2011 (M.B. 18.02.2011)
China	GB9685-2008 "Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials" September 09, 2008
The Czech Republic	Vyhlaska Ministerstva zdravotnictvi c. 38/2001 Sb, c. 186/2003 Sb, c. 207/2006 Sb, c. 551/2006 Sb, c. 271/2008, c.386/2008 Sb, c. 127/2009 Sb
Denmark	Fødevaredirektoratets Bekendtgørelse nr.1068 (13.11.2009)
EU	Regulation (EC) No 1935/2004 - so far applicable to polymer pellets. Commission Directive 2002/72/EC amended by 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC and Commission Regulation (EC) 975/2009 and Commission Regulation (EU) 2011/10, applicable from 1 May 2011 and replacing Commission Directive 2002/72/EC as amended. Commission Regulation (EC) 1895/2005 - BADGE, NOGE and BFDGE are not used for the production of this grade This material has been manufactured in accordance with the relevant requirements of Com-mission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials arti-cles intended to come into contact with food, as described in more detail in the Borealis statement "Food hygiene demands and standards"
Finland	KTM Asetukset 953/2002, 141/2005, 181/2005, 762/2006, 1065/2007, 107/2009 ja 106/2011
France	Repression des Fraudes (2002), No. 1227 et Arrêté du 2 janvier 2003, Arrêté du 29 mars 2005, Arrêté du 9 aout 2005, Arrêté du 19 octobre 2006, Arrêté du 25 avril 2008, Arrêté du 19 novembre 2008 et Arrêté du 03 septembre 2010
Germany	Bedarfgegenständeverordnung vom 23.12.1997 in der Fassung vom 11.10.2010, sowie BfR-Empfehlungen A VII Polypropylen, Stand 01.01.2010
Great Britain	England: Statutory Instrument 2009 No. 205; Northern-Ireland: Statutory Rule 2009 No. 56; Scotland: Statutory Instrument 2009 No. 30; Wales: Statutory Instrument 2009 No.481
Italy	and BPF-BIBRA (1995), Polymer Specification 5, Polypropylene Decreto Ministeriale n.220, 26.04.1993 and subsequent amendmends (last update: Decreto del 23.04.2009) and D.M. n.34, 21.03.1973
The Netherlands	Verpakkingen- en Gebruiksartikelenbesluit, 1979 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amendmended (last update from 14.02.2011)

**Declaration regarding POLYfill PPC B8060 FA Natural with regards to
COMMISSION REGULATION (EU) No 10/2011/EC.**

Based on the documentation available for the raw materials employed in POLYfill PPC B8060 FA Natural, it is our opinion that the product may be used for articles intended to come in contact with food, under all relevant temperature conditions, and that such use may be properly said to be in full compliance with the Plastics Regulation (EU) No. 10/2011/EC, the amending and correcting Commission Regulation (EU) No 1282/2011/EC, the respective national transpositions of this legislation, and Article 3 § 1(a) of the Framework Regulation (EU) No. 1935/2004/EC providing that the finished article made from POLYfill PPC B8060 FA Natural satisfy the overall migration limit of 10 mg/dm². Moreover the finished article made from POLYfill PPC B8060 FA Natural must comply with the Specific Migration Limit (SML) of some substances, listed under the respective raw material from which they originate.


The polypropylene copolymer (CAS Nr 9010-79-1) that is employed contains one or more additives subject to Specification Limits (SMLs). These additives can be disclosed on request.

This material contains one or more intentionally added dual use additives, which are subject to disclosure of adequate information as described in Annex IV of Commission 10/2011/EC. The identity of this/these substance/s can be disclosed for testing purposes upon special request and under maintained secrecy.

It is the responsibility of the convertor to check and confirm that the final article meets both the technical and regulatory requirements of the application.

Certified by:
Petter Schöld

Date: 141209






Polypropylene

BD310MO

Norway	Sosial- og helsedepartementets forskrift 1993-12-21-1381
Portugal	Decreto-Lei n° 29/2009 de 02.02.2009
Spain	Real Decreto 866/2008 y R.D. 103/2009 y ANAIP (1982), Anexo 1, Anexo 4
Sweden	Statens Livsmedelsverks kungörelse LIVSFS 2003:2 as amended (latest amendmend LIVSFS 2011:2)
Switzerland	Verordnung der EDI über Bedarfsgegenstände vom 23.11.2005 (817.023.21); Stand 01.04.2010, 3. Abschnitt Bedarfsgegenstände aus Kunststoff
USA	FDA, CFR, Title 21 (2010), 177.1520 (a)(3)(i)(c)(1), (b) and (c)3.2a Olefin polymers

Migration limits	<p>Monomers and additives used for the manufacturing of this grade 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>
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Migration testing	<p>In accordance with Article 2 of Directive 2002/72/EC (as amended), the overall migration shall not exceed 60 mg/kg resp. 10 mg/dm² from plastic materials and articles.</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 Directives 82/711/EEC (as amended) and 85/572/ECC. 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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Polypropylene BD310MO

Limits of use

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.**

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.