# Polypropylene
# Bormed™ RD808CF

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 and 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** as defined in the former *Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain*. Therefore this confirmation is restricted to the requirements as applicable for **Plastic Intermediate Materials** 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. All substances used in the manufacture meet requirements set by Article 8 and where applicable meet the high degree of purity requirement (Article 3a). All used monomers and additives are listed in Annex I of this regulation. For any relevant restriction as set by the Annexes I and/or II see chapter “migration testing”.
- 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 "Quality information document" on Borealis' homepage.
- 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 (EU) No. 2022/1616 as amended. Not applicable.
- Commission Regulation (EC) No. 1895/2005. BADGE, NOGE and BFDGE are not used in the production of this grade.
- Commission regulation (EC) No. 450/2009 on active and intelligent materials and articles is not applicable to Borealis' 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 used 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 national 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.

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| **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 |

Bormed is a trademark of the Borealis group.

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| | contact avec les denrées alimentaires, as amended and the French DGCCRF guidelines on food contact plastics. |
| **Germany** | BfR-Empfehlung<br>VII Polypropylen, Stand 01.06.2019 |
| **The Netherlands** | Verpakkingen- en Gebruiksartikelenbesluit, 2014 (Warenwet), Deel A, Hoofdstuk 1, Kunststoffen, as amended (last update from 01.07.2022 |

## Europe (Non-EU-countries)

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| **Norway** | Sosial- og helsedepartementets forskrift 1993-12-21-1381 - as amended (referring to Regulation EU No. 10/2011) |
| **Switzerland** | Verordnung der EDI über Bedarfsgegenstände vom 16.12.2016 (817.023.21); Stand 01.08.2026, 5. Abschnitt: Bedarfsgegenstände aus Kunststoff |
| **Türkiye** | Notification No. 2019/44 from 25.12.2019 - referring to Regulation EU No. 10/2011 and subsequent amendments |
| **United Kingdom** | The Materials and Articles in Contact with Food<br>SI 2019 No. 704 - (England) (Amendment) (EU Exit) Regulations 2019<br>SI 2018 No. 186 - (Nothern Ireland) (Amendment) Regulations 2018<br>SI 2019 No. 32 - (Scotland) (Amendment) Regulations 2019<br>SI 2018 No. 913 - (Wales) (Amendment) Regulations 2018<br>(referring to EU legislation) |

## World

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| **Brazil** | ANVISA RDC nº 56 /2012 as amended - Lista positiva de monômeros (Brazilian implementation of Mercosur RES 02/12 and amendments)<br>ANVISA RDC nº 326/2019 as amended - Lista positiva de aditivos (Brazilian implementation of Mercosur RES 39/19 and amendments) |
| **China** | GB 4806.1-2016 - National standard on general safety requirements for materials and articles in food contact - so far applicable to polymer resins.<br>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 "Quality information document" on Borealis homepage.<br>GB4806.7-2023 - National Food Safety Standard on Food Contact Plastic Materials and Articles - so far applicable to "Resin" as described in chapter 2.1.<br>Appendix A.1 - 63 - 1-Propene, polymer with ethene; propene accounting for the largest portion.<br>GB9685-2016 as amended - National standard on the use of additives in food containers and packaging materials, Appendix A - Table A1 |
| **Japan** | Positive list for food utensils, containers and packaging - Notification No. 324 as published on November 30, 2023 by MHLW (Japan Ministry of Health, Labour and Welfare) and subsequent amendments.<br>Appendix 1, Table 1 - Polymer group 2 - polymer composed of alkenes as the main monomer<br>Appendix 1, Table 2 - Additives<br>All used additives are permitted and - so far applicable - below the defined concentration limits. |
| **Mercosur** | MERCOSUR/GMC/RES. Nº 03/92 & MERCOSUR/GMC/RES. Nº 56/92 as amended by GMC/RES. Nº20/21 - so far applicable to polymer resins<br>MERCOSUR/GMC/RES. Nº 02/12 as amended by GMC/RES. Nº 19/21 and 28/24 - Lista positiva de monomeros<br>MERCOSUR/GMC/RES. Nº 39/19 as amended by GMC/RES. Nº 22/24 - Lista positiva de aditivos |
| **USA** | FDA, CFR, Title 21,<br>177.1520 (a)(3)(i)(c)(1), (b) and (c)3.2a Olefin polymers |

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**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 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), Mercosur (Res. 39/2019 Annexo 4.3.b and Res. 02/2012 chapter 4b) 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; S/V-ratio 6) did not show any migration above 0,04 mg/kg (limit of detection).

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**

In accordance with article 12 of Commission Regulation (EU) 10/2011, article 12 of Swiss ordinance 817.023.21, article 2.12 of Chinese standard GB4806.1 and Mercosur GMC Res No. 56/92 as amended by Res 20/2021, 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).

**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 GB31604.8-2021; Mercosur GMC Res No. 32/2010. 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.**

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## 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 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. To support such assessment from finished article, Borealis can on request provide a list of potentially present NIAS with their toxicological rating.

Annex IV of Commission Regulation (EU) 10/2011, as revised by Commission Regulation (EU) 2020/1245 and 2025/351, requires Declaration of Compliance (DoC) to include adequate information on the presence of NIAS if present in an amount that could cause non-compliance of a final material with Article 3 of Regulation (EC) No 1935/2004. This includes information on substances for this genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate materials and which could be present in an amount that foreseeable gives rise to an individual migration into food from the final plastic material or article exceeding 0,00015 mg/kg food. **To our present day knowledge, this product does not contain any such intentionally added or known non-intentionally added substances**.

**Prepared by** Borealis, Group Product Stewardship

**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.

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