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## DECLARATION OF COMPLIANCE TO FOOD CONTACT REGULATIONS

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 applicable unchanged 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 **intermediate plastic material** as defined in chapter 3.1. of 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, from 28.11.2013. Therefore this confirmation is restricted to the requirements as applicable for intermediate plastic 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 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 I of this regulation. For any applicable restrictions 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) 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 (b) (4) statement "Food hygiene demands and standards".
- Commission regulation (EC) No 450/2009 on active and intelligent materials and articles is **not applicable** to 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) 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 were rated as safe in a risk assessment acc. article 19 of Regulation (EU) 10/2011

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France

Germany

The Netherlands

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#### Europe (Non-EU-countries)

Norway

Switzerland

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#### World

China

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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

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#### Migration testing

#### 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

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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 (b) (4) products, covering the whole (b) (4) 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 (b) (4) cannot provide a final answer in this regard.

Prepared by

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#### 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 (b) (4) 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.**

**(b) (4) 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 (b) (4) 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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