Food Contact Statements for Heartland Polymers Products

Dear Customer,

All statements provided herein are valid up to the revision date specified in this document.

At Heartland Polymers, we are committed to upholding the highest standards of product quality and safety in accordance with the Good Manufacturing Practices (GMP) guidelines. Our dedication to excellence is reflected in every aspect of our manufacturing processes, ensuring that our products consistently meet or exceed industry standards. We employ rigorous quality management practices to safeguard against any deviations from required specifications and our facilities are certified to the ISO 9001:2015, underscoring our commitment to quality assurance.

We remain dedicated to providing you with the highest quality products and services, and thus comply with the following regulations and chemical inventories as established by industry recognized regulatory bodies, specified in this document.

Food Contact Homopolymer FDA:

The following Heartland Polymers homopolymer polypropylene products complies with 21 CFR 177.1520(a) (1) (i) and (c) (1.1a), set by the U.S. Food and Drug Administration (FDA). In addition, additives used in these products meet the requirements of their respective FDA regulations in Parts 178, and are generally recognized as safe (GRAS), subject to limitations on the Conditions on Use or food type contacted. It is the responsibility of the food packager or converter, that the final package meets the requirements and conditions under the foreseeable Conditions of Use.

Extraction experiments, with test samples of this reference or a comparable grade, are performed to demonstrate that the extraction limits are not exceeded.

Food Contact Copolymer FDA:

The following Heartland Polymers random copolymer polypropylene products complies with 21 CFR 177.1520(a) (3) (i), (c) (3.1a) and (3.2a). In addition, additives used in these products meet the requirements of their respective FDA regulations in Parts 178 and are generally recognized as safe (GRAS), subject to limitations on the Conditions on Use or food type contacted. It is the responsibility of the food packager or converter, that the final package meets the requirements and conditions under the foreseeable Conditions of Use.

Grade	Specifications 21 CFR 177.1520	Conditions of Use 21 CFR 176.170 (c)	Comments
H1002NA, H1003N, H5001, H5002 H5103, H5104, H5104A, H5012G, H5025G, H5235G, H3003, H3209, H3010SB, H7012, H7012N, H7012S, H7020S, H7035, H7035N, H7035E, H7050E, H7060E	(c) (1.1a)	A-H	All type of foods
R7035NA, R7050NA, R7045NA, R7030NA, R7020NA, R3207SB, R3208, R7012NA, R7012NA2, R1002.	(c) (3.1a)	C-H	All types of foods
R1302NS, R1302N	(c) (3.2a)	A-H	All types of foods

Canada Food and Drug Act, Division 23:

A "Letter of No Objection" (LONO) for food contact use of all polypropylene products manufactured by Heartland Polymers has been obtained from Canada's Health Protection and Food Branch (HPFB). If a file number is required, please contact a representative of Heartland Polymers.

Europe:

All polypropylene manufactured by Heartland Polymers complies with the relevant requirements for materials intended for direct food contact as specified in Regulation (EU) 10/2011 and all applicable amendments, including Regulation (EU) 2023/1627 of August 11, 2023, Regulation (EU) 2024/3190 of December 19, 2024 and Regulation (EU) 2025/351 of February 21, 2025. Additionally, it complies with Regulation (EC) 1935/2004 (Framework) and EC 2023/2006 (Good Manufacturing Practices). All monomers and additives used in our products are included in the Union List of Authorized Substances as outlined in Annex I of the Plastics Implementation Measure.

Specific Migration Limits (SMLs) have been established in the Commission Regulation EU No 10/2011 (including amendments up to EU 2020/1425) under the Union List in Table 1 of Annex 1. Any substances (i.e., additives) on the list will have SMLs listed in column 8. For substances not listed in any of the tables under Annex I, a generic SML of 60 mg/kg will be used. It is the responsibility of the food packager or converter to ensure that all finished articles that contact food undergo testing for overall and specific migration limits to ensure compliance of these requirements.

The following Heartland Polymers polypropylene are formulated with additives which have SMLs that are not classified under the generic 60 mg/kg:

Grade	Function	CAS Number	Specific Migration Limit
H5012G, H5025G, H5235G, H5240G H5008U, H5218G	Antioxidant	CAS No. 27676-62-6	5 mg substance/Kg of food
H523G	Acid Acceptor	CAS No. 1314-13-2	5 mg substance/Kg food as Zinc
R7012NA, R7012NA, R7020NA, R7030NA, R7035NA, R7045NA, R7050NA, R7070NA, R7085NA	Nucleate/clarifier	Ref No. 38550	5 mg substance/Kg Food
H1002NA, H1003N, R1302NS, R1302N	Nucleate/clarifier	Ref No. 66350	5 mg substance/Kg of food SML (T)=0.6mg/Kg Food (expressed as Li)
H1003NS, H1003N2, H5104A, H7275S, H3010SB, H7012, H7012N, H7012S, H7020S, H7020E, H7035N, H7035E, H7050E, H7060E	No additives with restriction	----	60mg substance /kg of food

Migration tests must be completed using the appropriate food and food stimulants at specific conditions as outlined in Conditions of Use A-H. Migration tests should always correspond to the most severe (worst foreseeable) conditions of contact between plastic material/article and the foodstuff. All packaging labels must indicate the maximum temperature for use.

In addition to the specific migration limits (SML) listed above, we confirm that no other non-intentionally added substances (NIAS) have been identified, in compliance with Article 19 of Regulation (EU) No. 10/2011. This statement is based on our rigorous assessment and verification process, ensuring that any potential NIAS are evaluated and fall within acceptable safety limits under the intended conditions of use.

Dual-use Additives:

Some polypropylene products manufactured by Heartland Polymers contain substances called dual-use additives, which are used in food contact plastics. These additives, utilized in food contact plastics, are categorized as food additives or flavorings, and are authorized for use in accordance with Commission Regulation (EU) No 10/2011.

Grade	Function	CAS Number	Specific Migration Limit
H5218G, H5012G,H7012S, H7012, H7020S, H5025G	Acid Acceptor	1592-23-0	60 mg substance /kg of food
H1003NS, H7012N, H7020EH7035N, H7035E, H7050E,H7060E	Nucleator	532-32-1	60 mg substance /kg of food
H1002NA, H5104A, H7275S, H7012S, H7020S, H7020E,H7035E, H7050E, H7060E R7012NA, R7012NA2, R7020NA, R7030NA, R7035NA, R7045NA, R7070NA, R7085NA	Antistatic	31566-31-1	60 mg substance /kg of food

China:

All polypropylene manufactured by Heartland Polymers complies with the relevant safety standards for materials intended for direct food contact, as outlined in GB 4806.1-2016, which governs plastic resins used in food contact materials (FCMs). Compliance also extends to GB 4806.6-2016 and GB 4806.7-2023, the national food safety standards for food contact plastic materials and articles. Furthermore, all monomers and additives used in our products are listed in GB 9685-2016, the national food safety standard for the use of additives in food contact materials, including the most recent update issued on March 16, 2025. The following Specific Migration Limits (SMLs) apply:

Grade	Function	CAS Number	Specific Migration Limit
H5012G, H5025G, H5235G, H5218G	Antioxidant	CAS No. 27676-62-6	5 mg substance/Kg Food
H5235G	Acid Acceptor	CAS No. 1314-13-2	25 mg substance/ Kg Food as Zinc
R7012NA, R7012NA2, R7020NA, R7030NA,	Nucleant/clarifier	FCA0038	5 mg substance/Kg Food

Grade	Function	Ref. Number	Specific Migration Limit
R7035NA, R7045NA, R7050NS, R7070NA, R7085NA			
H1002NA, H1003N, R1302NS, R1302N	Nucleant/clarifier	FCA0151	5 mg substance/Kg Food (T)=0.6mg/Kg Food (expressed as Li)

Japan:

All Heartland polypropylene polymers comply with the standards established by the Japanese Ministry of Health, Labor, and welfare (MHLW) under Notification No. 196 (2020) and the finalized Notification No. 324 (2023), including all amendments. All monomers and additives used in our products are listed in the Positive List of substances allowed for use in food contact materials and the inventory of Existing and New Chemical Substances (Japan ENCS).

Switzerland:

The composition of all Heartland polypropylene polymers complies with the requirements for food contact materials as outlined in the Swiss Chemical Ordinance of 813.11, which governs the safe use chemical substances and mixtures, specifically in Title 1, Article 2 and the Swiss Ordinance 817:023:21 including all the applicable amendments. This compliance includes adherence to Annex 2, substances permitted for the manufacture of plastic layers in plastic materials and articles, Annex 3, declaration of conformity for plastic materials and articles and Annex 4, compliance assessment regarding migration limits for plastic materials and articles.

Mercosur:

All polypropylene manufactured by Heartland Polymers complies with the relevant requirements outlined in GMC/RES No. 2/2012, including all applicable amendments, concerning the positive list of monomers and other starting substances. All additives used in Heartland polypropylene are listed in Appendix I of MERCOSUR/GMC/RES No. 39/2019, which provides the positive list of additives for the production of plastic materials, along with all its amendments. and also GMC/RES No 32/07.

Additionally, Heartland polypropylene complies with GMC/RES No. 03/1992, which outlines the criteria and classification of packaging materials in contact with food, and GMC/RES No. 56/1992, which establishes the general provisions for plastic packaging, including all applicable amendments. The following specific migration limits (SMLs) are specified:

Grade	Function	CAS Number	Specific Migration Limit
H5012G, H5025G, H5235G	Antioxidant	CAS No. 27676-62-6	5 mg substance/Kg Food
H5235G	Acid Acceptor	CAS No. 1314-13-2	5 mg substance/Kg Food as Zinc
R7012NA, R7012NA2, R7020NA, R7030NA, R7035NA, R7045NA, R7050NS, R7070NA, R7085NA, R8241, R8219	Nucleant/clarifier	MCA No 808	5 mg substance/Kg Food, including the sum of its hydrolysis products.
H1002NA, H1003N, R1302NS, R1302N	Nucleant/clarifier	MCA No 750	5 mg substance/Kg Food SML (T)=0.6mg/Kg Food (expressed as Li)

ANVISA (Brazil):

All polypropylene manufactured by Heartland Polymers complies with the relevant requirements of Resolution No. 56/12 and it's most recent amendment RDC No. 589 of December 22, 2021, provides the positive list of monomers and other starting substances authorized for use in the production of plastic packaging and equipment in contact with food. All monomers and additives used in our products are listed in ANVISA resolution No 326/2019, the technical regulation on the positive list of additives for plastic materials intended for packaging and equipment in contact with food.

Grade	Function	CAS Number	Specific Migration Limit
H5012G, H5025G, H5235G	Antioxidant	CAS No. 27676-62-6	5 mg substance/Kg Food
H5235G	Acid Acceptor	CAS No. 1314-13-2	5 mg substance/Kg Food as Zinc
R7012NA, R7012NA2, R7020NA, R7030NA, R7035NA, R7045NA, R7050NS, R7070NA, R7085NA, R8241, R8219	Nucleate/clarifier	MCA No 808	5 mg substance/Kg Food, including the sum of its hydrolysis products.
H1002NA, H1003N, R1302NS, R1302N	Nucleate/clarifier		Ask our representative

If you have any questions regarding food contact compliance, please contact a Heartland Polymers representative.

heartland polymers

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