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Product Regulatory Summary: CertyForm P1309

Internal referenc **1Q267, BEN44963** **Version 2.4 ; November 12, 2026**

European Union Food Contact

This product meets the relevant provisions of Regulation (EC) No. 1935/2004 (Framework Regulation) applicable to intermediate plastic materials, including plastic powders, granules, and flakes, intended for use in the manufacture of food contact materials and articles.

This product complies with the relevant requirements of Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (Plastic Implementation Measure, PIM), as amended, insofar as these requirements apply to intermediate materials such as plastic powders, plastic granules, and plastic flakes.

The monomers, starting substances, and additives used in the manufacture of this product are listed in the Union List of authorized substances set out in Commission Regulation (EU) No. 10/2011 and its subsequent amendments.

Commission Regulation (EU) No. 10/2011 establishes an Overall Migration Limit (OML) of 10 mg/dm² for finished plastic food contact materials and articles. Compliance with the applicable Overall Migration Limit (OML) and Specific Migration Limits (SMLs), where relevant, must be assessed on the finished plastic food contact material or article in accordance with the requirements of Commission Regulation (EU) No. 10/2011 and its subsequent amendments.

Determination of OML and SML compliance is the responsibility of the manufacturer of the finished food contact material or article. Furthermore, manufacturers of the finished food contact material or article are responsible for ensuring that, when produced in accordance with good manufacturing practice, the finished material or article does not adversely affect the organoleptic characteristics of the food.

SML Components

This product contains one or more substances for which Specific Migration Limits (SMLs) have been established under Commission Regulation (EU) No. 10/2011, as amended.

39815; 9,9-bis(methoxymethyl)-9H-fluorene; SML = 0.05mg/kg

This product contains traces of a substance regulated by a Specific Migration Limit (SML) under Annex II of Commission Regulation (EU) No. 10/2011, as amended. Migration studies conducted on representative samples showed migration levels well below the applicable SML. Based on these results, compliance with the relevant SML is expected under foreseeable conditions of food contact use.

SML = 1 mg/kg (expressed as Aluminium)

This product may contain trace levels of certain metals for which Specific Migration Limits (SMLs) are established under Annex II of Commission Regulation (EU) No. 10/2011, as amended. These metals are not intentionally added and may be present only as impurities associated with the raw materials used in the manufacturing process.
Migration testing performed on representative polyolefin samples demonstrated migration levels below the applicable SMLs. Based on these results, exceedance of the relevant SMLs under reasonably foreseeable conditions of use in contact with food is not expected.

Dual Use Additives

Based on the formulation and manufacturing process, Dual Use Additives (DUAs), as defined in Commission Regulation (EU) No. 10/2011, as amended, are not intentionally used in the manufacture or formulation of this product.

Genotoxicity

In accordance with Annex IV, Section 6, of Commission Regulation (EU) No. 10/2011, as amended, this product does not contain genotoxic substances that would be expected to migrate from the finished food contact material or article into food or food simulants at levels exceeding 0.15 μg/kg (0.15 ppb).

NIAS (Non-intentionally added substances)

Based on a review of declarations, compliance statements, and supporting documentation provided by raw material suppliers, this product complies with the applicable requirements of Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, as amended, including Commission Regulation (EU) 2025/351.

Based on the information received, the substances used in the manufacture of this product are considered to meet the high degree of purity requirements set out in Articles 3a and 8 of the Regulation. Furthermore, all intentionally used monomers and additives are reported by suppliers to be included in Annex I (Union List of Authorized Substances) of Regulation (EU) No. 10/2011, as amended.

In addition, a review of supplier-provided information relating to non-intentionally added substances (NIAS), including impurities, reaction by-products, and degradation products, where applicable, has been conducted. Based on the documentation reviewed and the information currently available, no NIAS have been identified that are expected to present a compliance concern under Regulation (EU) No. 10/2011, as amended, including the requirements introduced by Commission Regulation (EU) 2025/351.This assessment is based on supplier declarations and supporting documentation and does not constitute independent analytical verification of the finished product.

Regulation (EU) 2025/351

The assessment of this product against Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, as amended by Commission Regulation (EU) 2025/351, is based on documentation and compliance information provided by raw material suppliers.

Based on the information received, the substances used in the manufacture of this product are considered to comply with the high degree of purity requirements set out in Articles 3a and 8 of Regulation (EU) No. 10/2011, as amended. Furthermore, all intentionally added monomers and additives are reported by their respective suppliers to be included in Annex I (Union List of Authorized Substances) of the Regulation.

This statement is based on supplier-provided information and available documentation and does not constitute independent analytical verification of the finished product.

Regulation (EU) 2024/3190

Bisphenol A (BPA; CAS No. 80-05-7), as well as other bisphenols and bisphenol derivatives within the scope of Commission Regulation (EU) 2024/3190 of 19 December 2024 on the use of bisphenol A and other bisphenols and bisphenol derivatives with harmonized classification for specific hazardous properties in certain materials and articles intended to come into contact with food, as corrected by Commission Regulation (EU) 2026/250, are not intentionally used in the manufacture or formulation of this product.

This statement is based on product formulation information, supplier declarations, and available manufacturing process knowledge. However, this product has not been specifically tested for the presence of bisphenol A, other bisphenols, or bisphenol derivatives, and therefore no analytical verification is provided.

United States Food contact

The base resin used in this product complies with the applicable requirements of the U.S. Food and Drug Administration (FDA) regulations set forth in 21 CFR §177.1520(a)(1)(i) and §177.1520(c), Item 1.1a, for olefin polymers intended for food-contact applications.

In addition to the base resin, this product may contain adjuvant substances that may be safely used in polymers for food-contact applications. According to information available to us, these substances conform to the requirements of the applicable FDA regulations and comply with the provisions of 21 CFR §177.1520(b), where relevant.

Based on the regulatory status of its constituents, this product meets the applicable FDA requirements of 21 CFR §177.1520 for use in food-contact applications, including cooking. The product may be used under Conditions of Use A through H as defined in 21 CFR §176.170(c), Table 2, and is suitable for contact with all food types listed in 21 CFR §176.170(c), Table 1.

China Food Contact

GB4806.1- 2016 Food Contact Material & Articles General Safety Requirement

This product complies with the applicable requirements of GB 4806.1-2016, National Food Safety Standard General Safety Requirements for Food Contact Materials and Articles, insofar as these requirements apply to plastic resins used in food-contact applications.

GB31603-2015 General Hygiene Standard for Production of Food Contact Materials and Articles

The manufacturing process for this product complies with the applicable requirements of GB 31603-2015, National Food Safety Standard – General Hygienic Practice for the Production of Food Contact Materials and Articles, insofar as these requirements apply to the production of polymer resins intended for food-contact applications.

GB4806.7-2023 National Food Safety Standard: Plastic Materials and Articles in Contact with Foodstuffs

The base resin in this product complies with the applicable specifications set forth in GB 4806.7-2023, National Food Safety Standard – Plastic Materials and Articles in Contact with Food, Appendix A.1.

No monomers for which Specific Migration Limits (SMLs) have been established under GB 4806.7-2023 are present in the base resin.

GB9685-2016 National Food Safety Standard: Additives for use in Food Contact Materials and Articles

Based on the product formulation, no additives regulated under GB 9685-2016, National Food Safety Standard – Standard for the Use of Additives in Food Contact Materials and Articles, are intentionally used in the manufacture of this product.

General Remarks :
In accordance with Clause 8.4 of GB 4806.1-2016, National Food Safety Standard – General Safety Requirements for Food Contact Materials and Articles, the responsibility for demonstrating and declaring compliance with the Overall Migration Limit (OML) rests with the manufacturer of the finished plastic food contact material or article.

Final food contact materials and articles may be subject to additional regulatory and compliance requirements depending on their composition, intended use, and processing conditions. Verification of compliance with all applicable requirements is the responsibility of the manufacturer of the finished food contact material or article.

Japan

The constituents of this product comply with the applicable requirements of the Japanese Positive List system for Food Utensils, Containers, and Packaging, as established under the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370 of 1959, as amended by Notification No. 324 of 2023 and subsequent amendments in force as of May 30, 2025, including Cabinet Office Notification No. 95, which entered into force on June 1, 2025.

Compliance with applicable migration limits, specifications, and use restrictions should be verified for the finished food contact material or article under the intended conditions of use.

The base resin used in this product is listed in the Positive List of Base Polymers under Japan's Food Contact Material Positive List system, as established by the Ministry of Health, Labour and Welfare (MHLW) Notification No. 370 of 1959, as amended, including subsequent revisions in force as of June 1, 2025.

The additives used in this product are listed in the Positive List of Additives authorized for use with the base resin(s) in this product and are used within the applicable maximum use levels specified in the Positive List. Any additives not subject to Positive List requirements are used in accordance with the applicable regulatory provisions.

MERCOSUR

This product contains only monomers and/or polymers that are included in Part 1 of the Annex to MERCOSUR GMC Resolution No. 02/12, Positive List of Monomers and Polymers for Use in Food Contact Packaging. Accordingly, the monomers and polymers used in this product are authorized for use in materials and articles intended to come into contact with food, subject to any applicable restrictions and specifications set forth in the Resolution.

The additives used in this product are included in Table 1 of MERCOSUR GMC Resolution No. 39/19, Positive List of Additives for Use in Food Contact Packaging, and comply with the applicable requirements of the Resolution.

One or more components used in this product are subject to Specific Migration Limits (LMEs) established under applicable MERCOSUR food contact legislation. The manufacturer of the finished food contact material or article is responsible for demonstrating compliance with the applicable migration limits under the intended conditions of use.

Switzerland : Materials and Articles in Contact with Food (SR 817.023.21)

The composition of this product complies with the applicable requirements of the Swiss legislation governing materials and articles intended to come into contact with food, specifically Ordinance of the FDHA on Materials and Articles in Contact with Food (SR 817.023.21; formerly BGVO 817.023.21) of 23 November 2005, as amended.Based on available composition and supplier information, the substances used in the manufacture of this product conform to the relevant provisions of this legislation applicable to food-contact packaging materials.

Allergen - Food Allergen European Regulation 1169/2011

The food ingredients and substances listed in Annex II of Regulation (EU) No. 1169/2011 on the provision of food information to consumers are not intentionally used in the manufacture or formulation of this product.

However, this product has not been specifically tested for the presence of these substances, and no claim regarding their absence can be made based on analytical testing.

Animal Based Raw-Materials (BSE/TSE)

Based on the product formulation and manufacturing process, no ingredients, additives, processing aids, or other components derived from animal sources are intentionally used in the manufacture of this product.

US FDA Drug Master File (DMF)

Information relating to this product is referenced in U.S. Food and Drug Administration (FDA) Drug Master File (DMF) Upon request, Velogy can provide a DMF Letter of Authorization (LOA) to permit FDA review of the relevant DMF information in connection with a customer's regulatory submission.

Drug Master File (DMF) No. 44849.

ICH Harmonized Guideline Q3D (Elemental Impurities)

The elemental impurities classified as Class 1, Class 2, and Class 3 elements in ICH Harmonised Guideline Q3D(R2), Guideline for Elemental Impurities, Table 5.1 (dated 02 May 2022), are not intentionally used in the manufacture or formulation of this product.

However, this product has not been specifically tested for the presence of these elemental impurities. Accordingly, no analytical confirmation regarding their absence is provided.

Conflict Minerals and Extended Minerals (Responsible Minerals Initiative)

To the best of our knowledge and based on current product information, material specifications, supplier declarations, and due diligence processes, this product is not intentionally formulated with minerals or metals that fall within the reporting scope of the Responsible Minerals Initiative (RMI) reporting templates listed below:

Conflict Minerals Reporting Template (CMRT) Version 6.6, covering tin (Sn), tantalum (Ta), tungsten (W), and gold (Au) (3TG);
Extended Minerals Reporting Template (EMRT) Version 2.11, covering cobalt and mica; and
Additional Minerals Reporting Template (AMRT) Version 1.35, covering silver, zinc, aluminum, and iron.

Accordingly, Velogy is not required to report smelter or refiner information for these minerals under the above-mentioned RMI reporting templates.

An exception applies to aluminum, which may be present at trace levels as a result of the use of Ziegler-Natta catalyst systems during polymer manufacturing. Residual aluminum concentrations are typically in the range of approximately 5–50 ppm and are not intentionally added as a constituent of the product.This statement is based on available supplier information and due diligence processes and does not constitute analytical verification of the absence of the referenced minerals or metals.

Packaging and Packaging Waste (PPWR)

Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC, establishes specific requirements for substances present in packaging materials and packaging components.
Based on available raw material data, supplier information, and manufacturing process knowledge, the following can be declared for this product:
-The sum concentration of cadmium (Cd), hexavalent chromium (Cr(VI)), mercury (Hg), and lead (Pb) does not exceed 100 ppm.
-Per- and polyfluoroalkyl substances (PFAS) are not intentionally used in the manufacture or formulation of this product.

This statement is based on raw material composition data, supplier declarations, and production process knowledge. The product has not been specifically tested for heavy metals or PFAS, and no analytical verification is provided.

Toxics in Packaging Legislation (US CONEG)

Based on the available information and documentation provided by our raw material suppliers, this product complies with the requirements of the Model Toxics in Packaging Legislation (formerly known as CONEG legislation) Legislation concerning the sum concentration limit for the heavy metals lead (Pb), mercury (Hg), cadmium (Cd), and hexavalent chromium (Cr(VI)).

Accordingly, the combined concentration of these regulated heavy metals does not exceed the maximum limit specified by the Model Legislation, based on supplier-provided data.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

The Restriction of Hazardous Substances (RoHS) regulations apply to electrical and electronic equipment and do not specifically regulate plastic raw materials. Nevertheless, based on available information and documentation provided by our raw material suppliers, this product complies with the substance restrictions established under Directive 2002/95/EC and Directive 2011/65/EU (RoHS), as amended, including the applicable restrictions for cadmium (Cd), lead (Pb), mercury (Hg), hexavalent chromium (Cr(VI)), polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP).

Ozone Depleting Substances European Union

Based on the product formulation and available supplier information, no substances listed in Annexes I or II of Regulation (EU) 2024/590 are intentionally added or used in the manufacture of this product.

Ozone Depleting Substances United States

Based on the product formulation and manufacturing process, no Class I or Class II ozone-depleting substances regulated under the U.S. Clean Air Act Amendments of 1990 are intentionally added or used in the production of this product. This includes CFCs, HCFCs, halons, carbon tetrachloride, and 1,1,1-trichloroethane.

Persistent Organic Pollutants - POPs Commission Regulation (EU) 2019/1021

Based on the product formulation and available supplier information, compounds regulated under Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs), as amended, are not intentionally added or used in the manufacture of this product and are not expected to be present. This statement is based on formulation and supplier data; the product has not been analytically tested for these substances.

Switzerland VOC Declaration

Based on available formulation and supplier information, this product contains less than 3% volatile organic compounds (VOCs) consisting of substances included in the positive lists of the Swiss VOC incentive tax legislation (“VOC-Lenkungsabgabe”).

Epoxy Derivatives

The epoxy derivatives BADGE (Bisphenol A Diglycidyl Ether), BFDGE (Bisphenol F Diglycidyl Ether), and NOGE (Novolac Glycidyl Ether) are not intentionally used in the manufacture or formulation of this product as plasticizers, additives, or raw materials. Accordingly, this product complies with the applicable requirements of Commission Regulation (EC) No. 1895/2005 on the restriction of certain epoxy derivatives in materials and articles intended to come into contact with food.

Halal Certification

No Halal certification has been obtained for this product. Accordingly, the product should not be represented as Halal certified.

Kosher Certification

No Kosher certification has been obtained for this product. Accordingly, the product should not be represented or marketed as Kosher certified.

Latex

Based on the manufacturing, handling, and packaging processes employed, no latex-containing or natural rubber-containing materials are intentionally used in connection with this product.

Biocidal Products

Biocidal products, as defined in Article 3 of Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products, are not intentionally used in the manufacture or formulation of this product.

However, this product has not been specifically tested for the presence of biocidal active substances or biocidal products. Accordingly, no analytical confirmation regarding the absence of such substances is provided.

Nanomaterials

Nanomaterials, defined as natural, incidental, or manufactured materials containing particles in an unbound state or as aggregates or agglomerates, where 50% or more of the particles in the number-size distribution have one or more external dimensions in the range of 1 nm to 100 nm, are not intentionally used in the manufacture or formulation of this product.

However, this product has not been specifically tested for the presence of nanomaterials. Accordingly, no analytical confirmation regarding the absence of such materials is provided.

TSCA Section 6(h) is a provision of the U.S. Toxic Substances Control Act (TSCA)

Based on the raw materials used and the manufacturing processes employed, the following TSCA Section 6(h) substances are n intentionally added to the product and are not expected to be present:
- Phenol, isopropylated, phosphate (3:1) (CAS No. 68937-41-7)
- Bis(pentabromophenyl) ether (DecaBDE) (CAS No. 1163-19-5)
- 2,4,6-Tri-tert-butylphenol (CAS No. 732-26-3)
- Hexachlorobuta-1,3-diene (HCBD) (CAS No. 87-68-3)
- Pentachlorobenzenethiol (PCTP) (CAS No. 133-49-3)

CEN Standard EN 13432:2004

Based on its composition and intended performance characteristics, this product is not suitable for composting and does not meet the criteria specified in CEN Standard EN 13432:2004.

Energy Recovery - CEN Standard EN 13431:2004

This product is suitable for energy recovery in accordance with the principles of CEN Standard EN 13431:2004, Packaging – Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value. Polypropylene provides a calorific value of approximately 24 MJ/kg when recovered through appropriate energy recovery processes.

European Union Deforestation Regulation

Regulation (EU) 2023/1115 on the making available on the Union market and the export from the Union of certain commodities and products associated with deforestation and forest degradation (EUDR) applies only to the relevant commodities and derived products listed in Annex I of the Regulation, namely cattle, cocoa, coffee, oil palm, rubber, soya, wood, and specified products derived therefrom.

This product is not identified as a “relevant product” within the scope of Annex I of Regulation (EU) 2023/1115. Accordingly, the requirements and obligations of the EUDR are not applicable to this product.

This assessment is based on the current product composition and the scope of Annex I of Regulation (EU) 2023/1115 as applicable at the date of this declaration.

Commission Regulation (EU) 2022/1616

This product is not within the scope of Commission Regulation (EU) 2022/1616, as amended, relating to recycled plastic materials and articles intended to come into contact with foods. Therefore, the specific requirements of this Regulation are not applicable.

Waste Electrical and Electronic Equipment

This product is outside the scope of Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE) and is therefore not subject to the requirements of that Directive.

MOAH/MOSH

Mineral Oil Aromatic Hydrocarbons (MOAH) are not intentionally added during the manufacture of this product. However, this product has not been specifically tested for the presence of MOAH. Mineral Oil Saturated Hydrocarbons (MOSH) may be present at trace levels as a result of the manufacturing process and/or the origin of the raw materials used.

Please note that, with regard to MOSH, only white paraffinic mineral oils that comply with Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food (FCM Reference No. 95883) are used in the manufacture and/or formulation of this product.

Information on the Safety Data Sheet

REACH compliance information, including details regarding the presence of Substances of Very High Concern (SVHCs) identified on the European Chemicals Agency (ECHA) Candidate List, is provided in Section 15 (Regulatory Information) of the corresponding European Union Safety Data Sheet (SDS). The latest SDS documents are available at www.velogy.com

- If the SVHC section is marked "Not Applicable", this indicates that, based on available information and the regulatory thresholds in force on the SDS issue date, the product does not contain any Candidate List SVHCs that are subject to disclosure requirements (Less than 0.1 %)

- Information regarding the presence of substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR Categories 1A, 1B, or 2) in accordance with Annex VI of Regulation (EC) No. 1272/2008 (CLP Regulation), at concentrations requiring disclosure and/or classification of the product as hazardous, is provided in Section 2 of the applicable Safety Data Sheet (SDS).

- For information regarding endocrine-disrupting properties of substances contained in this product, please refer to the applicable Safety Data Sheet (SDS), specifically Sections 2.3, 11.2, and 12.6. These sections provide available information on endocrine-disrupting properties relevant to human health and the environment, in accordance with the applicable regulatory and hazard communication requirements.

- Section 15 of a Safety Data Sheet (SDS), provides details on the regulatory status of a chemical substance or mixture. In this section is chemical inventory compliance, which indicates whether the substance(s) contained in the product are listed on, exempt from, or otherwise comply with national and regional chemical inventories.

- Australian Inventory of Industrial Chemicals (AIIC)
- Canadian Domestic Substances List (DSL & NDSL)
- China. Inventory of Existing Chemical Substances in China (IECSC)
- Japan. ENCS - Existing and New Chemical Substances Inventory (ENCS)
- Korea. Korean Existing Chemicals Inventory (KECI)
- List of new substances notified or registered in Switzerland (SWISS)
- Mexico National Institute of Ecology, Directorate of Chemical Research and Ecotoxicology Risks (MXINSQ)
- New Zealand. Inventory of Chemical Substances (NZIOC)
- Philippines Inventory of Chemicals and Chemical Substances (PICCS)
- Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) *
- Taiwan Chemical Substance Inventory (TCSI)
- Thailand Existing Chemicals Inventory (TECI)
- Turkey - Registration, Evaluation, Permission and Restriction of Chemicals (KKDIK) *
- United Kingdon - Registration, Evaluation, Authorisation and Restriction of Chemicals (DUIN)
- United States (TSCA)
- Vietnam National Chemicals Inventory (NCI)

*) In the case of polymers, this includes the registration of the relevant monomers.

Explanation on the wording "Amended"

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Unless otherwise stated, all regulations, directives, standards, guidelines, notifications, resolutions, and other legal or regulatory instruments referenced in this document shall be deemed to include their original text together with any applicable amendments, revisions, updates, corrigenda, delegated acts, implementing acts, successor legislation, and other relevant regulatory provisions in force as of the release date of this document.

References to specific regulatory requirements are therefore intended to reflect the applicable legal framework in effect at the date of issuance of this document

Disclaimer

The information contained in this document is believed to be accurate and reliable to the best of our knowledge as of the date of publication. This document is intended solely to provide general information regarding the safe handling, use, processing, storage, transportation, disposal, and release of the product.

The information provided herein does not constitute, and shall not be construed as, a warranty, guarantee, or quality specification of any kind, whether express or implied, including, without limitation, any implied warranties of merchantability, fitness for a particular purpose, non-infringement, or regulatory compliance.

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