

Product Regulatory Summary: KeyForm H0520

Internal Ref. Number: 1Q171, BEN6418, Version 1.1, June 2026

Global Food Contact Status:**European Union**

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP) and as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

EU Regulation 10/2011/EC specifies 10 mg/dm² as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

SML Components

This product contains one or more components with Specific Migration Limits (SMLs).

This product contains traces of a substance which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Annex II). Migration tests showed a migration level significantly below the SML, thus exceeding this SML under foreseeable conditions of use involving food contact is not expected.

SML = 1 mg/kg (expressed as Aluminium)

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This product may contain minor trace levels of other metals, which are regulated with a specific migration limit in EU (Commission Regulation 10/2011 as amended; Annex II).

These metals are not intentionally added but may be present as impurity of the raw materials used. Migration tests on representative polyolefin samples showed a migration level below the SMLs, thus exceeding these SMLs under foreseeable conditions of use involving food contact is not reasonably expected.

Annex IV, Part 6 - Genotoxicity

In accordance with the requirements of Regulation 10/2011/EC (PIM), Annex IV, part 6, this product does not contain genotoxic substances which would migrate from a final material at a level exceeding 0.15 ppb in food or food simulant.

Dual Use Additives

This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC.

- ▶ E 470a Calcium salts of fatty acids

United States

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.2a.

This product may also contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, the substances used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

Allergen Statements

Allergen - Food Allergen European Regulation 1169/2011

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

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Biomedical Policy

This product(s) may not be used in:

(1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; or (2) applications involving permanent implantation into the body.

Prior written approval for each specific product and application must be given by Velogy before this product(s) is used in any:

(1) U.S. FDA Class I, Health Canada Class I, and/or European Union Class I Medical Devices; (2) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (3) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; or (4) packaging in direct contact with a pharmaceutical active ingredient and/or dosage form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration

All references to U.S. FDA, Health Canada, and European Union regulations include other country's equivalent regulatory classifications.

Velogy may further prohibit or restrict the sale of its products into certain applications.

Animal Based Raw-Materials (BSE/TSE)**Tallow**

Tallow derived additives may be used in the manufacture of this product.

Europe - BSE/TSE - "Mad Cow"

Tallow derived materials used in this product fulfill the requirements laid down in the Regulations 1069/2009/EC, and 142/2011/EC, and the "Note for Guidance EMA/410/01, and as amended.

Biocidal Products (as defined in art.3 of Regulation (EU) No 528/2012 of 22 May 2012 as amended

Biocidal Products (defined in art.3 of Regulation (EU) No 528/2012, 22 May 2012 and as amended, specifically as "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action") are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

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Epoxy Derivatives

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

Halal Certification

This product is not certified as Halal.

Kosher Certification

This product is not certified Kosher.

Latex

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

Metals**Content US****CONEG**

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

EU Packaging and Packaging Waste

Based on the available documentation from raw materials suppliers, this product complies with the directive 94/62/EC and as amended concerning the defined limit(s) of heavy metals.

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

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC and 2011/65/EU, as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

Nanomaterials

Nanomaterials (defined as natural, incidental or manufactured materials containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm) are not used in the manufacture of or the formulation of this grade. However, this product has not been tested for these chemical substances.

Other Chemicals

The chemical materials listed below are not intentionally used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

- ▶ 2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol; (Benzotriazole); CAS# 3846-71-7;
- ▶ 2,4,4'-trichloro-2'-hydroxydiphenyl ether; (Triclosan); CAS# 3380-34-5
- ▶ 2-mercaptobenzothiazole; MBT; CAS# 149-30-4;
- ▶ Acrolein; (propenal); (CAS# 107-02-8);
- ▶ Acrylamide; CAS# 79-06-1;
- ▶ Aromatic amines;
- ▶ Asbestos;
- ▶ Azo Dyes and Pigments;

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▶ Polyaromatic Hydrocarbons - PAHs:

1,2-dihydro-acenaphthene; (CAS# 83-32-9);
9H-Fluorene; (CAS# 86-73-7);
Acenaphthylene; (CAS# 208-96-8);
Anthracene; (CAS# 120-12-7);
Benz(a)anthracene; (CAS# 56-55-3);
Benzo(a)pyrene; (CAS# 50-32-8);
Benzo(b)fluoranthene; (CAS# 205-99-2);
Benzo(e)pyrene; (CAS# 192-97-2);
Benzo(ghi)perylene; (CAS# 191-24-2);
Benzo(j)fluoranthene; (CAS# 205-82-3);
Benzo(k)fluoranthene; (CAS# 207-08-9);
Dibenzo(a,h)anthracene; (CAS# 53-70-3)
Chrysene; (CAS# 218-01-9);
Dibenz(a,h)anthracene; (CAS# 53-70-3);
Fluoranthene; (CAS# 206-44-0);
Indeno(1,2,3-cd)pyrene; (CAS# 193-39-5);
Naphthalene; (CAS# 91-20-3);
Phenanthrene; (CAS# 85-01-8);
Pyrene; (CAS# 129-00-0);

▶ Benzophenone; CAS RN 119-61-9;

▶ BPA and other Bisphenols including B, C, E, F, G, M, P, S, T and Z;

▶ Bisphenol A; (BPA); CAS# 80-05-7;

▶ Bisphenol A diglycidyl ether; (BADGE); CAS# 1675-54-3;

▶ Bisphenol F diglycidyl ether; BFDGE; CAS# 2095-03-6;

▶ Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5;

▶ Butylated hydroxytoluene; (BHT); CAS# 128-37-0

▶ Chlorinated paraffins;

▶ Cobalt;

▶ Cyanuric acid; (Isocyanuric Acid or CYA); CAS# 108-80-5;

▶ Dimethyl fumarate; (DMF); CAS# 624-49-7;

▶ Dioxins;

▶ Epichlorohydrin; (ECH); CAS# 106-89-8;

▶ Fluorocarbons;

▶ Fluorotelomers

▶ Formaldehyde; CAS# 50-00-0;

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- ▶ Formaldehyde in specific conditions could be formed during further resin processing (see SDS)
- ▶ Gold(Au); CAS# 7440-57-5;
- ▶ Halogenated Flame Retardants
- ▶ Isopropylthioxanthone (ITX); CAS 5495-84-1
- ▶ Isopropyl thioxanthone [4-ITX]; CAS# 83846-86-0
- ▶ Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1; ▶ Mica
- ▶ Nonylphenol; CAS# 25154-52-3;
- ▶ Nonylphenol ethoxylates;
- ▶ Novolac glycidyl ether;
- ▶ Organotin compounds;
- ▶ Perfluorochemicals; (PFCs);
- ▶ Phenol, isopropylated phosphate (3:1); (PIP (3:1)); CASRN: 68937-41-7
- ▶ Perfluoroalkylated and Polyfluoroalkylated Substances; PFASs;
- ▶ Perfluorooctane sulfonate; (PFOS); CAS# 1763-23-1;
- ▶ Perfluorooctanoic acid; (PFOA); CAS# 335-67-1;
- ▶ Polybrominated biphenyls; (PBBs);
- ▶ Polybrominated diphenyl ethers; (PBDEs);
- ▶ Polybrominated terphenyls; (PBTs);
- ▶ Polychlorinated biphenyls; (PCBs);
- ▶ Polychlorinated naphthalenes; (PCNs);
- ▶ Polychlorinated terphenyls; (PCTs);
- ▶ Polystyrene;
- ▶ Polyvinyl chloride; (PVC); CAS# 9002-86-2;
- ▶ Polyvinylidene chloride; CARN 9002-85-1; PVdC;
- ▶ Radioactive substances;
- ▶ Radon; CAS# 10043-92-2;
- ▶ Styrene monomer; CAS# 100-42-5;

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- ▶ Sulphur dioxide; CAS# 7446-09-5;
- ▶ Tin oxide (SnO₂); (Cassiterite); CAS# 8062-08-6;
- ▶ Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4;
- ▶ Vinyl chloride monomer; CAS RN 75-01-4; VCM
- ▶ Wolframite; Tungsten (W); CAS# 1332-08-7;
- ▶ MOAH; Mineral Oil Aromatic Hydrocarbons;

Phthalates

Phthalates are not used in the manufacture of or the formulation of this product. However, this product has not been tested for phthalates.

Ozone Depleting Substances**European Union**

The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation (EU) 2024/590 of 7 February 2024 repealing Regulation (EC) No. 1005/2009, are not intentionally used in the manufacture of or formulation of this product.

United States

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFC's and Class II, HCFC's, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

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

The chemical materials listed below are not used in the manufacture or the formulation of this product and are not expected to be present. However, this product has not been tested for these chemical materials.

Compounds covered under Commission Regulation (EU) EC No.: 2019/1021, and as amended on Persistent Organic Pollutants (POPs).

VOC Content**Switzerland VOC Declaration**

This product contains less than 3% VOC's of the substances in the positive lists of the Switzerland Regulations "VOC-LENKUNGSABGABE."

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CEN Standard EN 13432:2004

This product is not suitable for composting.

Energy Recovery - CEN Standard EN 13431:2004

The calorific gain from polyethylene in an energy recovery process is 22 MJ/Kg.

Disclaimer

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