



Declaration of Conformity

Version 2021.03

27 September 2021

with the legislations mentioned hereafter

Sumitomo Polypropylene - Homopolymer

Grade Y101

Manufactured by Petro Rabigh (Kingdom of Saudi Arabia)

Based on current and available information, we declare that the above-mentioned product is compliant with the requirements of:

- 1935/2004/EC - Food Contact Materials - Framework Regulation
- 10/2011 - European Commission Regulation on plastic materials and articles intended to come into contact with food amended by (EU) 2020/1245 of 2 September 2020
- 94/62/EC - Packaging and Packaging Waste Directive and its amendments
- 1895/2005/EC - Restriction on the Use of certain epoxy derivates (BADGE, NOGE & BFDGE) in materials and articles intended to come into contact with food.
- 2000/53/EC - End of Live Vehicles Directive and its amendments
- 2011/65/EC - EC Council Directive 2011/65/EC (RoHS 2) and its amendment Commission Delegated Directive (EU) 2015/863 of 31 March 2015, 2017/2102/EU of 15 November 2017, 2019/1846/EU of 8 August 2019 (on the restriction of the use of certain hazardous substances in electrical and electronic equipment)
- 2023/2006 - Good Manufacturing Practice for materials and articles intended to come into contact with food
- CONEG - Coalition of Northeastern Governors
- GADSL - Global Automotive Declarable Substance List
- Proposition 65 - California's Safe Drinking Water and Toxic Enforcement Act of 1986
- EN71 - Safety of toys – part 3(2013): migration of certain elements (EU2009/48/EC)
- 1169/2011 - Restriction on food allergens -Annex II
- 1223/2009 - Cosmetics – Annex III
- 850/2004/EC - Persistent organic pollutants (POP's) – Annex I, II, III & IV
- 2006/125/EC - Cereal based food – Annex VI & VII
- FDA regulation
- US Conflict Mineral substances

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Unmodified the above-mentioned Sumitomo Polypropylene Homopolymers comply with the requirements for materials used in articles or components of articles intended to come into contact with food as described in:

European Union EU:

- ▶ Commission Regulation (EU) No. 10/2011 of January 14 2011 amended by (EU) 2020/1245 of 2 September 2020, provided that the final articles coming into contact with foodstuff complies with general provisions for food contact material and does not endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof.

The final articles coming into contact with foodstuff must comply with the overall migration limit of 10 mg/dm² contact surface or 60 mg/kg food.

This material contains no monomers and no additives which are regulated with a specific migration limit (SML). This material contains a dual use additive which can be disclosed for the purpose of assessment of the compliance after signing of confidentiality agreement.

This material has been manufactured in accordance with the relevant requirements of Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

This grade also meets the relevant requirements of framework Regulation 1935/2004/EC (27/10/2004) on materials and articles intended to come into contact with food.

United States of America (USA):

- ▶ US FDA Regulation, CFR, Title 21 (2011) §177.1520(a)(1)(i) for Olefin polymers; extraction test results conducted on Y101, or similar resins meet extraction limits specified by FDA 21 CFR §177.1520(c) 1.1a (specification).

Belgium:

- ▶ Koninklijk Besluit/Arrêté Royal 3.07.2005, Annex Chapter I, Lists 1-6" incl. subsequent amendments like "Koninklijk Besluit/Arrêté Royal 5.07.2006", "Koninklijk Besluit/Arrêté Royal 18.09.2008" and Koninklijk Besluit/Arrêté Royal 8.03.2009".

France:

- ▶ Arrêté du 2 janvier 2003, Journal Officiel de la République Française, n°24" (29.1.2003) incl. subsequent amendments like "Arrêté du 19 octobre 2006, Journal Officiel de la République Française" (10.11.2006)

Germany:

- ▶ "Bedarfgegenständeverordnung (BedGgstV), Anlage 3 (Stoffe und Erzeugnisse für die Herstellung von Lebensmittelbedarfsgegenständen), last amended on December 13th, 2011.
- ▶ BfR, Empfehlung VII, Stand vom 1.1.2012

Italy:

- ▶ "Decreto Ministeriale del – 21.03.1973, (Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale) last amended by Decreto Ministeriale n° 113 del 18/05/2010

Netherlands:

- ▶ Commodity Act Packaging and Food Utensils Regulation of The Netherlands of 20.11.1979 and its amendments up to and including VGP/VC 2979366 (12.01.2010)

Spain:

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- ▶ Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positiva de sustancias permitidas para la fabricacion de materiales polimricos destinados a entrar en contacto con los alimentos

Switzerland:

- ▶ "Verordnung uber Bedarfsgegenstande, SR 817.023.21, stand 1. Mai 2011"

United Kingdom:

- ▶ "Statutory Instruments 2012, No 2619, The Plastic Materials and Articles in Contact with Food (England) Regulations 2012".

China:

- ▶ **Y101** with 500 μ mt or under complies with GB4806.1-2016 "National Food Safety Standard - General safety requirements of food contact materials and articles" and GB4806.6-2016 "National Food Safety Standard - Food contact plastic resins" for general usage under general conditions considering data of sensory evaluation, soak solution evaluation and n-hexane extract.

All additives used in **Y101** are listed in GB9685-2016 "National Food Safety Standard - Standard for the use of additives for food contact materials and articles" and its amendments. This material contains no monomers and no additives which are regulated with a specific migration limit (SML) or maximum residue limit (QM).

Y101 with 500 μ mt or below complies with GB9685-2016 for general usage under general conditions considering data of metals' migration test under 4 %(V/V) acetic acid at 60oC for 10 days.

The details about GB4806.1-2016, GB4806.6-2016 and GB9685-2016 can be disclosed for the purpose of assessment of the compliance after signing of confidentiality agreement.

Chemical Registration status:

Area	Regulation	Status
Japan	ENCS	(6)-402
USA	TSCA	Listed
Canada	DSL	Listed
EU	REACH	Registered
China	IECSC	Listed
Korea	KECI	KE-29389
Philippines	PICCS	Listed
Taiwan	TCSI	Listed
Australia	AICS	Listed
Thailand	TECI	55-1-06714
Mexico	INSQ	Listed
New Zealand	NZIoC	nzG

The hereafter mentioned substances as such have not been intentionally used or added for the production or the formulation of our above mentioned Polypropylene Homopolymer:

- 1-[(2-amino-7H-purin-6-yl) oxy]-3-methylbutan-2-one (MBP)
- 2-ethoxyethanol
- 2-ethyl hexyl acrylate

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- 2-ethylhexylhexanoic acid
- 2,6-DIISOPROPYLNAPHTHALENE (DIPN), CAS 24157-81-1
- 4-dimethylaminobenzoate (EHDAB)
- 4-NP (4-Nonylphenol)
- 4,4'- Diaminodiphenylmethane (MDA), CAS 101-77-9
- Acetaldehyde
- Acrylamide
- Alkanes, C10-13, chloro - (SCCP), CAS 85535-84-8
- Alkylphenol ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Anthracene
- Antimony Tris(Ethylene Glycoxide)
- Antimony (Sb), Arsenic (As), Barium (Ba), Selenium (Se), Silver (Ag), Nickel (Ni), Cadmium (Cd), Lead (Pb), Mercury (Hg), hexavalent Chromium (Cr^{VI}), Fluorine (F), Bromine (Br), Iodine (I), Astatine (At)
- Aromatic amines & Sulfonated aromatic amines
- Asbestos
- Azo pigments
- Azodicarbonamide
- Bamboo flour
- Benzene
- Benzo[a]pyrene
- Benzotriazole
- Bisphenol A, F, S
- Bis(2-ethylhexyl) phthalate (DEHP)
- Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) (Substances of animal origin)
- (Brominated) Flame retardants
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Butyl benzyl phthalate (BBP)
- Corn flour
- Chlorinated paraffins
- Chlorofluorocarbons (CFCs)
- Colorants:
 - ▶ All the materials listed in Resolution AP(89)1 ([use of colorants in plastic materials coming into contact with food](#))
 - ▶ Azo colorants, Carbon Black,
- Cyanides
- DecaBDE
- Diazine
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)
- Dimethylfumarate (DMF)
- Dioxin and furans
- Engineered nanomaterials
- Epoxy derivates: Bisphenol- A diglycidyl ether (BADGE), Bisphenol-F diglycidyl ether (BFDGE) and Novolac glycidyl ether (NOGE)
- Ethyl benzene
- Fenocarb
- Formaldehyde
- gamma-Butyrolactone (GBL)
- Genetic modified organisms (GMO)
- Glycol ethers
- Glycerol tricaprylate
- Hexabromocyclododécane (HBCDD), CAS 25637-99-4 & 3194556
- Isocyanate
- Latex
- Melamine
- Methoxyethanol

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- N methyl-2-pyrrolidone
- Nonylphenol and Nonylphenol ethoxylates
- O-phenylphenol
- Oils:
 - ▶ Epoxidized soja and linseed oil
 - ▶ Refined or unrefined oils and lubricants
- Para-di-chlorobenzene
- Pentachlorophenol (PCP)
- Perchlorate
- Perfluorooctanoic acid (PFOA)
- Perfluorooctane sulfonates (PFOS)
- Pesticides
- Phthalates - a very low level of phthalates (typical value less than 15.0 ppm based on mass balance calc.) may be found, originated from the used catalyst system
- Pigments containing diarylid
- Polybrominated biphenyls (PBB)
- Polybrominated diphenyl ethers (PBDE)
- Polybutylene terephthalate (PBT)
- Polychlorinated biphenyls (PCBs)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polychlorinated Naphthalene (PCN)
- Perfluorochemicals (PFC)
- Radioactive substances
- Recycled materials
- Semicarbazide
- Short Chain Chiaro Paraffines
- Silicone
- Substances listed in:
 - ▶ Any substance classified as carcinogenic, mutagenic, or toxic to reproduction (CMR)
 - ▶ California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) revised on March 19, 2021
 - ▶ Chemical weapon convention List I, II, III
 - ▶ GADSL – Global Automotive Declarable Substances list version 1.0 of 2020 updated 1 February 2021
 - ▶ US Conflict Mineral substances: Columbite-tantalite (coltan), Cassiterite, Gold, Wolframite, Tantalum, Tin and Tungsten
 - ▶ Ozon depleting substances according to the Montreal protocol
 - ▶ EU Regulation 850/2004/EC Annex I, II, III & IV (POP's)
 - ▶ EU Regulation 2006/125/EC Annex VI & VII (pesticides)
 - ▶ EU Regulation 1223/2009 annex III (cosmetic regulation)
 - ▶ EU Regulation 1169/2011, Annex II (allergens)
 - ▶ Annex XVII of REACH legislation, (List of restrictions on the manufacture, placing on the market and use of dangerous chemical substances, mixtures or articles)
- Tetradecane
- Toluene-2,4-diisocyanate
- Toluene and Trichlorebenzene
- Tris (Nonylphenyl) Phosphite (TNPP)
- Trioxide d'antimoine, CAS 1309-64-4
- Vinyl chloride monomer (VCM) and Polyvinyl Chloride (PVC)
- Xylene

Although the above-mentioned substances as such are not intentionally added this does not eliminate the presence of negligible traces due to other reasons such as impurities in the components supplied by external parties and used in the production. With respect to the heavy metals: cadmium, lead, mercury, and hexavalent chromium, we would not expect the total of these incidental metals to exceed 100 ppm. Additionally, this material is not subject to the selective waste requirements.

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According to the European Regulation Dir.1999/45/EC, our Polypropylene Homopolymers are not hazardous preparations and therefore there is no labeling/classification required. These Polypropylene Homopolymers do not represent any harm to humans or the environment when handled correctly. It is highly recommended to follow safety guidelines and recommendations mentioned in the material safety data sheet (MSDS) during handling and storage. MSDS can be provided upon request.

It is the responsibility of both the manufacturers of finished food contact articles and the food packers to check that these articles in their actual use are compliant with all applicable regulations and requirements. Because use conditions and applicable laws may differ from one location to another, the customer is responsible for determining whether products and information in this document are appropriate for the customers use.

Unmodified **Y101** is a biologically inert solid, considered non-toxic and non-biodegradable. It is readily stable (does not decompose) in landfills or in aquatic systems. Polypropylene is insoluble in water and mostly will float on the water surface and considered biologically inactive material in aquatic systems.

When Polypropylene buried in landfill or in garbage dump it is not expected to migrate through soils. In case of exposure to sunlight Polypropylene will decompose very slowly because of the UV photodegradation. No toxic products are known to be produced because of such degradation. Unmodified Polypropylene is suitable for recycling & disposal by reuse via reprocessing, incineration with heat recovery and disposal in landfills. Recycling and disposal by incineration must be in accordance with applicable local regulations.

This material is not subject to the selective waste requirement as described in the EC Council Directive 2012/19/EC on waste electrical and electronic equipment (WEEE) -Annex II.

This declaration applies to **Y101** as it leaves the Petro Rabigh production facility and does not cover any components, additives, pigments, etc., subsequently incorporated by the converter.

This declaration has been prepared and issued on the basis of our best knowledge and expertise currently available and applies to the polymers delivered by SUMITOMO CHEMICAL EUROPE.

Sumitomo Chemical Europe is founded on a management system in concordant with the principles of on world scale accepted management systems like ISO 9001 (Quality), ISO 45001 and ISO 14001 (Environment). A comprehensive management system is the result of different activities in the areas of these standards and beyond, which is implemented and practised throughout the company. The Petro Rabigh production plant is ISO 9001, ISO 45001, and ISO 14001 certified, copies of these certificates can be provided upon request.

The information included in this document is valid from the stated version date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We, therefore, recommend our customers to verify the regulatory status periodically by accessing our Responsible Care department. It will be renewed in all cases where the previous conformity is no longer ensured and in case of changes in the regulations.

Responsible Care Office

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