



Declaration of Conformity

Version 2021.01

20 July, 2021

with the legislations mentioned hereafter

Sumitomo Polyethylene - LLDPE

Grade FS350A

Manufactured by Petro Rabigh (Kingdom of Saudi Arabia)

Based on current and available information, we declare that the above-mentioned product is in compliance 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,
- 2023/2006 - Good Manufacturing Practice for materials and articles intended to come into contact with food
- CONEG - Coalition of Northeastern Governors
- 94/62/EC - Packaging and Packaging Waste Directive and its amendments
- 1895/2005/EC - Restriction on the Use of certain epoxy derivatives (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)EN71 - Safety of toys – part 3(2013): migration of certain elements (EU2009/48/EC)
- GADSL - Global Automotive Declaration Substance List
- 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
- EN 71 The requirements of European Standard EN 71 "Safety of Toys", Part 3 (2013) by Directive EU 2009/48/EC
- FDA regulation
- US Conflict Mineral substances
- California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65)

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Unmodified the above-mentioned Sumitomo Polyethylene LLDPE grade complies 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 which are regulated with a specific migration limit (SML). This material contains at least one additive which is regulated with a SML which can be disclosed for the purpose of assessment of the compliance after signing of confidentiality agreement. This material is free of dual use additives.

Specific Restrictions:

The specific migration has been evaluated by migration simulation with the software Migratest Lite based on the initial content, a migration layer thickness of 0.025 cm and a default surface/volume ratio of 6 dm² per kg foodstuff for 3% Acetic Acid (representing aqueous food) and Olive Oil (representing fatty food). Simulations have been conducted up to a maximum application temperature of 100°C.

Aqueous food: FS350A meets the specific migration limit met when it comes into contact with aqueous food.

Fatty food (>20% fat): For Olive Oil an equilibrium concentration of 13.1 mg/kg food has been evaluated. Based on the application of the fat reduction factor FRF of 2.18 for food containing more than 43.7% (acc. to Reg.(EU) No. 10/2011, Annex V, 4.), the specific migration limit for any layer thickness and any time and temperature condition is met provided that also an eventually listed food specific D2 reduction factor according to Annex III of Reg. (EU) No. 10/2011 is considered. With a layer thickness of 120 µm FS350A, the SML is met under all time and temperature conditions for all kind of food.

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):

- ▶ FDA, CFR, Title 21 (2012) §177.1520(a)(3)(i) for Olefin polymers; extraction test results conducted on FS350A or similar resin meet extraction limits specified by FDA 21 CFR §177.1520(c)3.1a and 3.2a (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)

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Germany:

- ▶ "Bedarfgegenständeverordnung (BedGgstV), Anlage 3 (Stoffe und Erzeugnisse für die Herstellung von Lebensmittelbedarfsgegenständen), last amended on December 13th, 2011.
- ▶ BfR, Empfehlung III, Stand vom 1.3.2011

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:

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

Switzerland:

- ▶ "Verordnung über Bedarfsgegenstände, 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:

- ▶ **FS350A** with 120 µm 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 **FS350A** 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 which are regulated with a specific migration limit (SML) or maximum residue limit (QM). This material contains at least one additive which are regulated with a SML and/or QM.

FS350A with 120 µm or below complies with GB9685-2016 for general usage under general conditions considering data of migration tests under 95 % ethanol at 60°C for 10 days or other conditions.

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.

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The hereafter mentioned substances as such have not been intentionally used or added for the production or the formulation of our Polyethylene LLDPE grade:

- 2-ethyl hexyl acrylate
- 2-ethylhexylhexanoic acid
- 1,2-cyclohexane dicarboxylic acid diisononyl ester (DINCH)
- 4-dimethylaminobenzoate (EHDAB)
- 4-methylbenzofenon (CAS 134-84-9)
- 4-NP (4-Nonylphenol)
- Adipates
- Adipic acid (CAS 124-04-9) and derivatives
- Acetaldehyde
- Acrylamide
- Acrylonitrile
- Alkylphenol ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate
- Antimony trioxide
- Anthracene
- Antimony (Sb), Arsenic (As), Barium (Ba), Selenium (Se), Silver (Ag), Nickel (Ni)
- Aromatic amines & Sulfonated aromatic amines
- Asbestos
- Azo pigments
- Azodicarbonamide
- Benzene
- Benzo[a]pyrene
- Benzotriazole
- Bisphenol A, F, S
- Bis(2-ethylhexyl) phthalate (DEHP)
- Bovine Spongiform Encephalopathy (BSE)
- (Brominated) Flame retardants
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Butyl benzyl phthalate (BBP)
- Chlorinated paraffins
- Chlorofluorocarbons (CFCs)
- Chlorhexidine (CAS 55-56-1)
- Citric acid (CAS 77-92-9) and derivatives
- Citrates
- Colorants:
 - ▶ Azo pigments, Carbon Black
 - ▶ All the materials listed in the Resolution AP(89)1 on the use of colorants in plastics
- Cyanides
- DecaBDE
- Diantimony trioxide (CAS 1309-64-4)
- Diazine
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)
- Diethylhexyl Malate (CAS 142-16-5)
- Diethyl phthalate (DEP) (CAS 84-66-2)
- Dimethylfumarate (DMF)
- Dioxines & furans
- Engineered nanomaterial's

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- Epoxy derivatives: Bisphenol-A diglycidyl ether (BADGE), Bisphenol-F diglycidyl ether (BFDGE) and Novolac glycidyl ether (NOGE)
 - Epoxydised soja and linseed oil
 - Ethyl benzene
 - Fenocarb
 - Formaldehyde
 - gamma-Butyrolactone (GBL)
 - Genetic modified organisms (GMO)
 - Glycerol tricaprylate
 - Glycolethers
 - Isocyanate
 - Latex
 - Lilia (CAS 80-54-6)
 - Melamine
 - Mineral oil hydrocarbons
 - Nonylphenol and Nonylphenol ethoxylates
 - Ortho-phenylphenol
 - Para-di-chlorobenzene
 - Perfluorooctanoic acid (PFOA)
 - Perfluorooctane sulfonate (PFOS)
 - Perfluorochemicals (PFC)
 - Pesticides
 - Petroleum stocks
 - 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
 - Polyacrylonitril
 - Polyaminopropyl biguanide (PAPB)
 - Polybrominated biphenyls (PBB)
 - Polybrominated diphenyl ethers (PBDE)
 - Polybutylene terephthalate (PBT)
 - Polychlorinated biphenyls (PCBs)
 - Polychlorinated Naphthalene (PCN)
 - Polychloropreen (PCP)
 - Polycyclic aromatic hydrocarbons (PAHs)
 - Polyethylene Glycol (PEG) & derivates
 - Polyvinyl chloride (PVC) / PVCD
 - Polystyrene
 - Quaternium 15 (CAS 4080-31-3)
 - Radioactive substances
 - Refined or unrefined oils and lubricants
 - Recycled materials
 - Semicarbazide
 - Silicone
 - Short chain chlorinated paraffins
 - Styrene
 - 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 March 19,2021
 - ▶ Chemical weapon convention List I, II, III
 - ▶ GADSL – Global Automotive Declarable Substances list version 1.0 of 2018 updated 1 February 2018

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- ▶ 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 certain dangerous chemical substances, mixtures and articles)
- Tetradecane
- Toluene and Trichlorebenzene
- Transmissible Spongiform Encephalopathy (TSE)
- Triclosan
- Tris(Nonylphenyl) Phosphite (TNPP)
- Vinyl chloride monomer (VCM) and Polyvinyl Chloride (PVC)
- Vinylidene chloride
- Waxes
- 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.

FS350A is a not dangerous preparation according to directive 1999/45/EC of the European parliament and the council of 31 May 1999, concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labeling of dangerous preparations.

According to OSHA Hazard Communications Standard (CFR1910.1200), FS350A is considered not hazardous chemical. 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 in compliance 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. The purchaser remains responsible for determining whether the use complies with all relevant regulations.

Unmodified **FS350A** is a biologically inert solid, considered non-toxic and non-biodegradable. It is readily stable (does not decompose) in landfills or in aquatic systems. Polyethylene is insoluble in water and mostly will floats on the water surface and considered biologically inactive material in aquatic systems.

When Polyethylene buried in landfill or in garbage dump it is not expected to migrate through soils. In case of exposure to sunlight Polyethylene will decompose very slowly because of the UV photodegradation. No toxic products are known to be produced because of such degradation. Unmodified Polyethylene 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.

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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 **FS350A** 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 45001and 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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