



# SUMITOMO CHEMICAL EUROPE S.A. / N.V.

Woluwelaan 57 B-1830 Machelen Belgium Tel: +32 (0)2 251 06 50 Fax: + 32 (0)2 251 60 21

## Declaration of Conformity

version2021.05

27 September 2021

with the legislations mentioned hereafter

## Sumitomo Polyethylene - HDPE

### Grade F0554

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:

- CONEG – Coalition of Northeastern Governors
- 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
- 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
- 2002/61/EC – Restriction on the Use of Aromatic Amines
- 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))
- 2003/11/EG – Restriction on the Use of Brominated Flame Retardants
- 1169/2011 – Restriction on food allergens -Annex II
- 2004/21/EG – Restriction on the Use Azo Colourants
- 2005/59/CE – Restriction on the Use of Toluene and Trichlorobenzene
- 2005/84/EG – Restriction on the Use of Phthalates in toys and Childcare articles
- 2006/122/EG – Restriction on the Use of Perflurooctaansulfonates and decaBDE
- California's Safe Drinking Water and Toxic Enforcement Act (Proposition 65)
- FDA regulation
- US Conflict Mineral substances
- EN71 – Safety of toys – part 3(2013): migration of certain elements (EU2009/48/EC)
- GADSL – Global Automotive Declaration Substance List

# Declaration of Conformity

## Sumitomo Polyethylene – HDPE

Grade F0554

vs2021.05

- 
- |             |   |
|-------------|---|
| 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                            |
- 

Unmodified Sumitomo Polyethylene F0554 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/dm<sup>2</sup> contact surface or 60 mg/kg food.

This material contains no monomers which are regulated with a specific migration limit (SML). This material contains an additive which contains dual use additives 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)(3)(i) for Olefin polymers; extraction test results conducted on F0554, or similar resins meet extraction limits specified by FDA 21 CFR §177.1520(c) 3.1a and 3.2a (specification) for use in articles used for packing or holding food during cooking.

### Belgium:

- ▶ ARRETE ROYAL du 3 JUILLET 2005 relatif aux matériaux et aux objets en matière plastique destinés à entrer en contact avec les denrées alimentaires, modified by ARRETE ROYAL du 5 JUILLET 2006 and by ARRETE ROYALE du 8 MARS 2009.

### France:

- ▶ French Régulation Arrête du 1er avril 2011 modifiant J'arrête du 11e janvier 2003 relatif aux matériaux et objets en matière plastique mis au destinés à être mis au contact des denrées, produits et bois alimentaires.

### 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:

- ▶ Warenwet, the Dutch Packaging and Consumer Regulation for plastics, chapter Warenwet Hoofdstuk I – Kunststoffen, covering plastic materials intended to come into contact with foodstuffs, amended by Regulation VGP/VC 2979366 on 12, January 2010.

### Spain:

- ▶ Real Decreto 866/2008, de 23 de mayo, por el que se aprueba la lista de sustancias permitidas para la fabricación de materiales y objetos plásticos destinados a entrar en contacto con los alimentos y se regulan determinadas

# Declaration of Conformity

## Sumitomo Polyethylene – HDPE

Grade F0554

vs2021.05

condiciones de ensayo, dated 23ro of May, 2008 and modified on 22 of March, 2011 by Decision Orden PRE/626/2011, de 22 de marzo.

### 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

### China:

- ▶ **F0554** with 500 µmt 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 **F0554** 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) and/or maximum residue limit (QM). This material contains at least one additive which are regulated with a SML and/or QM.

**F0554** with 500 µmt or below complies with GB9685-2016 for general usage under general conditions considering data of migration tests under 4 %(V/V) acetic acid at 60oC for 10 days and 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.

The hereafter mentioned substances as such have not been intentionally used or added for the production or the formulation of our Polyethylene F0554 grade:

- 2-chloracetamid
- 2-ethoxyethanol
- 2-ethyl hexyl acrylate
- 2-ethylhexylhexanoic acid
- 3-Benzylidene Camphor
- 4-dimethylaminobenzoate (EHDAB)
- 4-methylbenzophenone (CAS 134-84-9)
- 4-Methylbenzylidene Camphor
- 4-NP (4-Nonylphenol)
- Acetaldehyde
- Acrylamide
- Adipic acid (CAS 124-04-9) and derivates
- Alkylphenol (AP)
- Alkylphenol ethoxylates, including nonylphenol ethoxylate, octylphenol ethoxylate and all isomers
- Ammonium Nitrate
- Anthracene
- Antimony Tris(Ethylene Glycoxide)
- Antimony (Sb), Arsenic (As), Barium (Ba), Bromine (Br), Chlorine (Cl), Florine (F), Iodine (I), Selenium (Se), Silver (Ag), Nickel (Ni), Cadmium (Cd), Lead (Pb), Mercury (Hg), hexavalent Chromium (Cr<sup>VI</sup>)
- Aromatic amines & Sulfonated aromatic amines
- Asbestos
- Azodicarbonamide
- Azo pigments
- Bamboo flour

# Declaration of Conformity

## Sumitomo Polyethylene – HDPE

Grade F0554

vs2021.05

- Benzene
- Benzo[a]pyrene
- Benzophenone-1, Benzophenone-2
- Benzotriazole
- Bis (2-ethylhexyl) phthalate (DEHP)
- Biocide Dimethylfumarate products
- Bisphenol: A (CAS 80-05-7), AF(CAS 1478-61-1), AP (CAS 1571-75-1), B (CAS 77-40-7),  
BP (CAS 1844-01-5), C (CAS 14868-03-2), E (CAS 2081-08-5), F (CAS 620-92-8),  
FL (CAS 3236-71-3), G (CAS 127-54-8), M (CAS 13595-25-0), P (CAS 2167-51-3),  
S (CAS 80-09-1), PH (CAS 24038-68-4), TMC (CAS 129188-99-4), Z (CAS 843-55-0)
- Boric acid
- Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE) (Substances of animal origin)
- (Brominated) Flame retardants
- Bromochlorocarbons substance
- Bromochlorofluorocarbons substance
- Bromofluorocarbons substance
- Bromomethane
- Butylated Hydroxytoluene (BHT) and Butylated Hydroxyanisole (BHA)
- Butyl benzyl phthalate (BBP)
- Chlorofluorocarbons (CFCs)
- Chlorhexidine (CAS 55-56-1)
- Chlorinated paraffins
- Chlorophenols
- Citric acid (CAS 77-92-9) and derivatives
- Corn flour
- 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
- Cyclotetrasiloxane
- DecaBDE
- Diazine
- Dibutyl phthalate (DBP)Dihydroxybiphenyl
- Diethylhexyl malate (CAS 142-16-5)
- Diethyle phthalate (DEP) (CAS 84-66-2)
- Diisobutyl phthalate (DIBP) (CAS 84-69-5)
- Dimethylfumarate (DMF)
- Dioxin and furans
- Engineered nanomaterial's
- Epoxy derivatives: Bisphenol- A diglycidyl ether (BADGE), Bisphenol-F diglycidyl ether (BFDGE) and Novolac glycidyl ether (NOGE)
- Ethyl benzene
- Ethylhexyl Methoxycinnamate (OMC)
- Fenocarb
- Formaldehyde
- Furfural (Furan-2-aldehyde)
- gamma-Butyrolactone (GBL)
- Genetic modified organisms (GMO)
- Glycerol tricaprylate
- Glycol ethers
- Halogenated solvent
- Hydrobromofluorocarbons

# Declaration of Conformity

## Sumitomo Polyethylene – HDPE

Grade F0554

vs2021.05

- 
- Hydrocinnamic acid
  - Isocyanate
  - Jatropha plant derives
  - Latex
  - Lialial (CAS 80-54-6)
  - Lithium Hydroxide
  - Lsothiazolinone
  - Methoxyethanol
  - Melamine
  - Methylparaben, ethylparaben, Propylparaben, Butylparaben
  - N methyl-2-pyrrolidone
  - Natural and synthetic latex
  - Nitrosamine
  - Nonylphenol and Nonylphenol ethoxylates, 4Nonylphenol (4NP)
  - Oils: Epoxydised soja and linseed oil
    - Mineral oil saturated hydrocarbons (MOSH)
    - Mineral oil aromatic hydrocarbons (MOAH)
    - Palm oil
  - O-phenylphenol
  - Organotin Compounds
  - Parabens
  - Para-di-chlorobenzene
  - Perchlorate
  - Perfluorooctanoic acid (PFOA)
  - Perfluorooctaan sulfonates (PFOS)
  - Perfluorochemicals (PFC)
  - Per- and Polyfluoroalkyl (PFAS)
  - Pesticides
  - Phthalates
  - Pigments containing diarylid
  - Plasticizer
  - 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)
  - Quaternium 15 (CAS 4080-31-3)
  - Radioactive substances
  - Recycled materials
  - Refined or unrefined oils and lubricants
  - Resorcinol
  - Semicarbazide
  - Short Chain Chloro Paraffines
  - Silicone
  - Substances listed in:
    - ▶ All substances 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

## Declaration of Conformity

### Sumitomo Polyethylene – HDPE

Grade F0554

vs2021.05

- ▶ US Conflict Mineral substances: Columbite-tantalite (coltan), Cassiterite, Gold, Wolframite, Tantalum, Tin and Tungsten  
Chemical weapon convention List I, II, III
- ▶ Ozon depleting substances according to the Montreal protocol
- ▶ GADSL – Global Automotive Declarable Substances list version 1.0 of 2020 updated 1 February 2021
- ▶ 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)
- Tetrachloromethane
- Tetradecane
- Toluene and Trichlorebenzene
- Toluene-2,4-diisocyanate
- Trichloroethane
- Tris(Nonylphenyl) Phosphite (TNPP)
- Vinyl chloride monomer (VCM) and Polyvinyl Chloride (PVC)
- Volatile organic compounds (VOC)
- 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.

F0554 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), F0554 is considered as 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 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 **F0554** 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.

## Declaration of Conformity

### Sumitomo Polyethylene – HDPE

Grade F0554

vs2021.05

---

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 **F0554** 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

#### **SUMITOMO CHEMICAL EUROPE NV/SA**

Woluwelaan 57 | B-1830 Machelen | Belgium

tel. +32 2 251 06 50 | fax. +32 2 255 76 79

[RC@sce.sumitomo-chem.be](mailto:RC@sce.sumitomo-chem.be)