



## **Regulatory Affairs and Product Stewardship Information**

**2021: Version 2**

Polyethylene Relene O21010

### **US FDA Food Contact**

The grade and the additives incorporated in it comply with the FDA: CFR Title 21, 177.1520 olefin polymers. To the best of our knowledge, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21CFR 177.1520. This product meets the FDA criteria in 21CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21CFR176.170(c), Table 2.

### **Good Manufacturing Practices**

The product complies with the requirements of Regulation 2023/2006/EC (GMP) applicable to intermediate materials.

### **European Commission Regulation (EU) No 10/2011 (Food Contact)**

The grades conform to EU Directive 1935/2004 on materials and articles intended to come into contact with food. The product complies with the requirements of Regulation EU/10/2011 and its subsequent amendments applicable to intermediate materials (Amendments applicable are 2020/1245, 2019/1338, 2019/37, 2018/831, 2018/79, 2017/752, 2016/1416, 2015/174, 202/2014, 1183/2012, 1282/2011).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation EU/10/2011. The grade complies with the requirement of Overall Migration Limit (OML) of 60 mg/kg as mentioned in EU/10/2011.

### **IS Food Contact**

The product complies with Indian Standard IS 10146:1982 on "Specification for polyethylene for its safe use in contact with foodstuffs, pharmaceuticals and drinking water". It also conforms to IS 16738:2018 on "Positive list of constituents for polypropylene, polyethylene and their copolymers for its safe use in contact with foodstuffs and pharmaceuticals".

The grade conforms to Overall Migration limit of 60 mg/kg as measured by IS 9845: Determination of Overall Migration of Plastic materials and articles intended to come in contact with Food Stuffs - Method of Analysis.

### **China Food Contact Compliance**

The grade meets requirements of Chinese “positive list” Food Standard GB 9685-2016 Hygienic standards for use of additives in food containers and packaging materials.

The grade meets the requirements of GB 4806.1-2016 National Food Safety Standard-General Safety Requirements for Food Contact Materials and Articles which are applicable to the product. The base resin in this product complies with the specifications established in GB 4806.6-2016, “National Food Safety Standard: Food Contact Resins”.

### **German Food contact Compliance**

The grade conforms to BfR Recommendations on Food Contact Materials, Regulation III Polyethylene.

### **Latin America MERCOSUR Food Contact status**

The grade complies to MERCOSUR GMC resolution No. 56/92, GMC resolution no. 39/19 (supersedes the previous regulation on FCMs, GMC 32/07) and GMC Res. No. 02/12.

### **SVHC Declaration**

ECHA has so far identified 211 chemical substances as the Substances of Very High Concern (SVHC), which are in the Candidate List of REACH Regulation (EC/1907/2006) (Updated January 2021). We confirm that these substances are not present in more than 0.1% weight / weight in this grade. As the list is subjected to be updated from time to time, we will also update you on the SVHC status of any such chemical, if included at later stage.

### **Japan Food Safety Law**

We confirm that as per manufacturing process of the above grade, base polymers (monomers) and additives used are below the maximum level usage and are listed in the positive list (Appended Table 1, Table 2 of the "Standards for the utensils or containers and packaging or the raw materials" (UCP) under Food Sanitation Act (Article 18, Section 1) under Japan Ministry of Health, Labour and Welfare (MHLW).

### **EU Directive - Packaging and Packaging Waste (94/62/EC) and CONEG (Coalition of North-eastern Governors)**

The grade conforms to amendments to 94/62/EC (Amendment number EU/2015/720, 2004/12/EC, 2005/20/EC, 219/2009). This grade meets the requirement of less than 100 ppm for total incidental Cadmium, Lead, Chromium, and Mercury.

### **Restriction of Hazardous Substances (ROHS) Directive 2011/65/EU**

The grade meets the requirements specified in EU directive 2011/65/EU, amended directive EU/2015/863, on the restriction of use of certain hazardous substances in electrical and electronic equipment. We do not intentionally use or add any hazardous substances like Polybrominated biphenyl (PBB) or Polybrominated diphenyl ether (PBDE), benzyl butyl

phthalate (BBP), dibutyl phthalate (DBP), bis-2-ethyl hexyl phthalate (DEHP), di-iso-butyl phthalate (DIBP), Lead (Pb), Mercury (Hg), Cadmium (Cd), Hexavalent Chromium (Cr<sup>6+</sup>), and/or its compound..

### **ELV directive 2000/53/EC and its amendments**

According to the formulation of this product, the quantity of Cadmium, Lead, Chromium, and Mercury is below the limits given in Annex II (Note) of 2005/673/EC. As per the regulation after shredding 80% of the material should be recyclable. Products made out of the grade are 100 % recyclable.

### **Toy Standards**

The grade also conforms with EN 71-3:2019, ISO 8124-3:2020, Toy safety 2009/48/EC (Annexure II, Part III “Chemical Properties”) and Applicable Parts ANNEX XVII of REACH including Phthalates. We do not intentionally use or add any hazardous substance like Lead (Pb), Antimony (Sb), Arsenic (As), Barium (Ba), Chromium (Cr), Cadmium (Cd), Mercury (Hg), Selenium (Se) and/or its compound.

Also, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 are not used in this grade.

### **California’s Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

The grade presents no significant risk for cancer to the people of California. This grade contains no substance that has been included in the list of substances which cause reproductive toxicity at a level of exposure subject to the requirements of Proposition 65.

### **Cosmetics Regulation:**

The product does not contain any of the prohibited substance mentioned in Annex II of EU/1223/2009.

### **Elemental Impurities**

The elemental impurities/ toxic solvents listed in the USP/ ICH residual solvents class1, class 2A and 2B, class 3 elements are not intentionally used in the formulation or manufacture of the product. Class 1 (As, Cd, Hg, Pb); Class 2A (Co, Ni, V); Class 2B (Ag, Au, Ir, Os, Pd, Pt, Rh, Ru, Se, Tl); Class 3 (Ba, Cr, Cu, Li, Mo, Sb, Sn).

### **Animal Derived Components (BSE) / (TSE) (EC 999/2001)**

The above grade is neither derived from animal or human origin nor manufactured utilizing intermediates and / or auxiliary agents which are of animal or human origin. The grade does not contain Bovine Spongiform Encephalitis (BSE) and Transmissible Spongiform Encephalitis (TSE). Hence the issue of Animal Spongiform Encephalopathy does not arise.

Therefore our product is in accordance with the current revision of note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01, rev.3- July 2011).

### **Phthalates**

According to the recipe of product of this grade we do not intentionally use or add phthalates, plasticisers, fillers, or flexibilisers. No phthalate plasticizers such as di(2-ethylhexyl) phthalate (DEHP) or di-octyl phthalate (DOP), di-iso-nonyl phthalate (DINP), di-iso decyl phthalate (DIDP), di-butyl phthalate (DBP), di-n-butyl phthalate (DNBP), butyl benzyl phthalate (BBP), di-n-octyl phthalate (DNOP) are added or used intentionally in manufacturing of this grade.

### **Nanomaterials**

During the manufacture of this product, we do not intentionally add or use any of the nanomaterial as per definition set in 2011/696/EU.

### **Regulation EC/1895/2005**

BADGE (Bisphenol-A DiGlycidyl Ether), NOGE (novolac glycidyl ethers) and BFDGE (Bisphenol-F DiGlycidyl Ether) have not been used in the manufacture or formulation of this grade.

### **Polychlorinated aromatics and ethers**

According to 76/769/EC, Polychlorinated biphenyls (PCBs) and polychlorinated terphenyls (PCTs) are not used in the manufacturing of this product. Also, polychlorinated naphthalenes (PCNs), polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs) and polybrominated terphenyls (PBTs) have not been used in the manufacture or formulation of this product.

### **BHT (butylated hydroxytoluene) (CAS no. 128-37-0) and BHA (butylated hydroxyanisole) (CAS no. 121-00-6 and 25013-16-5)**

According to the recipe of the product BHT and BHA are not used in the manufacture of this product, (the statement is true based on the testing done from laboratory with limit of quantification- LOQ 0.1 ppm).

### **Genetically Modified Organisms**

Herewith we confirm that above grades manufactured by RIL do not originate from / neither contain genetically modified organisms, in other words they are GMO-FREE.

### **MOSH-MOAH declaration**

This is to confirm that we do not add POSH, Mineral Oil Saturated Hydrocarbons (MOSH) or Mineral Oil Aromatic Hydrocarbons (MOAH) intentionally during the manufacturing of this grade.

## **Conflict Minerals**

The grade do not contain conflict minerals- Cassiterite, Columbite-tantalite (coltan), Gold, Wolframite, Tin, Tantalum, Tungsten, which are from Democratic Republic of Congo or its adjoining countries Sudan, Uganda, Rwanda, Burundi, United Republic of Tanzania, Zambia, Angola. This grade is not intentionally formulated or manufactured using above listed conflict minerals as per section 1502 of the Dodd- Frank Wall Street Reform and Consumer Protection act, however we donot analyse these specific substances or compounds.

## **Ozone Depleting Chemicals (ODCs)**

The ODCs listed in Annexes I and II of the Regulation EC/1005/2009, are not used in the manufacture of this product.

## **Persistent Organic Pollutants**

The grade does not contain POPs chemicals listed under Stockholm Convention (Annex A), Rotterdam Convention (Annex III) & EU POPs Regulation (EU) 2019/1021 (Annexure I, IV).

## **Food Allergens**

The following list of allergens are not used in the manufacture of this product:

- Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof
- Peanuts, peanut oil or any peanut product
- Tree nuts such as almonds, Brazil nuts, chestnuts, hazelnuts, hickory nuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts, Grains.
- Refined or unrefined oils
- Palm oil or Palm kernel oil or its derivatives or fraction.
- Milk or milk products, dairy products, dairy derivatives, lactose with protein
- Eggs or egg products
- Soybeans, soy flour or any soy products
- Fish or fish products, Shell fish and Crustaceans
- Mustard and products thereof and Sesame seeds and products thereof
- Molluscs or mollusc products
- Food colours
- Celery or celery products, Wheat or wheat products, Seeds or seed products, Grains
- Aspartame
- Monosodium glutamate (MSG)
- Caffeine
- Hydrogenated vegetable protein (VHP)
- Lupine or lupine products.

## **Halal and Koshar Compliance**

We hereby confirm that above grades does not contain any ingredient derived from animal origin. The product does not contain ethyl alcohol and ethyl alcohol has not been used in the manufacturing process. The equipment used for manufacturing the product is not used for the manufacturing of products containing ingredients of animal origin.

The product(s) manufactured by us are neither derived from animal or human origin nor manufactured utilizing intermediates and / or auxiliary agents which are of animal or human origin. Thus the grade is Kosher Compliant.

## **Substances and Chemicals**

Following substances have not been used intentionally in the manufacture or formulation of this product, however we have not analysed these substances or compounds:

DMF (dimethyl fumarate) (CAS # 624-49-7)

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS # 3380-34-5)

2-(2H-1,2,3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol (CAS # 3846-71-1)

2-Mercaptobenzothiazole (MBT) (CAS # 149-30-4)

Polycyclic Aromatic Hydrocarbons (PAHs)

- 1,2-dihydro-acenaphthene (CAS # 83-32-9)
- Acenaphthylene (CAS 208-96-8)
- 9H-fluorene (CAS 86-73-7) and 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)
- Chrysene (CAS 218-01-9)
- Dibenz(a,h)anthracene (CAS 53-70-3)
- Fluoranthene (CAS 206-44-0)
- Fluorine (CAS 86-73-7)
- 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)

Organo-tin Compounds:

- Tributyl-tin (TBT), di-butyl tin (DBT),
- monobutyl-tin (MBT) or any other organo-tin compound
- Acrylamide and Acrylonitrile
- Aniline
- Aromatic Amines
- Asbestos
- Atrazine
- Benzene
- Benzofuranes - Flame Retardants
- Benzophenone
- Bisphenol-A, B, F, S
- Chlorine, Bromine
- Chlorofluorocarbon (CFC)
- Dioxin
- Halogenated Flame Retardants
- ITX Photoinitiators
- Melamine
- Mercury
- Naphthalene
- N-Nitrosamines and N-Nitrosatables
- Tris(4-nonylphenyl, branched and linear) phosphite (TNPP), 4-Nonylphenol (4NP) and nonylphenol ethoxylates
- Paraben
- Plasticisers
- Polynuclear aromatic hydrocarbons (PNA)/ Polycyclic Aromatic Hydrocarbons (PAH)
- Per- and polyfluoroalkyl substances (PFAS), Perfluorooctanesulfonic acid (PFOA) and Perfluorooctane sulfonate (PFOS)
- Polybrominated Terphenyls (PBTS)
- Recycled materials
- Radioactive substances
- Silicone
- Silver
- Styrene and polystyrene
- Sulphur
- TAA adhesion promoters

- Vinyl Chloride and Polyvinyl chloride (PVC)
- Natural rubber latex, natural rubber or synthetic Latex
- Pyridine
- Gamma Picoline
- Beta Picoline
- Morpholine
- Sodium Sulphide
- Potassium Carbonate
- Acetone
- Phosphorous Trichloride
- Phosphorous Pentachloride
- Phosphorous Oxychloride
- Hydrogen Peroxide
- Precipitated Barium Carbonate
- Sodium Formaldehyde Sulphoxylate
- Sodium Tripolyphosphate
- Sulphur dioxide and sulphites

**The declarations given above are applicable to the material as it leaves the RIL production facilities and does not include any substance subsequently added by the converter or any other agency. As the conditions of usage at the customer's place are beyond the control of RIL, Customers are advised to make their own decision regarding their use of our grade is safe, lawful and suitable for the intended applications.**

**This certificate is valid for two years, however as the above mentioned regulations have amendments regularly, our declarations will be updated accordingly. Hence, customers are requested to check for new declarations from time to time before usage. This declaration replaces all previous versions.**

*(Computer generated statement, hence does not require any signature)*