



Regulatory Statement

Regulatory Statement for NOVAPOL[®] TR-0338-UI/UIG Polyethylene Resin

CAS Registry Number

The basic polymer consists of ethylene-hexene copolymer, CAS Reg. No. 25213-02-9.

Chemical Inventory

All components of this product are in compliance with the following chemical inventories:

- United States: Toxic Substances Control Act Inventory (TSCA), "Active".
- Canada: Domestic Substances List (DSL).
- Europe: This product complies with the registration requirements of the REACH Regulation (EC) No 1907/2006. The component substances have been duly registered, or are exempt from registration. This covers those EU importers included in NOVA Chemicals' Only Representative scheme.
- Australia: Australian Inventory of Industrial Chemicals (AIIC). All substances are "listed introductions" under the Australian Industrial Chemicals Introduction Scheme (AICIS).
- South Korea: Korea Existing Chemicals Inventory (KECL). Please contact your NOVA Chemicals representative.
- Japan: Existing and New Chemical Substances List (ENCS).
- The Philippines: Philippine Inventory of Chemicals and Chemical Substances (PICCS).
- New Zealand: New Zealand Inventory of Chemicals (NZIoC). All the components have an individual Hazardous Substances and New Organisms (HSNO) or a group standard approval or may be used as a component in a product covered by a group standard.
- Taiwan: Taiwan Chemical Substance Inventory (TCSI). Please contact your NOVA Chemicals representative regarding the registration requirements under the Regulations of New and Existing Chemical Substances Registration.
- China: Inventory of Existing Chemical Substances in China (IECSC).

U.S. Food Contact Status

The subject resin, as supplied by NOVA Chemicals Corp., complies with the provisions of the United States Federal Food, Drug and Cosmetic Act which are applicable to the resin, and all applicable Food and Drug Administration (FDA) regulations.

Specifically, the subject resin complies with the specifications contained in the FDA regulation 21 CFR 177.1520 for olefin polymers, para. (c) 3.2a, and may thus be used in the United States as an article or component of an article intended for use in contact with food. This resin is subject to the specific limitations that it may contact food only in articles having a volume of at least 18.9 L (5 gal. U.S.), only at temperatures of 150°F and below, and may not be used to hold ready-prepared foods intended to be reheated in the container at time of use (21 CFR 176.170(c) Table 2, conditions of use D–G).

The information cited above is subject to good manufacturing practice, technical suitability, and any limitations which are part of the regulations. It is recommended that you consult the regulations for complete details.





Canada Food Contact Status

Please contact your NOVA Chemicals representative.

EU Food Contact Status

The composition of the subject resin, as supplied by NOVA Chemicals, complies with the European Union's food contact regulations, including the Framework Regulation (EC) No 1935/2004, Regulation (EC) No 2023/2006 (GMP) and Regulation (EU) No 10/2011, as amended, Annex I (including Table 1, Union list of authorised substances) and Annex II. In addition, the resin complies with the relevant national regulations of the EU member states and non-EU countries which have adopted the European Union legislation.

Certain components of the resin are subject to Specific Migration Limits (SML) or other restrictions; based on the use amounts, articles up to 37 µm (1.5 mil) thick composed solely of the subject resin will comply without testing. In addition, the resin does not contain any intentionally introduced dual-use additives.

Details are listed on the resin's Declaration of Compliance for Food-Contact Materials and Articles, which can be provided upon request.

MERCOSUR Food Contact Status

We have reviewed Grupo Mercado Comun (GMC) Resolution No 39/2019 "MERCOSUR Technical Regulation on the Positive List of Additives for the Preparation of Plastic Materials and Polymeric Coatings that Come into Contact with Food (repeal of GMC Resolution 32/07)", GMC Resolution No 19/21 "Amendment of MERCOSUR GMC Resolution No 02/2012, "MERCOSUR Technical Regulation on Positive List of Monomers, Other Starting Substances and Polymers Authorized for the Manufacture of Plastic Packaging and Equipment That Come into Contact with Food", and GMC Resolution No 20/21 "Amendment of MERCOSUR GMC Resolution No 56/92 "General Provisions for Plastic Packaging and Equipment in Contact with Food", and find that the composition of the subject resin, as supplied by NOVA Chemicals, complies with these Resolutions.

The resin is subject to an overall migration limit of 60 mg/kg simulant.

Certain components of the resin are subject to Specific Migration Limits (SMLs) or other restrictions; based on the use amounts, articles up to 37 µm (1.5 mil) thick composed solely of the subject resin will comply without testing. Further details can be provided upon request.

Brazil Food Contact Status

The composition of the subject resin, as supplied by NOVA Chemicals, complies with the following Brazilian food contact regulations: Agência Nacional de Vigilância Sanitária (ANVISA) Resolução de Diretoria Colegiada (RDC) No 326, RDC No 56, and RDC No 589.

The resin is subject to an overall migration limit (limites de migração total) of 60 mg/kg simulant.

Certain components of the resin are subject to Specific Migration Limits (limites de migração específica, LME) or other restrictions; based on the use amounts, articles up to 37 µm (1.5 mil) thick composed solely of the subject resin will comply without testing. Further details can be provided upon request.





China Food Contact Status

All of the additives deliberately introduced into the subject resin grade by NOVA Chemicals are listed in China's "Standard for Uses of Additives in Food Contact Materials and Articles" (GB 9685-2016), per the unofficial English translation available to us at this time.

Certain components of the resin are subject to Specific Migration Limits (SML) or other restrictions; based on the use amounts, articles up to 37 µm (1.5 mil) thick composed solely of the subject resin will comply without testing. Further details can be provided upon request.

EU RoHS (2)

We have reviewed the Commission Delegated Directive (EU) 2015/863 of 31 March 2015, which amends Annex II of Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("RoHS 2" or "RoHS Recast"). We confirm that the subject resin complies with the applicable requirements of these directives, as well as the applicable requirements of the original RoHS Directive 2002/95/EC as last amended by Commission Decision 2010/571/EU.

Specifically, NOVA Chemicals does not deliberately add lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB's), polybrominated diphenyl ethers (PBDE's), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) to the resin, nor are such substances present, to the best of our knowledge, in any of the raw materials used in the resin's manufacture.

EU REACH—Absence of SVHC

NOVA Chemicals does not deliberately add any substance in the European Chemical Agency's Candidate List of Substances of Very High Concern to the product at levels above the applicable threshold (0.1%).

California Proposition 65

To the best of our knowledge, the subject resin does not require a warning under the California Safe Drinking Water and Toxic Environment Act of 1986 (Proposition 65).

TPCH

The resin as supplied by NOVA Chemicals will not contain cadmium, hexavalent chromium, lead, mercury, per- and polyfluoroalkyl substances (PFAS) or ortho-phthalates at concentrations exceeding the allowable limits, thus satisfying the applicable requirements of the Toxics in Packaging Clearinghouse Model Legislation (TPCH).

PFAS

NOVA Chemicals does not deliberately add per- and polyfluoroalkyl substances (PFAS) to the subject resin, nor are PFAS deliberately added, to the best of our knowledge, to any of the raw materials used in the manufacture of the resin.

Absence of Heavy Metals

NOVA Chemicals does not deliberately add cadmium, hexavalent chromium, lead or mercury to the subject resin. NOVA Chemicals has carried out testing on representative grades and the above heavy metals were not detected. The resin as supplied by NOVA Chemicals will not contain cadmium, hexavalent chromium, lead or mercury at concentrations of 100 ppm (total) or above, thus satisfying the applicable requirements of the Toxics in Packaging Clearinghouse (TPCH) Model Toxics in Packaging Legislation (the Coalition of Northeastern Governors, (CONEG)), the California Toxics in Packaging Prevention Act (California Health and Safety Code, §25214.11–25214.21), and EU Directive 94/62/EC, Packaging Regulations for heavy metals, as amended.





Ozone-Depleting Chemicals

The subject resin, as supplied by NOVA Chemicals, does not contain, and is not manufactured with, any Class I or Class II ozone-depleting chemicals. Thus, the resin will not require labeling under 40 CFR 82, subpart E (U.S. Stratospheric Ozone Protection Regulations, Labeling of Products using Ozone-Depleting Substances). In addition, please be advised that the resin does not contain, and is not manufactured with, any atmospheric ozone layer-depleting chemicals cited in the Montreal Protocol of 1987, as amended.

Absence of Animal Derived Ingredients

NOVA Chemicals does not deliberately add to the subject resin any animal-derived substances (including bovine or tallow-derived substances), kosher/halal-offending constituent substances, or any animal substances that may carry the risk of transmitting Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE), nor are such substances present, to the best of our knowledge, in any of the raw materials used in the resin's manufacture. The raw materials used in the manufacture of the resin contain no animal by-products. Consequently, we have no reason to suspect that any animal-derived materials, or kosher- or halal-offending constituent substances, would be present in the resin as supplied by NOVA Chemicals at the time of transfer of title to the customer.

You should therefore anticipate no difficulty in obtaining formal kosher/halal certifications with the use of the resin should you decide to pursue this course.

Absence of Food Allergens

NOVA Chemicals does not deliberately add to the subject resin any food allergens, specifically peanuts, peanut oil, any peanut products, tree nuts (almonds, brazil nuts, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, Queensland nuts, pecans, pine nuts, pistachios, cashews, and walnuts), wheat (gluten), milk (casein), milk products, dairy products, dairy derivatives, lactose with protein, eggs or egg products, soybeans, fish (e.g. bass, flounder, cod, salmon), fish products, shellfish, crustaceans (e.g. shrimp, crabs, lobsters, oysters, clams, scallops, crayfish), molluscs (e.g. snails, clams, squid, octopi) or mollusc products, sulfites, sulfur dioxide, nitrites, food colours, celery or celery products, seeds (e.g. cotton, poppy, sesame, sunflower, mustard) or seed products, aspartame, monosodium glutamate (MSG), caffeine, hydrolyzed vegetable protein (HVP), grains (e.g. rye, barley, oats, spelt, kamut), or lupine or lupine products; nor are these substances present, to the best of our knowledge, in any of the raw materials used in the manufacture of the resin. While we have not specifically analyzed for the presence of the above-mentioned substances, we have no reason to suspect that they would be present in the resin as supplied by NOVA Chemicals.

Absence Declarations

With any exceptions listed below, NOVA Chemicals does not deliberately add any of the following substances or materials to the subject resin, nor to the best of our knowledge, are such substances/materials deliberately added to the raw materials used in the manufacture of the resin. Please note that NOVA Chemicals does not carry out any specific analysis in order to detect the following substances/materials, and therefore cannot warrant that such substances/materials are not present.

2-Ethoxyethanol, 2-methoxyethanol, N-methyl-2-pyrrolidone
 Acrylamide
 Acrylonitrile
 Alkylphenol ethoxylates including octyl- and
 nonylphenol ethoxylates
 Aromatic amines (restricted in EU Directive 2002/61/EC)
 Artificial musks
 Asbestos

Long-chain (C₉₋₂₀) perfluorocarboxylic acids (PFCAs),
 their salts, and their precursors
 Melamine
 Metals: antimony, arsenic, beryllium, bismuth, boron,
 cadmium, chromium (VI), copper, gold, indium,
 lead, manganese, mercury, nickel, palladium, selenium,
 silver, strontium, tantalum, tellurium, thorium, tin, and
 tungsten, and their chemical compounds





Azocolorants (restricted in EU Dir. 2002/61/EC)
 Azodicarbonamide
 Benzophenones (e.g. 4-benzophenone)
 BHA, tertiary-butylhydroquinone (TBHQ)
 Biocides (pesticides, herbicides, insecticides), including
 Triclosan
 Bisphenol A and certain epoxy derivatives (e.g. NOGE,
 BFDGE, BADGE)
 Bisphenol AP, AF, B, BP, C, E, F, G, M, P and S
 Butadiene
 CFC, HCFC, Halons, HFC, PFC
 Chlorinated hydrocarbons, including short-chain and
 medium-chain chlorinated paraffins
 Colophony/Rosin
 Conflict minerals: tantalum (Ta), tin (Sn), gold (Au) and
 tungsten (W), and their derivatives
 Colourants (incl. tartrazine), dyes, pigments,
 optical brighteners, inks
 Dimethyl fumarate
 Dioxins and furans
 2-EHA, ethoxyquin, ITX, thiuram
 Epichlorohydrin
 Epoxidised soybean oil (ESBO)
 Extended conflict minerals: mica, cobalt
 Flame retardants, including brominated and halogenated (e.g.
 HBCD/HBCDD, PBB, PBDE)
 Fluorotelomers, PFOA, PFOS, PFHxS, PFNA, PFCAs, PFPE,
 PTFE, including the five perfluoroalkyl PFAS effectively
 banned from the food contact applications in 2016
 by the U.S. FDA
 Formaldehyde
 Genetically modified organisms (GMO)
 Hexachlorobenzene
 Isothiazolinones
 Derivatives from plants in the genus “Jatropha”
 Latex or natural rubber (including natural rubber latex
 and dry natural rubber)

Mineral oil saturated hydrocarbons (MOSH), mineral oil
 aromatic hydrocarbons (MOAH)
 Nanomaterials
 Nitrosamines (e.g. N-nitrosodimethylamine (NDMA))
 Octyl- and nonylphenols
 Organotin compounds
 Oxo- or biodegradable additives
 Pentachlorophenol (PCP)
 Parabens
 Perchlorates
 Persistent Organic Pollutants (POP's)
 Plasticisers (adipates, phthalates including ortho-phthalates)
 Polycarbonate(s)
 Polychlorinated bi- or terphenyls (PCB/PCT)
 Polychlorinated dibenzodioxins (PCDD), polychlorinated
 dibenzofurans (PCDF)
 Polychlorinated naphthalenes
 Polycyclic aromatic hydrocarbons (PAH)
 Polytetrafluoroethylene
 Radioactive substances
 Recycled materials
 Resorcinol
 Silanes
 Silicones, siloxanes
 Styrene, polystyrene (PS), expandable polystyrene (EPS)
 Synthetic fungicides, biocidal or antimicrobial
 preservatives, or fumigants
 TSCA 6(h) PBT Chemicals: decabromodiphenyl ether (DecaBDE);
 phenol, isopropylated phosphate (3:1) (PIP); 2,4,6-tris (tert-butyl)
 phenol (2,4,6-TTBP); pentachlorothiophenol (PCTP);
 hexachlorobutadiene (HCBd)
 Tris-nonylphenyl phosphite (TNPP)
 UV initiators and curing agents
 Vinyl chloride, vinylidene chloride, PVC or PVDC

Exceptions:

NOVA Chemicals does not deliberately add BHT (butylated hydroxytoluene: 2,6-bis[1,1-dimethylethyl]-4-methylphenol, CAS RN 128-37-0) to the subject resin. While trace levels of BHT are present in a component of one of the raw materials used in the manufacture of the resin, residual BHT levels in the resin will not exceed, and are expected to be well below, 6 ppb. Please contact your NOVA Chemicals Technical Service Specialist if you require further information.

As noted below, we cannot however be held responsible for any further addition of, or contamination with, any of the above-referenced substances or materials which may occur during processing of the resin to produce finished articles, packaging materials, or their components.





This information is believed to be correct as of the date of this statement. However, since regulations and product specifications are subject to change, we recommend that you contact us in one year's time to confirm the foregoing.

[signed]

A handwritten signature in blue ink, appearing to read "K. Sonnenberg".

Kenneth L. Sonnenberg, M.Sc.
Senior Advisor, Product Regulatory Compliance
Product Safety

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The above is based on the information known by NOVA and the regulatory requirements in place as of the date below, and does not consider further processing or compounding of the product. As regulations are subject to change, we recommend that updated regulatory statements be requested periodically to ensure the above remains current. In providing the above, NOVA is not providing legal interpretation or advice. NOVA recommends you seek independent legal advice regarding regulatory compliance.

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