

Revised January 24, 2024

Low Density Polyethylene, LDPE – Regulatory Fact Sheet **EF923SG**

US Food & Drug Administration Statement

Westlake Polymers LLC confirms that prime grade EF923SG, as manufactured and shipped from Westlake facilities, can be used in complying with Title 21 of the Code of Federal Regulations, CFR, per the conditions below:

EF923SG is a homopolyethylene resin that is defined under 21 CFR § 177.1520(a)(2)(i) and complies with extractive limitations set forth in paragraph (c) 2.1 thereunder. Antioxidant components are defined under § 178.2010 and one is restricted to a use limit of 0.25 wt% maximum in the resin. Additional components of EF923SG are defined for use in § 178.3860 and GRAS 182.90. EF923SG may be used in non-cooking applications pursuant to paragraph (c) 2.1 under § 177.1520. This resin may be used in complying with food-contact applications defined by Parts 177, 176, and 175, subject to the provisions of use and food contact types as specified under each Part.

Westlake confirms that prime grade EF923SG is produced with raw materials and operating practices that would not render the polymer unsafe or unsuitable for contact with food within the meaning of Sections 402 and 409 of the Federal Food, Drug, and Cosmetic Act and its implementing regulations including the Good Manufacturing Practice regulation, 21 CFR §174.5 “General Provisions applicable to indirect food additives”.

EU Food Contact Statement

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, may be used in compliance with Regulation (EU) No. 10/2011¹ and amendments EU 321/2011, EU 1282/2011, EU 1183/2012, EU 202/2014, EU 2015/174, EU 2016/1416, EU 2017/752, EU 2018/79, EU 2018/213, EU 2018/831, EU 2019/37, EU 2019/1338, EU 2020/2045, EU 2023/1442, and EU 2023/1627 for all times and temperatures of use. Westlake confirms that EF923SG is produced using the monomer and additives listed in Annex I of Regulation 10/2011 as described below:

FCM #	Restriction
125	None
433	SML = 6 mg/kg
69	SML = 30 mg/kg
292	SML = 5 mg/kg
734	None
271	None

We list below the identities and concentrations of substances in the resins that are subject to restrictions in Annex II of the Plastics Regulation:

Substance	Maximum concentration in the resins	SML in Annex II of the Plastics Regulation
Aluminum	<2700 mg/kg	1 mg/kg
Antimony	<1500 mg/kg	0.04 mg/kg

¹ Regulation (EC) No. 10/2011 on plastic materials and articles intended to come into contact with food.

Arsenic	<9 mg/kg	Not Detected (ND) at a limit of detection (LOD) of 0.01 mg/kg
Barium	<3 mg/kg	1 mg/kg
Cadmium	<3 ug/kg	ND at a LOD of 0.002 mg/kg
Chromium	<3 mg/kg	ND at a LOD of 0.01 mg/kg
Cobalt	<1500 ug/kg	0.05 mg/kg
Copper	<10 mg/kg	5 mg/kg
Europium	<3.5 ug/kg	0.05 mg/kg
Gadolinium	<10 ug/kg	0.05 mg/kg
Iron	<70 mg/kg	48 mg/kg
Lanthanum	<40 ug/kg	0.05 mg/kg
Lead	<20 mg/kg	ND at a LOD of 0.01 mg/kg
Lithium	<25 mg/kg	0.6 mg/kg
Manganese	<9 mg/kg	0.6 mg/kg
Mercury	<125 ug/kg	ND at a LOD of 0.01 mg/kg
Nickel	<80 ug/kg	0.02 mg/kg
Terbium	<1.5 ug/kg	0.05 mg/kg
Zinc	<30 mg/kg	5 mg/kg

We confirm that no primary aromatic amines (“PAAs”) are expected to be present in this resin.

Westlake confirms that any Polymer Production Aids (‘PPAs’), Aids to Polymerization, and Non-Intentionally Added Substances (‘NIAS’) present in the EF923SG product are incorporated into the polymer or removed such that only trace amounts would remain in the resin as delivered to your company. Westlake has conducted a risk assessment of these trace amounts of PPAs, Aids to Polymerization, and NIAS, concluding that any, if present are at safe levels.

Westlake can confirm that prime grade EF923SG is produced with raw materials and operating practices that would not endanger human health, create an unacceptable change in the composition of the food, or create deterioration in the organoleptic characteristics thereof in compliance with Good Manufacturing Practice as defined under the Framework Regulation (EC) 1935/2004² and Regulation (EC) 2023/2006.³ Westlake facilities all incorporate a Quality Management System which fully recognizes the position in the supply chain of these resins as intermediate materials for plastic packaging that may come into contact with food.

- **Dual Use Additives**

EF923SG resin does not contain dual use additives (*i.e.*, substances that are also authorized food additives or food flavorings in the EU pursuant to Regulation (EC) No. 1333/2008 on food additives, as amended or Regulation (EC) No. 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on food, as amended) that are subject to a restriction in food.

- **Nanomaterials**

No nanomaterials, as defined by European Commission Recommendation 2011/696/EU,⁴ are intentionally used in the production of EF923SG resin.

- **Suppliers’ Information**

This Food Contact statement has been prepared in reliance on the Declarations of Compliance provided to us by our raw material suppliers.

² Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food.

³ Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

⁴ Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU).

- **Mutual Recognition**

EF923SG resin may be placed directly on the market in the following EU Member States: Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, the Slovak Republic, Slovenia, Spain, Sweden and the United Kingdom, in full compliance with the applicable legislation therein.

EF923SG resin is being lawfully marketed in Austria based on the mutual recognition principle given that Austria has a general prior-authorization procedure that applies to substances that are not specifically regulated at the EU level, such as PPAs used in the manufacture of plastic materials and articles that are not listed on the Plastics Regulation.

- **Further verifications in the final article**

Please be aware that during processing at high temperatures the polymer will oxidize forming alkyl aldehydes, ketones, and carboxylic acids.

Regulation (EU) No. 10/2011 requires that the final article made from EF923SG must meet either the Overall Migration Limit of 10 mg/square decimeter of the food contact surface (or 60 mg/kg in the case of plastic materials and articles intended to be brought into contact with food intended for infants and young children). Because fabrication into the food contact article or material may affect migration, only the manufacturer of the final plastic material or article can guarantee that specific and overall migration limits will not be exceeded. It is the responsibility of the manufacturer of the final plastic material or article to comply with these requirements and to ensure compliance with Article 3.1 c) of Regulation (EC) No. 1935/2004, as amended, prohibiting the alteration of the organoleptic characteristics of the food.

Health Canada Food Contact Statement

EF923SG does not have No Objection Letter status under Health Canada, Health Products and Food Branch, HC-HPFB. Westlake will make a customer specific disclosure as needed to HC-HPFB for this resin grade.

Heavy Metals

Westlake Polymers LLC confirms that we do not intentionally add during the polymerization or formulation processes the heavy metals, lead, cadmium, mercury, and hexavalent chromium to prime grade EF923SG. Based on raw material supplier assurances and the use in our process, EF923SG contains less than 100 ppm total combined concentration of lead, mercury, cadmium, and hexavalent chromium, and therefore meets the heavy metal criteria set forth in the California Toxics in Packaging Prevention Act (AB2021), Toxics in Packaging Clearing House - CONEG model legislation, the EU Directives 94/62/EC, EU RoHS (2002/95/EU) and amendment 2011/65/EC and EU WEEE (2002/96/EU). Raw materials containing such heavy metals as arsenic, antimony, barium, beryllium, cobalt, nickel, tin, or selenium are not used in the manufacture of this resin.

EF923SG contains an antiblock ingredient which is derived from natural ores and does contain trace levels of some heavy metals. Use of heavy metals in this form does not constitute "intentional addition" per the regulations listed above. These metals may be present at a calculated concentration typically of less than 500 ppb for the loading of antiblock in this resin. Because these metals are not in a form that is extractable with conventional mineral acids, Westlake does not analyze for their presence.

Animal based materials

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, is produced with chemicals that are synthetically derived, and free from animal derived materials (ADM), including bovine derived materials. Based on our raw material supplier assurances, and the use in our process, and our delivery of the LDPE resin to your company, we can confirm that EF923SG does not contain any animal products or byproducts, including

ruminants, milk or milk derivatives, derivatives of wool and hair of ruminants, and thus is free from Transmissible Spongiform Encephalopathies, TSE, and Bovine Spongiform Encephalopathies, BSE.

California Proposition 65

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, may be used in compliance with California's "Safe Drinking Water and Toxic Enforcement Act of 1986" (Proposition 65). EF923SG contains no substances known to the State of California to cause cancer or reproduction toxicity at levels of exposure subject to the requirements of Proposition 65.

Ozone Depleting Substances

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, is not manufactured with ingredients, which contain ozone depleting substances, Class I (Group 1, 2, 3, or 4) or Class II, as listed under 40 CFR Part 82. Therefore, this resin is not subject to the labeling requirements of 40 CFR § 82.106 (Warning statement requirements).

Latex

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, does not contain chemical substances identifiable as "natural rubber latex", "dry natural rubber latex", or "synthetic latex".

Allergens

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, does not contain ingredients designated as "allergens" or sensitizers per the list below:

PEANUTS (including peanut butter, peanut flour) and other peanut products
TREE NUTS (including almond, Brazil, cashew, hazelnut, macadamia, pecan, pine, pistachio, walnut) and products thereof
MILK (including butter, casein, cheese, curds, whey, cream, custard, pudding, sodium caseinate, sour cream, yogurt) and products thereof
GELATIN - from any source
EGGS (including mayonnaise, meringue, egg whites) and other egg products
WHEAT/GLUTEN, rye, barley, oats (including flours, brans, cereal extracts, cracker meals, farina, graham flours, malts wheat germ, wheat gluten, wheat starch, semolina)
BUCKWHEAT & products thereof
SOY & SOYBEANS (including miso and tofu) and products thereof
FISH and fish products
SHELLFISH (shrimp, crab, lobster, oyster, clam, scallops, crayfish, molluscs) and products thereof
Sulphur Dioxide and Sulfites – (not an allergen but cause problems, particularly with asthmatics.
FOOD COLORS – including FD&D Yellow #5.
HYDROLYZED VEGETABLE PROTEINS – from any source including enzyme & acid processes
CELERY (including celery root, stalk, leaf and/or seed) and products thereof
SEEDS (including cottonseed, poppy, mustard, sesame and sunflower) and products thereof
MUSTARD – and products thereof
NATURAL RUBBER LATEX
MONOSODIUM GLUTAMATE, MSG

ASPARTAME

Therefore, this resin may be used in complying with the US FDA Food Allergen Labeling and Consumer Protection Act (FALCPA) and EU Directives 2000/13/EC and 2007/68/EC, as well as EU Regulation No.1169/2011, and does not require labeling.

RoHS

Westlake Polymers LLC confirms that prime grade EF923SG resin, as manufactured and shipped from Westlake facilities, is not manufactured with ingredients that would intentionally add the chemicals and metals listed below:

- Lead
- Cadmium
- Mercury
- Hexavalent Chromium
- PBB (Polybrominated biphenyls)
- Chlorinated Paraffins
- PBDE (Polybrominated diphenyl ethers) – including Decabromodiphenyl ether (DBDPO – CAS # 1163-19-5)
- Hexabromocyclododecane – HBCDD – CAS 25637-99-4
- Bis(2-ethylhexyl) phthalate, DEHP
- Butyl benzyl phthalate, BBP
- Dibutyl phthalate, DBP
- Diisobutyl phthalate, DIBP

Therefore, based on raw material supplier assurances and the use in our process, Westlake confirms that prime grade EF923SG may be used in complying with the European Directive RoHS (2002/95/EU), its amendments, Directive 2011/65/EU, and Directive 2015/863/EU.

Specific chemicals and chemical groups:

EF923SG, as manufactured and shipped from Westlake facilities, does not intentionally incorporate during the polymerization or formulation processes the following chemicals:

1. Acrolein
2. Asbestos
3. Acrylamide
4. Aromatic Amines
5. Azo compounds
6. Benzene
7. Benzophenone and alkyl or aryl substituted benzophenones
8. Bisphenol A, BPA, other Bisphenols including B, C, E, F, S, Z
9. Brominated flame retardants, including Penta-, Octa-, & Deca- bromodiphenyl ethers
10. Flame retardants of any type
11. Brominated chemicals of any type
12. Butylated Hydroxy Anisole, BHA
13. t-Butylhydroquinone
14. Chlorofluorocarbons (CFC), Hydrochlorofluorocarbons (HCFC), Hydrofluorocarbons (HFC)
15. Diethylhexyl Adipate, DEHA
16. Dimethyl Fumarate, CAS # 624-49-7
17. Dioxins of any type
18. Epichlorohydrin, oxirane
19. Epoxy resins or their components including BADGE – Bisphenol A diglycidyl ether, BFDGE – Bisphenol F diglycidyl ether, NOGE – Novalac glycidyl ether
20. Fluoroteleomers
21. Furans of any type

22. Genetically Modified Organisms, GMO
23. Hexachlorobenzene
24. Melamine
25. Nitrosamines of any type
26. Nonyl, Octyl Phenol Ethoxylates, other Alkyl Phenol Ethoxylates
27. Organo tin compounds of any type, alkyl or aryl derivatives including mono, di, tri, tetra-Butyl derivatives, tin oxide derivatives
28. Other heavy metals including arsenic, antimony, barium, beryllium, cobalt, nickel, tin, and selenium
29. Perfluorooctanoic acid, PFOA CAS # 335-67-1, and Perfluorooctane sulfonate, PFOS CAS # 1763-23-1, or any type of Perfluoroalkyl Sulfonate including polymeric forms
30. Phthalates, including DEHP (diethyl hexyl phthalate, CAS# 117-81-7), DBP (di-butyl phthalate, CAS# 84-74-2), DEP (di-ethyl phthalate, CAS# 84-66-2), BBP (butyl benzyl phthalate, CAS# 85-68-7), DMP (di-methyl phthalate, CAS# 131-11-3), DNPP (di-n-pentyl phthalate, CAS# 131-18-0), DIPP (di-isopentyl phthalate, CAS#605-50-5), NPIPP (n-pentyl-iso-pentyl phthalate, CAS# 84777-06-0), DNHP (di-n-hexyl phthalate, CAS# 84-75-3), DNOP (di-n-octyl phthalate, CAS# 117-84-0), DINP (di-isononyl phthalate, CAS# 28553-12-0), DIDP (di-isodecyl phthalate, CAS# 26761-40-0 or 68515-49-1), and DMEP (di-2-methoxyethyl phthalate, CAS# 117-82-8)
31. Polycarbonate
32. Polychlorinated Biphenyls, PCB, PCBs
33. Polychlorinated Terphenyls, PCT, PCTs
34. Polybrominated Biphenyls, PBB, PBBs
35. Polybrominated Terphenyls, PBT, PBTs
36. Polynuclear Aromatics, Polycyclic Aromatics
37. Polyvinyl chloride, Vinyl chloride monomer
38. Radioactive substances
39. Styrene and Polystyrene
40. Silicone
41. Toluene

This resin grade contains Tris Nonylphenyl Phosphite, TNPP, and may contain nonyl and octyl phenols due to hydrolysis of the TNPP.

REACH

Westlake Polymers LLC confirms that EF923SG contains Tris-(nonylphenyl)phosphite (i.e. TNPP), published as a ECHA REACH Candidate List substance on July 16, 2019. While TNPP has recently been designated a “substance of very high concern” (SVHC), the amount used in EF923SG falls below the 1,000 ppm threshold for notification under Article 33. Westlake also notifies users of EF923SG that, while not an intentionally added material, nonylphenol, also a Candidate List SVHC, is a known degradation byproduct resulting from the hydrolysis of TNPP.

Further, Westlake confirms that EF923SG does not intentionally add any other SVHCs defined under EU Regulations 552/2009 and 1907/2006 as

- Restricted substances in ANNEX XVII Appendices 1 – 10*,
- Substances recently classified as under Authorization - ANNEX XIV substances,
- Candidate List substances published on 10-28-2008, 1-13-2010, 3-30-2010, 6-18-2010, 12-15-2010, 6-20-2011, 12-19-2011, 6-18-2012, 12-19-2012, 6-20-2013, 12-16-2013, 6-16-2014, 12-17-2014, 7-15-2015, 12-17-2015, 6-20-2016 1-12-2017, 7-7-2017, 1-15-2018, 6-27-2018, 1-15-2019, 7-16-2019, 1-16-2020, 6-25-2020, 1-19-2021, 7-8-2021, 1-17-2022, 6-10-2022, 1-17-2023, 6-14-2023, 1-24-2024.

*Westlake's polyethylene resins are provided in solid pellet and powder forms, which fall into the definition of synthetic polymer microparticles (commonly referred to as "microplastics") under EU Regulation 2023/2055 (amending Annex XVII to Regulation (EC) No. 1907/2006). Annex XVII, as amended, restricts placement of microplastics on the EU Market. Under the regulation, however, several categories of microplastics are exempt from this restriction. Specifically, synthetic polymer microparticles as substances on their own or in mixtures for use at industrial sites are exempt from the restriction. Westlake's polyethylene resins are intended for use at industrial sites and fall under this exemption. Please see Paragraphs 7 through 14 of Annex XVII, as amended, for details regarding future reporting and product labeling requirements for EU manufacturers, importers, and down-stream users. As a member of Operation Clean Sweep (OCS), an international program designed to prevent and help keep plastic litter materials out of the marine environment, Westlake manages our plastic products responsibly by implementing operational practices and engineering controls to prevent Westlake polyethylene pellets, flake or particles from entering waterways. Westlake encourages its customers and downstream industrial users to follow the same responsible approach to managing plastic particles in their industrial processes.

Please note that, with the exception of TNPP, Westlake does not directly incorporate SVHCs into our LDPE resin. As such, Westlake does not analyze for the presence of substances which are not direct additions to the LDPE product formulation.

Finally, it is your responsibility to determine that our product is safe, lawful, and technically suitable for your intended uses. Please note that this fact sheet is provided to you as one of the means to assist you in analyzing our product, and does not serve to modify or amend our sales arrangement or contract with you.

Westlake Polymers LLC does not endorse or claim suitability of its product for any particular use. WESTLAKE MAKES NO WARRANTY OF MERCHANTABILITY AS TO ITS EF923SG RESIN. WESTLAKE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OR FITNESS OF ANY WESTLAKE PRODUCT FOR ANY PARTICULAR USE. Westlake's liability and your exclusive remedy for any claim arising out of the sales of its products are expressly limited at Westlake's option to replacement of non-performing goods or payment not to exceed the purchase price plus transportation charges thereon in respect to any material which damage is proven and claimed.

The information in this letter is valid for cited regulations published as of the date this document was prepared, as shown below (herein). Updates may be prepared as the regulations are amended or pending revised information about the resin.

It is the customer's responsibility to seek updated regulatory information on any specific resin.

This fact sheet (letter) is being sent to your company for regulatory compliance purposes solely and no other person or entity may rely on this fact sheet (letter) without the prior written consent of Westlake