

June 2020

Durasyn[®] Polyalphaolefin Regulatory Bulletin

FORWORD

This bulletin summarizes the regulatory information for Durasyn[®] Polyalphaolefins manufactured by INEOS Oligomers, including chemical inventory status and clearances for applications such as cosmetics/personal care, food contact and other frequently requested information.

INEOS Durasyn products are produced entirely from petrochemical feedstocks, with all raw materials traceable to oil or gas derivatives. Ancillary chemicals used through production are synthetic, production and onward logistics are carefully controlled to prevent contamination.

MANUFACTURIGN ORIGIN AND PURITY

Durasyn products are additive and solvent free products. No materials of animal or biological origin are expected to be present. INEOS has every reason to expect that Durasyn products are free from the following contaminants, however this has not been confirmed by analysis or testing:

- BSE (Bovine Spongiform Encephalopathy)
- TSE (Transmissible Spongiform Encephalopathy)
- GMO (Genetically Modified Organisms)

Chemical Inventory Information

Many countries have chemical control legislation in place including a comprehensive list of existing chemicals which may be marketed, manufactured, or imported. These lists are known as chemical inventories. Durasyn Polyalphaolefins have been evaluated to determine compliance with these chemical inventories; information regarding the compliance to countries chemical inventories may be found in section 15 of the product Safety Data Sheet (SDS).

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FOOD CONTACT APPLICATIONS

Durasyn Polyalphaolefin Grades 125, 126, 127, 128, 145, 146, 147, 148, 156, 157, 162, 164, 164X, 166, 166X, 168, 170, 174I, 180I, and 180R, are authorized for use as components of non-food articles intended for contact with food as specified in 21 CFR § 178.3620(b), Technical Grade White Mineral Oil, for the following applications:

- § 175.105 for use in Adhesives.
- § 176.200 for use as Defoaming agents used in coatings.
- § 176.210 for use as Defoaming agents used in the manufacture of paper and paperboard.
- § 177.2260 in Resin-bonded filters; substances employed in fiber finishes.
- § 177.2600 as plasticizers in rubber articles intended for repeated use subject to limitations specified.
- § 177.2800 in Textiles and Textile Fibers for use at levels not to exceed 0.15 wt.% of finished fibers.
- § 178.3570 in Lubricants with incidental food contact subject to the limitations specified.
- § 178.3910 in Surface lubricants used in the manufacture of metallic articles.

Lubricants with Incidental Food Contact and Ingredients for use in Lubricants with Incidental Food Contact.

National Sanitation Foundation (NSF) Registrations

The U.S. Department of Agriculture administered an authorization program for Proprietary Substance and Nonfood Compounds until February 1998. In January 2000, the National Sanitation Foundation revived the USDA program as a voluntary registration program, incorporating previous USDA authorizations and new NSF registrations. The NSF Nonfood Compounds Registration Program is a continuation of the USDA product approval and listing program, which is based on meeting regulatory requirements including FDA 21 CFR for appropriate use, ingredient and labeling review. Further information and listing of authorized substances can be found at NSF's website: www.nsf.org.

Table 1- Summary of Durasyn Polyalphaolefin products registered by NSF as H1-Lubricants with Incidental Food Contact and HX1- Ingredients for use in Lubricants with Incidental Food Contact.

Durasyn 125	Durasyn 147	Durasyn 168
Durasyn 126	Durasyn 148	Durasyn 170
Durasyn 126B	Durasyn 156	Durasyn 174I
Durasyn 127	Durasyn 162	Durasyn 180I
Durasyn 128	Durasyn 164	Durasyn 180R
Durasyn 133	Durasyn 164E	
Durasyn 136	Durasyn 164X	
Durasyn 145	Durasyn 166	
Durasyn 146	Durasyn 166X	

REACH, CLP Regulation and Substance of Very High Concerns (SVHC)

The following Durasyn grades are Polymers, and Polymers are exempt from REACH Registration:

Durasyn 147, 166, 166X, 170, 174I, 174R, 180I, and 180R.

For the purposes of re-importing these Durasyn polymers into the EU, the monomers have been registered.

All other Durasyn grades have been registered according to the REACH requirements. For more details, please contact your INEOS representative.

INEOS Durasyn products do not meet the criteria outlined in Article 57 (Substances to be included in Annex XIV for the REACH for authorization), in Article 50 (Substances to be included in Annex XVII of the REACH for restrictions) and are not regarded as substance of very high concern (SVHC). Durasyn products do not contain any substances meeting the criteria outlined in Article 57 (Substances to be included in Annex XIV of the REACH for authorization), in Article 50 (Substances to be included in Annex XVII of the REACH for restrictions) and any of the substances of very high concern (SVHC) published by ECHA.

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CALIFORNIA PROPOSITON 65

The manufacturing process for Durasyn Polyalphaolefins supports the premise that the products present “no significant risk” for cancer to the people of California. The products contains no substances known to the State of California (see current Proposition 65 list under <http://www.oehha.org>) to cause reproductive toxicity at a level of exposure subject to the requirements of Proposition 65.

RoHs, WEEE, Packaging Waste, USCONEG, ELV

The Annex II to Directive 2011/65/EC (recast RoHs Directive) requires:

“Restricted substance referred to in Article 4(1) and maximum concentration values tolerated by weight in homogeneous materials:

Lead	(0.1 %)
Mercury	(0.1 %)
Cadmium	(0.01 %)
Hexavalent chromium	(0.1 %)
Polybrominated biphenyls (PBB)	(0.1 %)
Polybrominated diphenyl ethers (PBDE)	(0.1 %)
Bis(2-ethylhexyl) phthalate (DEHP)	(0,1 %)
Butyl benzyl phthalate (BBP)	(0,1 %)
Dibutyl phthalate (DBP)	(0,1 %)
Diisobutyl phthalate (DIBP)	(0,1 %)

The combined heavy metals content does not exceed 100ppm. PBDE (Polybrominated diphenyl ethers) and PBB (Polybrominated biphenyls) are flame retardant additives and Phthalates are plasticizers. As we do not use any of such substances in the manufacture of our Durasyn® Polyalphaolefin range there is no possibility of their presence, so we do not analyze for them.

Durasyn products comply with the WEEE Directive (2012/19/EC and its amendments), the RoHS Directive (2011/65/EC and its amendments), the Waste Packaging Directive (94/62/EC and its amendments), the End-of-Life Vehicle Directive (2000/536/EC and its amendments), and the USA CONEG regulation for packaging.

ABSENCE OF SUBSTANCES AND CHEMICALS

Please request the regulatory statement from your INEOS representative.

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SAFETY DATA SHEETS

Safety Data Sheets (SDS) are available for all INEOS Oligomers products, and will describe the health, safety, and environmental characteristics of these products as well as advice on handling precautions and emergency procedures.

SDS should be consulted and fully understood before handling, storage or use of INEOS products.

SDS for INEOS Oligomers products have been made available on line, may be requested from your INEOS Oligomers representative or by sending an email to oligomersmsds@ineos.com.

For more information regarding an INEOS Oligomers product please contact your INEOS contact or call on of the following numbers

In North America – 1-866-363-2454

In Europe - +32 (0)67 875 980

In Asia - +86 21 6103 5970

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