

# INEOS Oligomers

April 2020

## Silkflo® 362 Didecene and Silkflo® 364, 366, 380I and 380R Polydecene Regulatory Bulletin

### FOREWORD

This bulletin summarizes the regulatory information for Silkflo® 362 Didecene and Silkflo® 364, 366, 380I and 380R Polydecenes manufactured by INEOS Oligomers, including chemical inventory status and clearances for applications including, cosmetics/personal care, food contact and other frequently requested information.

INEOS Silkflo 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.

### MANUFACTURING ORIGIN AND PURITY

Silkflo products are additive and solvent free products. No materials of animal or biological origin are expected to be present. Therefore INEOS has every reason to expect that Silkflo 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. Silkflo products 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).

### FOOD CONTACT STATUS

Silkflo 362, 364, 366, 380I and 380R, 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. |

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- § 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.

## European Regulations:

Silkflo grades 364 and 366 are in compliance with Annex I of the Regulation on plastic materials and articles intended to come into contact with food, EC/10/2011 and its amendments:

FCM substance No: 789

Ref. No: 60027

Substance name: Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-dodecene and/or 1-tetradecene

Use as additive or polymer production aid

No SML.

Average Molecular weight not less than 440 Da.

Viscosity at 100°C not less than 3.8 cSt

They are not Dual Use additives, and do not contain any Dual Use additives.

INEOS can also confirm that the Silkflo grades 364 and 366 are manufactured under Quality Assurance, Quality Control and traceability system that are consistent with the provisions of the EU Regulation 1935/2004 and its amendments on materials and articles intended to come into contact with food and the EU Regulation 2023/2006 and its amendments on good manufacturing practice for materials and articles intended to come into contact with food.

## COSMETICS/PERSONAL CARE PRODUCTS

Silkflo Didecene and Polydecenes are used in various cosmetic and personal care applications.

The CFTA/INCI name for Silkflo 364, 366, 380I and 380R is Hydrogenated Polydecene CAS # 68038-01-4

The CFTA/INCI name for Silkflo 362 is Hydrogenated Didecene CAS # 68649-11-6

Silkflo 364 and 366 products meet the requirements specified in the JSCI Ingredient Code 502029, “-Olefine Oligomer”, Standard Code 42. They can therefore be used in the cosmetic applications specified for these components, categories 1 through 11 inclusive.

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## Comprehensive Licensing Standards (CLS)

- 1- Cleansing Preparations
- 2- Hair Care preparations
- 3- Treatment Preparations
- 4- Makeup Preparations
- 5- Fragrant Preparations
- 6- Suntan and Sunscreen Preparations
- 7- Nail Makeup Preparations
- 8- Eyeliner Preparations
- 9- Lip Preparations
- 10- Oral Preparations
- 11- Bath Preparations

The manufacturing process for these products supports the premise that no products listed in annex II and III of the Cosmetic Directive (76/768/EC, 1223/2009/EC and its amendments) will be added or formed during the production process. INEOS has every reason to expect that Silkflo products are free of such products or below the restriction limits, where applicable.

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

The following INEOS Silkflo grades are Polymers, and Polymers are exempt for REACH Registration:

Silkflo 366, 380R and 380I Polydecene

For any other Silkflo grade, they have been registered according to the REACH requirements. For more details, please do request this from your INEOS contact.

INEOS Silkflo do not meet 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 are not regarded as a substance of very high concern (SVHC).

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

### **CALIFORNIA PROPOSITON 65**

The manufacturing process for Silkflo 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.

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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%)
Cadmium	(0.1%)
Mercury	(0.1%)
Hexavalent Chromium	(0.1%)
Polybrominated biphenyls (PBB)	(0.1%)
Polybrominated diphenyl ethers (PBDE)	(0.1%)

As originally manufactured and packaged Silkflo products comply with this Directive (RoHS) and its amendments.

The combined heavy metal content does not exceed 100ppm. Additionally, PBDE and PBB are flame retardant additives which are not used in the manufacturing process for Silkflo products. Although analysis has been conducted it is expected that these chemicals would not be found in the final product.

Silkflo 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 contact or by sending an email to [oligomersmsds@ineos.com](mailto: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

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