INEOS Oligomers

Biological Endpoint Summary for

[redacted]

Notified Substance	Synonym
[redacted]	Notified Substance Durasyn® 133 [redacted]

INEOS Oligomers

[redacted]

Test Method	Notified Substance	Notified Substance Mol. Weight (Mn)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
OECD 301B	[redacted]	392 Daltons	[redacted]	YES	87.8% @ 28 days	[redacted]	NO

[redacted] the OECD 301B procedure.

INEOS Oligomers

[redacted]

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO			
OECD 117 (B)	1-Tetradecene homopolymer, hydrogenated	412 Daltons	$C_{28\text{-}56}$ $H_{58\text{-}114}$ $H\text{-}(C_{14}H_{28})_n\text{-}H$ n =2-4	YES	log K_{ow} = 7.09	Analytical Bio-Chemistry Laboratories, Inc	YES

[redacted]

(Test Report B)

The bioaccumulation potential of the notified substance, [redacted] was determined using two surrogate substances by two methods.

The n-Octanol/Water partition coefficient (Pow) for the surrogate **substance A**, ***1-Tetradecene homopolymer, hydrogenated***, was estimated to be 7.09 by direct measurement using a High Performance Liquid Chromatographic method based on OECD Method 117.

Droy has shown that substances with very high values of log K_{ow} are not expected to bio-accumulate (Droy, B. "Chapter 25: Environmental Impact" from Synthetic Lubricants and High Performance Functional Fluids by R. L. Shubkin, ed., 1993, Marcel Dekker, p 533).

INEOS Oligomers

[redacted]

[redacted]

(TEST REPORT C)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	412 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
Japanese Protocol (C)	1-decene homopolymer Hydrogenated (CASRN 68037-01-4)	1,582 Daltons	$C_{20\text{-}1160}\ H_{42\text{-}2322}$ $H^{-}(C_{10}H_{20})_n{}^{-}H$ n =2-116	YES	96-hr LC_{50} >10 mg/L	LSI Medience Corporation	YES

Bioaccumulation of [redacted]

Summary (Test C)

The bio-concentration potential of [redacted] was determined in a second set of experiments using **surrogate test substance B, a hydrogenated 1-decene homopolymer**. While surrogate substance B had a number average molecular weight of 1,582 Daltons, this test material contained a number of components with molecular weights below 1,000 Daltons. Several of these components were identified and evaluated for their bio-concentration potential using Japanese rice fish (*Oryzias latipes*). The surrogate test substance did not bioconcentrate.

The 96-hr LC_{50} of the test substance to Carp (Medaka) in a concurrent acute toxicity test was calculated to be >10 mg/L.

INEOS Oligomers

[redacted]

Acute Oral Toxicity for [redacted]

(Test Report D0, D1)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
16 CFR 1500	Emery 3002 RS (c) (CASRN 68649-11-6)	287 Daltons	$C_{20\text{-}30}$ $H_{42\text{-}62}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-3	YES	Acute Oral Toxicity >5,000 mg/kg	Hill Top Biolabs	YES
16 CFR 1500	Emery 3004 RS (b) (CASRN 68037-01-4)	438 Daltons	$C_{30\text{-}50}$ $H_{62\text{-}102}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =3-5	YES	Acute Oral Toxicity >5,000 mg/kg	Hill Top Biolabs	YES

Acute Toxicity Summary for [redacted]

The acute oral toxicity of ***1*** [redacted] was evaluated using four hydrogenated 1-decene-based polyalphaolefin surrogate compounds.

The four hydrogenated 1-decene-based polyalphaolefin surrogate compounds, also known as RS(c), RS(b), RS(a), and RS(d), were evaluated in compliance with the conditions specified in the Regulation for the Enforcement of the Federal Hazardous Substances Act (16 CFR 1500).

For each test substance, the acute oral LD50 value was found to be greater than 5,000 mg/kg in male and female Sprague-Dawley rats.

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Oral (Gavage) 91-Day Toxicity Study in Rats for [redacted] with an In utero Exposure Phase (TEST REPORT E_0, E_1, E_2, E_3, E_4)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
US FDA Method 1966	Ethylflo 166 RS(a), (CASRN 68037-01-4)	531 Daltons	C_{30-70} H_{62-142} $H^-(C_{10}H_{20})_n{}^-H$ n =3-7	YES	NOEL =1,000 mg/kg/day	Springborn Laboratories (Charles River)	YES

Oral Gavage 91 Day Toxicity Test Summary for [redacted]

A study was conducted to evaluate the potential oral toxicity of [redacted] using a hydrogenated 1-decene-based polyalphaolefin surrogate substance (RS (a)).

RS (a), also known as Emery 3006, was prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance, [redacted].

RS (a)) was administered orally, by gavage, to rats as a single dose daily for a minimum of 91 days (91-day toxicity phase). There were no apparent gross necropsy observations or histopathologic lesions that could be related to test compound RS (a) treatment. Because there were no apparent toxic effects on the numerous parameters measured, the **no-observed-effect-level for RS (a) was judged to be 1,000 mg/kg/day.**

RS (a) given orally at dose levels of 0, 100, 500 and 1000 mg/kg/day to FO male and female rats did **not produce any apparent toxicity in these animals or have any effect on their fertility. In addition, the F1 pups did not demonstrate any test article-related toxicity during the parturition and lactation phases.**

An Oral (Gavage) Two Generation Reproductive Study in Rats For [redacted]

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 416	Pentadecane, 7-methylene-, mixed with 1-tetradecene, dimers and trimers, hydrogenated Durasyn® 164X RS (Q) CASRN 1000172-11-1	433 Daltons	$C_{22\text{-}56}\ H_{46\text{-}114}$ $H\text{-}(C_{14}H_{28})_n\text{-}\text{-}(C_{16}H_{32})_n\text{-}\ H$ n =1-2	YES	NOEL =1,000 mg/kg/day	Harlan Laboratories	YES

Oral Gavage Two Generation Toxicity Test Summary

A study was conducted using OECD Guideline 414 to evaluate the potential oral toxicity of [redacted] using a hydrogenated 1-Tetradecene and Pentadecane-7-methylene-based polyalphaolefin surrogate substance (RS (Q)).

RS (Q), also known as Pentadecane, 7-methylene-, mixed with 1-tetradecene, dimers and trimers, hydrogenated, was administered to pregnant rats by oral gavage during organogenesis at dose levels of 100, 300 and 1000 mg/kg bw/day. **There were no toxicologically significant effects at any dose level**. The `No Observed Effect Level' (NOEL) was therefore, considered to be 1000 mg/kg bw/day. No toxicologically significant changes were detected in the offspring parameters measured. The `No Observed Effect Level' (NOEL) for reproductive and developmental toxicity was therefore considered to be 1,000 mg/kg bw/day.

Dermal Toxicity in the Rat of [redacted]

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 402	1-Tetradecene, polymer with 1-dodecene, distn. residues, hydrogenated, C24-56 fraction Durasyn® 125 RS (P) CASRN 883233-48-5 NGP-5G	514 Daltons	$C_{24-56}H_{50-114}$	YES	Negligible dermal toxicity LD_{50} >2,000 mg/kg	Product Safety Laboratories	YES

Dermal Toxicity Summary for [redacted]

.

A study was conducted to determine the dermal toxicity of an analog of [redacted] The surrogate substance Durasyn 125, also known as reference compound RS(p), is a hydrogenated 1-tetradecene and 1-dodecene -based polyalphaolefin that was prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance, [redacted]

Two thousand milligrams of the surrogate test substance RS (p) per kilogram of body weight was applied to the skin of ten healthy rats for 24 hours. The animals were observed for mortality, signs of gross toxicity, and behavioral changes at least once daily for 14 days. Body weights were recorded prior to application and again on Days 7 and 14 (termination). Necropsies were performed on all animals at terminal sacrifice.

Dermal Toxicity Summary for [redacted] - continued

All animals survived, gained body weight, and appeared active and healthy during the study. There were no signs of gross toxicity, dermal irritation, adverse pharmacologic effects, or abnormal behavior. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

Primary Skin Irritation Study in Rabbits of [redacted] TEST REPORT

H_0, H_1, H_2, H_3]

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
16 CFR 1500	Emery 3002 RS (c) (CASRN 68649-11-6)	287 Daltons	C_{20-30} H_{42-62} $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-3	YES	Not a primary irritant; Not corrosive	Hill Top Biolabs	YES
16 CFR 1500	Emery 3004 RS (b) (CASRN 68037-01-4)	438 Daltons	C_{30-50} H_{62-102} $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =3-5	YES	Not a primary irritant; Not corrosive	Hill Top Biolabs	YES
16 CFR 1500	Emery 3006 RS (a) (CASRN 68037-01-4)	531 Daltons	C_{30-70} H_{62-142} $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =3-7	YES	Not a primary irritant; Not corrosive	Hill Top Biolabs	YES
16 CFR 1500	Emery 3008 RS (d) (CASRN 68037-01-4)	609 Daltons	C_{20-30} H_{42-62} $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-3	YES	Not a primary irritant; Not corrosive	Hill Top Biolabs	YES

Primary Skin Irritation Summary for [redacted]

Several closely related hydrogenated 1-decene derived polyalphaolefin surrogate compounds were tested to model the primary skin irritation potential of [redacted]
.
These polyalphaolefin surrogate compounds were prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance, [redacted]

The lowest viscosity polyalphaolefin surrogate test compound (Emery 3002, also known as hydrogenated 1-decene dimer; viscosity≈ 2 mm^2/s at 100°C), was determined to have a Primary Irritation Index of 3.1 based on erythema and edema. No evidence of tissue damage was found. This material was not classified as a primary irritant or as a corrosive by dermal application.

The other surrogate materials were also found not to be primary irritants or corrosive by dermal application.

Guinea Pig Sensitization Maximization Test of [redacted]

(TEST REPORT I_0,I_1,I_2)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
Magnusson -Kligman Protocol 423	Ethylflo 362 RS (c) (CASRN 68649-11-6)	287 Daltons	$C_{20\text{-}30}$ $H_{42\text{-}62}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-3	YES	No Sensitiz-ation evident	Pharmacon Research International	YES
Magnusson -Kligman Protocol 423	Ethylflo 364 RS (b) (CASRN 68037-01-4)	438 Daltons	$C_{30\text{-}50}$ $H_{62\text{-}102}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =3-5	YES	No Sensitiz-ation evident	Pharmacon Research International	YES
Magnusson -Kligman Protocol 423	Silkflo 366 RS (a) (CASRN 68037-01-4)	531 Daltons	$C_{30\text{-}70}$ $H_{62\text{-}142}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =3-7	YES	No Sensitiz-ation evident	Pharmacon Research International	YES

Guinea Pig Sensitization Summary

Several closely related hydrogenated polyalphaolefin surrogate compounds were tested to model the sensitization potential of [redacted] These polyalphaolefin surrogate compounds were prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance, 1-Tetradecene homopolymer hydrogenated, by-products from, C28-C42 fraction.

Guinea Pig Sensitization Summary- continued

A low viscosity polyalphaolefin surrogate test compound derived from 1-decene (Ethylflo 362 NF Polydecene, also known as hydrogenated 1-decene dimer; viscosity≈ 2 mm^2/s at 100°C) was shown not to cause dermal sensitization in guinea pigs when intra-dermally induced at 5.0% and topically induced and challenged at 10%.

Hydrogenated 1-decene dimer is lower in molecular weight than the lowest molecular weight component present in the Notified Substance, [redacted]

Two additional hydrogenated 1-decene oligomers with molecular weights of 438 Da (Ethylflo 364 NF Polydecene) and 531 Da (Silkflo 366 NF Polydecene) were tested for sensitization potential. Neither of these 1-decene-based hydrogenated polyalphaolefins was considered to be a sensitizer in guinea pigs.

Ocular Irritation Test of [redacted]

(TEST REPORT J0,J1)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	1-[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
16 CFR 1500	Emery 3002 (c) (CASRN 68649-11-6)	287 Daltons	C_{20-30} H_{42-62} $H^-(C_{10}H_{20})_n^-H$ n =2-3	YES	No Ocular Irritation evident	Hill Top Bio Labs	YES
16 CFR 1500	Emery 3004 RS (b) (CASRN 68037-01-4)	438 Daltons	C_{30-50} H_{62-102} $H^-(C_{10}H_{20})_n^-H$ n =3-5	YES	No Ocular Irritation evident	Hill Top Bio Labs	YES

Ocular Irritation Test Summary for [redacted]

[redacted] ocular irritancy of several hydrogenated 1-decene polyalphaolefin surrogate compounds, with structures similar to the notified substance, was evaluated in compliance with the conditions specified in the Regulation for the Enforcement of the Federal Hazardous Substances

Act (16 CFR 1500). None of the test compounds were classified as irritants by ocular application as defined in 16 CFR 1500.

Testing for Mutagenic Activity with *Salmonella typhimurium* TA 1535, TA 1537, TA 98 and TA 100 and *Escherichia coli* WP2uvrA for [redacted]

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 471	Silkflo 366NF RS (a) (CASRN 68037-01-4)	531 Daltons	C_{30-70} H_{62-142} $H^{-}(C_{10}H_{20})_n^{-}H$ n =3-7	YES		Inveresk Research	YES

Mutagenic Activity Summary

A closely related hydrogenated 1-decene-based polyalphaolefin surrogate compound (known as Silkflo 366 NF or RS (a), was tested to model the likely mutagenic activity of [redacted] This polyalphaolefin surrogate compound was prepared using the same catalyst (BF_3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance, *1-Tetradecene homopolymer hydrogenated, by-products from, C28-C42 fraction.* The 1-decene-based hydrogenated polyalphaolefin surrogate compound, RS(a), was tested for mutagenic activity in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 98, TA 100 and *Escherichia coli* WP2uvrA at concentrations ranging from 156.25 to 5,000 μg per plate.

As the test substance RS(a) proved insoluble, a homogeneous emulsion was prepared using the surfactants Sorbitan stearate and Polysorbate 60 along with polyalphaolefin test compound RS(a).

No mutagenic activity was observed in any of the 5 bacterial strains tested. There was no toxicity to the bacteria.

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INEOS Oligomers

Micronucleus Toxicity in the Mouse of [redacted] TEST REPORT L)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 474	Alkane 5 RS (o) (CASRN 151006-60-9)	533 Daltons	$C_{30\text{-}72}\ H_{62\text{-}146}$ $H\text{-}(C_{10\text{-}12}H_{20\text{-}24})_n\text{-}H$ n =3-6	YES	Non-genotoxic	Safepharm Laboratories	YES

Micronucleus Toxicity Summary

The test material, Alkane 5, a hydrogenated 1-decene / 1-dodecene copolymer, also known as RS (o), was used as a surrogate substance to assess the potential fo[redacted]o produce damage to chromosomes when administered via the intraperitoneal route to mice. The method followed that described in the OECD Guidelines for Testing of Chemicals No. 474 "Micronucleus Test", Method B12 of EEC Commission Directive 84/449/EEC, US, EPA, TSCA and FIFRA guidelines and the Japanese Ministry of International Trade and Industry Guidelines for testing new chemical substances.

In the micronucleus study, groups of ten mice (five males and five females) were given a single intraperitoneal dose of the test material at 1250, 2500 and 5000 mg/kg. Animals were killed 24, 48 or 72 hours later, the bone marrow extracted and smear preparations made and stained. Polychromatic and normochromatic erythrocytes were scored for the presence of micronuclei, 1000 polychromatic erythrocytes were scored per animal.

There was no evidence of a statistically significant increase in the incidence of micronucleated polychromatic erythrocytes in animals dosed with the test material when compared to the concurrent vehicle control group. No significant change in the PCE/NCE ratio was observed after dosing with the test material. The test material, RS (o) was considered to be non-genotoxic under the conditions of the test.

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Ames Reverse Mutation Test for [redacted] TEST REPORT M)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 471	Pentadecane, 7-methylene-, mixed with 1-tetradecene, dimers and trimers, hydrogenated Durasyn® 124 RS (Q) CASRN 1000172-11-1	433 Daltons	$C_{22\text{-}56}\ H_{46\text{-}114}$ $H\text{-}(C_{14}H_{28})_n\text{-}\text{-}(C_{16}H_{32})_n\text{-}\ H$ n =1-2	YES	NOEL = 5,000 µg/plate	SafePharm Laboratories Ltd	YES

Ames Reverse Mutation Summary

A study was conducted using OECD Guideline 471 (Bacterial Reverse Mutation) to evaluate the potential bacterial mutagenicity of the notified substance, [redacted] using a surrogate substance consisting of a hydrogenated dimer and trimer of 1-Tetradecene and 1-Octene dimer (i.e. Pentadecane-7-methylene). This polyalphaolefin is called RS (Q) or Pentadecane, 7-methylene-, mixed with 1-tetradecene, dimers and trimers, hydrogenated.

RS (Q), also known as Durasyn 124, was prepared using the same catalysts and basic process chemistry that were used to produce the notified substance, *1-Tetradecene homopolymer hydrogenated, by-products from, C28-C42 fraction.*

RS (Q)) caused no visible reduction in the growth of the bacteria at any dose level. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. The test material was thus concluded to be non-mutagenic under the conditions of the test.

Chromosome Aberration Test in Human Lymphocytes *In Vitro* Of [redacted] REPORT N)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A
Surrogate Substance Details							
Test Method	**Notified Substance**	**Notified Substance Mol. Weight (M_n)**	**Surrogate Substance Carbon Range**	**Surrogate Substance Used In this Test?**	**Result**	**Test Lab**	**GLP?**
OECD 473	1-Dodecene Trimer, Hydrogenated Alkane 4 RS (n) CASRN 151006-62-1	527 Daltons	$C_{36\text{-}48}H_{74\text{-}98}$ $H\text{-}(C_{12}H_{24})_n\text{-}H$ n =3-4	YES	Non-clastogenic to human lymphocytes	Safepharm Laboratories Limited	YES

Chromosome Aberration Test Summary

A study was performed to assess the effect of the Notified Substance, [redacted] on human lymphocytes. A closely related analog substance was tested. The analog substance was a hydrogenated dodecene-based polyalphaolefin also known as RS(n) or Alkane 4.

The analog test material, hydrogenated dodecene-based polyalphaolefin RS(n), did not induce a statistically significant increase in the frequency of cells with chromosome aberrations or polyploid cells in either the presence or absence of a liver enzyme metabolizing system. The analog substance RS(n),is therefore considered to be non-clastogenic to human lymphocytes in vitro. **By extension, the Notified Substance, [redacted] anticipated to be similarly non-clastogenic to human lymphocytes under similar conditions.**

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Chemical Induction of Gene Mutation at the HGPRT Locus in Cultured Chinese Hamster Ovary Cells by [redacted] TEST REPORT 0)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 476	1-Dodecene Trimer, Hydrogenated Alkane 4 RS (n) CASRN 151006-62-1	527 Daltons	$C_{36\text{-}48}H_{74\text{-}98}$ $H\text{-}(C_{12}H_{24})_n\text{-}H$ n =3-4	YES	Test substance not mutagenic	Sitek Research Laboratory	YES

Gene Mutation Summary

A study was performed to assess the effect of the Notified Substance, [redacted] on gene mutation. A surrogate substance was used in testing. The surrogate substance was a hydrogenated dodecene-based polyalphaolefin also known as RS (n) or Alkane 4.

The test material, RS (n), was tested in two independent assays for its potential to cause gene mutations at the HGPRT locus in cultured CHO cells. The results of both CHO/HGPRT Gene Mutation Assays indicated that the test article did not cause an increase in the mutant frequency at the HGPRT locus in the presence or absence of metabolic activation. All criteria for a valid assay were met in both the definitive and confirmatory assays.

Under the conditions of the study, the test article, RS (n), was not mutagenic in the CHO/HGPRT Gene Mutation Assay. **By extension, the Notified Substance is anticipated to be similarly non-mutagenic under similar conditions.**

Algal Inhibition of [redacted] (TEST REPORT P)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 201	1-Dodecene Polymer with 1-Decene, hydrogenated Alkane 5 RS (o) CASRN 151006-60-9	533 Daltons	$C_{30\text{-}72}$ $H_{62\text{-}146}$ $H\text{-}(C_{10\text{-}12}H_{20\text{-}24})_n\text{-}H$ n =3-6	YES	ELR50 (Effective Loading Rate) values of greater than 1,000 mg/L	Safepharm Laboratories	YES

Algal Inhibition Summary

A study was performed to assess the effect of the Notified Substance, [redacted] on the growth of Selenastrum capricornutum.

A closely related analog of the Notified Substance, a hydrogenated decene and dodecene - based polyalphaolefin, also known as RS (o), was used as a surrogate test substance.

The polyalphaolefin surrogate compound, RS (o), was prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance. Only the alpha-olefin starting materials were different.

Exposure of Selenastrum capricornutum to the RS(o) test material gave ELR50 (Effective Loading Rate) values of greater than 1,000 mg/L loading rate of the Water Accommodated Fraction and correspondingly the No Observed Effect Concentration was greater than or equal to 1,000 mg/L loading rate of the Water Accommodated Fraction.

Bacterial Toxicity of [redacted]

Bacterial Toxicity of [redacted] (TEST REPORT Q)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
DIN 38412, Part 8	1-decene Dimer, Hydrogenated RS (c) (CASRN 68649-11-6)	287 Daltons	$C_{20\text{-}30}$ $H_{42\text{-}62}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-3	YES	*no chronic toxic effect detected in the test system, Pseudomonas putida* 10g/L	Institut Fresenius Chemische and Biologische Laboratorien GmbH	YES

Bacterial Toxicity Summary for [redacted]

A closely related hydrogenated polyalphaolefin surrogate compound derived from 1-decene was used to model the bacterial toxicity of [redacted] The polyalphaolefin surrogate compound was prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance. Only the starting alpha-olefin employed was different.

The surrogate compound, hydrogenated 1-decene dimer, also known as Durasyn 162, was tested for chronic bacterial toxicity according to DIN 38412, Part 8. In order to determine the toxic effect of the test substance against the test system, *Pseudomonas putida* was subjected to different concentrations of the test substance. After 16 ± 1 hours incubation time, the retardation in the proliferation of the bacteria was determined and compared to a control solution without the test substance in order to assess the extent of the toxic effect on the test system. Under the conditions used in this study, no chronic toxic effect at the highest test concentration (10g/L).

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Fish Toxicity of 1-Tetradecene homopolymer hydrogenated , by-products from, C28-C42 fraction (TEST REPORT R)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 203	1-decene Dimer, Hydrogenated RS (c) (CASRN 68649-11-6)	287 Daltons	C_{20-30} H_{42-62} $H-(C_{10}H_{20})_n-H$ n =2-3	YES	no toxic effect for water extract of test substance	Institut Fresenius Chemische and Biologische Laboratorien GmbH	YES

Fish Toxicity Summary

Hydrogenated 1-decene dimer, a closely related hydrogenated polyalphaolefin surrogate compound derived from 1-decene, was used to model the fish toxicity of [redacted] The polyalphaolefin surrogate compound was prepared using the same catalyst (BF3: CASRN 7637-07-2) and basic process chemistry that was used to produce the notified substance. Only the starting alpha-olefin starting materials were different.

Hydrogenated 1-decene dimer is lower in molecular weight to the lowest molecular weight component present in the Notified Substance, 1-Tetradecene homopolymer hydrogenated, by-products from, C28-C42 fraction.

The surrogate substance, was tested for acute toxicity towards fish according to OECD-Test Guideline 203. In order to investigate the influence of the test substance, the fish were exposed to a water extract of hydrogenated 1-decene dimer. After incubation times of 24, 48, 72 and 96 hours the number of dead animals was recorded.

Under the conditions used for the test, ***no toxic effect of the test substance towards fish was observed***. Therefore, the concentration where no toxic effect occurred (LC_0) was determined as being the concentration of test substance in the water extract from 10 g test substance in one liter drinking water.

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Full Life-Cycle Toxicity Test with Water Fleas of [redacted]

(TEST REPORTs S.T,U)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO	N/A	N/A	N/A

Surrogate Substance Details

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Surrogate Substance Carbon Range	Surrogate Substance Used In this Test?	Result	Test Lab	GLP?
OECD 211	1-decene Dimer, Hydrogenated RS (c) (CASRN 68649-11-6)	287 Daltons	$C_{20\text{-}30}$ $H_{42\text{-}62}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-3	YES	*The No-Observed-Effect Loading Rate (NOELR) = 125 mg/L*	Springborn Smithers Laboratory	YES
OECD 211	Durasyn 166 RS (a) (CASRN 68037-01-4)	531 Daltons	$C_{30\text{-}70}$ $H_{62\text{-}142}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =3-7	YES	*The No-Observed-Effect Loading Rate (NOELR) = 125 mg/L*	Springborn Smithers Laboratory	YES
OECD 202	1-Dodecene Polymer with 1-Decene, hydrogenated Alkane 5 RS (o) CASRN 151006-60-9	533 Daltons	$C_{30\text{-}72}$ $H_{62\text{-}146}$ $H\text{-}(C_{10\text{-}12}H_{20\text{-}24})_n\text{-}H$ n =3-6	YES	*No Observed Effect Concentration was greater than or equal to 1000 mg/L.*	SafePharm Laboratories	YES

Toxicity of [redacted]

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[redacted] to Activated Sludge in Respiration Inhibition (TEST REPORT V0, V1)

Test Method	Notified Substance	Notified Substance Mol. Weight (M_n)	Notified Substance Carbon Range	Notified Substance Used In this Test?	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO			
OECD 209	1-Tetradecene homopolymer hydrogenated	412 Daltons	$C_{20\text{-}50}$ $H_{42\text{-}102}$ $H\text{-}(C_{10}H_{20})_n\text{-}H$ n =2-5	YES	No impact	Charles Rivers Environmental Sciences Laboratory	YES

Activated Sludge Summary for [redacted]

The effect of 1-tetradecene homopolymer hydrogenated, by-products from, C28-C42 fraction on the respiration of activated sewage sludge was determined using [redacted] as a surrogate substance. The method followed OECD No. 209 Guidelines.

Activated sewage sludge was exposed to an aqueous dispersion of the surrogate test substance at concentrations of 10, 100 and 1000 mg/L for a period of 3 hours. The rate of respiration was determined after 3 hours contact time and compared to data for the control and a reference item, 3,5-dichlorophenol. 1-tetradecene homopolymer hydrogenated test compound had no impact on the respiration of activated sewage sludge.

Inhalation Toxicity of [redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	Result	Test Lab	GLP?
N/A	[redacted]	392 Daltons	[redacted]	NO			
OECD 412	1-tetradecene homopolymer, hydrogenated (CASRN 1857296-89-9)	412 Daltons	$C_{28\text{-}56}\ H_{58\text{-}114}$ $H\text{-}(C_{14}H_{28})_n\text{-}H$ n =2-4	YES	NOAEL) of 0.743 mg/L.	Covance	YES

Inhalation Toxicity Summary for [redacted]

The inhalation toxicity of 1-tetradecene homopolymer hydrogenated, by-products from, C28-C42 was accessed using an aerosol of the surrogate test substance [redacted] at 0, 0.25, 0.75 and 2.5 mg/L in a 28 day inhalation study conducted using OECD Guideline 412 (Sub-acute Inhalation Toxicity).

In a range finding study with 1-Tetradecene homopolymer hydrogenated, exposure levels of 0.544 and 2.15 mg/L appeared to be well tolerated by the test animals (Han Wistar Rats) following exposure for 6 hours per day, 5 days per week for 2 weeks. However, adverse histopathological changes were evident in the lungs of animals exposed to the test substance at a concentration of 5.64 mg/L. For the detailed study, 2.5 mg/L of the test substance was selected as the high exposure level. Intermediate and low exposure levels of 0.75 and 0.25 mg/L were also explored in order to identify a no adverse effect level (NOAEL).

Test animals exposed to 2.35 mg/L of 1-tetradecene homopolymer hydrogenated exhibited an inflammatory response that was consistent with an irritant effect and the accumulation of the test item in the lungs. Histopathological findings were consistent with the inhalation of poorly soluble particulate matter. Test animals were not observed to recover after two weeks without exposure to the test substance.

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Inhalation Toxicity of [redacted]

Test animals exposed to 0.743 mg/L of 1-tetradecene homopolymer hydrogenated exhibited higher group mean white blood cells after 4 weeks of treatment. However, the adverse effects evident at the 2.35 mg/L exposure level were minimal or absent at this exposure level.

Based on results in this study the No Observed Adverse Effect Level (NOAEL) of 1-tetradecene homopolymer hydrogenated, by-products from, C28-C42 fraction is considered to be 0.743 mg/L.

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