

SCREENING-LEVEL HAZARD CHARACTERIZATION

SPONSORED CHEMICAL

1-Decene, Tetramer, Mixed with 1-decene Trimer, Hydrogenated (CASRN 68649-12-7)

SUPPORTING CHEMICALS

(See Section 1)

The High Production Volume (HPV) Challenge Program¹ was conceived as a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsored chemicals; sponsorship entailed the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data did not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to “SIDS” (Screening Information Data Set^{1,2}) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency’s Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals by developing hazard characterizations (HCs). These HCs consist of an evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. They are not intended to be definitive statements regarding the possibility of unreasonable risk of injury to health or the environment.

The evaluation is performed according to established EPA guidance^{2,3} and is based primarily on hazard data provided by sponsors; however, in preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor’s responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge submission to the present: (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, IARC, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. OPPT’s focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available.

OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and

¹ U.S. EPA. High Production Volume (HPV) Challenge Program; <http://www.epa.gov/chemrtk/index.htm>.

² U.S. EPA. HPV Challenge Program – Information Sources; <http://www.epa.gov/chemrtk/pubs/general/guidocs.htm>.

³ U.S. EPA. Risk Assessment Guidelines; <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>.

Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments.

These hazard characterizations are technical documents intended to inform subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public.

<p>Chemical Abstract Service Registry Number (CASRN)</p>	<p style="text-align: center;"><u>Sponsored Chemical</u></p> <p style="text-align: center;">68649-12-7</p> <p style="text-align: center;"><u>Supporting Chemicals</u></p> <p style="text-align: center;">68037-01-4 151006-60-9 163149-28-8 151006-62-1</p>
<p>Chemical Abstract Index Name</p>	<p style="text-align: center;"><u>Sponsored Chemical</u></p> <p style="text-align: center;">1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated</p> <p style="text-align: center;"><u>Supporting Chemicals</u></p> <p style="text-align: center;">1-Decene, homopolymer, hydrogenated 1-Dodecene, polymer with 1-decene, hydrogenated 1-Dodecene, polymer with 1-decene and 1-octene, hydrogenated 1-Dodecene trimer, hydrogenated</p>
<p>Structural Formula</p>	<p style="text-align: center;">See Section 1</p>
<p style="text-align: center;">Summary</p> <p>CASRN 68649-12-7 is a clear, colorless liquid mixture with low vapor pressure and negligible water solubility. It is expected to have low mobility in soil. Volatilization of CASRN 68649-12-7 is considered high based on its Henry's Law constant; however, adsorption to suspended solids and sediment is expected to attenuate the rate of volatilization. The rate of hydrolysis is considered negligible due to the lack of hydrolyzable functional groups. The rate of atmospheric photooxidation is considered moderate. CASRN 68649-12-7 is expected to have low persistence (P1) and low bioaccumulation potential (B1).</p> <p>No data are available for the sponsored substance. Acute oral, inhalation and dermal toxicities of the supporting chemicals, CASRN 151006-60-9 and CASRN 151006-62-1 are low in rats. Acute oral toxicity of the supporting chemical, CASRN 163149-28-8, and acute inhalation toxicity of the supporting chemical, CASRN 68037-01-4, are low in rats. Repeated oral exposure to the supporting chemical, CASRN 68037-01-4, to rats for periods of 4 weeks</p>	

(gavage) or 90 days (dietary and gavage administration), showed no significant systemic effects. The NOAEL for systemic toxicity is 5000 mg/kg-day (4-week) and 1000 mg/kg-day (90-day) (highest dose tested). Repeated oral exposure to the supporting chemical, CASRN 151006-62-1, for 28 days, showed no significant treatment-related effects in rats. The NOAEL for systemic toxicity is 1000 mg/kg-day (highest dose tested). Repeated dermal exposures of the supporting chemical, CASRN 163149-28-8, for 4 weeks, showed no significant effects in rats up to 2000 mg/kg-day; the NOAEL for systemic toxicity is 2000 mg/kg-day (highest dose tested). In a combined oral repeated-dose/reproductive toxicity study in rats with the supporting chemical CASRN 68037-01-4, no reproductive toxicity was observed up to 1000 mg/kg-day; the NOAEL for reproductive toxicity is 1000 mg/kg-day. In a dermal prenatal developmental toxicity study in rats with the supporting chemical, CASRN 68037-01-4, no treatment-related effects were observed up to 2000 mg/kg-day. The NOAEL for maternal and developmental toxicity is 2000 mg/kg-day (highest dose tested). Available data for the supporting chemicals indicate negative results for genotoxicity. The supporting chemicals, CASRNs 151006-60-9, 163149-28-8 and 151006-62-1, were negative for gene mutations in bacteria *in vitro*. The supporting chemicals, CASRNs 163149-28-8 and 151006-62-1, were negative for chromosomal aberrations in mammalian cells *in vitro*. The supporting chemicals, CASRN 68037-01-4, CASRN 151006-60-9 and CASRN 151006-62-1, were negative for the induction of micronuclei *in vivo*.

No data are available for the sponsored substance. However, the low water solubility and high Log K_{ow} of CASRN 68649-12-7 is not expected to have any toxic effects on aquatic organisms.

No data gaps were identified under the HPV Challenge Program.

The sponsor, the American Chemistry Council Higher Olefins Panel, submitted a Test Plan and Robust Summaries to EPA for 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated (CASRN 68649-12-7; CA Index name: 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated) on December 20, 2001. EPA posted the submission on the ChemRTK HPV Challenge website on January 29, 2002 (<http://www.epa.gov/chemrtk/pubs/summaries/1dectmix/c13433tc.htm>). EPA comments on the original submission were posted to the website on September 9, 2002. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on October 4, 2002, which were posted to the ChemRTK website on February 5, 2008.

Justification for Supporting Chemicals

The sponsored substance (1-decene, tetramer, mixed with 1-decene trimer, hydrogenated, CASRN 68649-12-7) is a long chain branched alkane (a hydrogenated polyalphaolefin). In addition to data on the sponsored substance, the sponsor provided data for four closely related supporting chemicals, including 1-decene homopolymer, hydrogenated (decene homopolymer) (CASRN 68037-01-4); 1-decene/1-dodecene copolymer, hydrogenated (decene/dodecene copolymer) (CASRN 151006-60-9); 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated (octene/decene/dodecene copolymer) (CASRN 163149-28-8) and 1-dodecene trimer, hydrogenated (dodecene trimer) (CASRN 151006-62-1). Each supporting chemical contains long-chain branched alkanes, derived from C8, C10 and/or C12 alpha olefins. Based on similar molecular structures and comparable toxicological effects data, EPA agrees with the use of data for these supporting chemicals to address the data gaps for the sponsored substance.

1. Chemical Identity

1.1 Identification and Purity

The test plan states that decene tetramer/trimer is a long chain branched alkane (a hydrogenated polyalphaolefin). The predominant (~85%) and shortest oligomers present is a C30 chain, with a C40 oligomer comprising most of the remainder.

The chemical structures are summarized in Table 1.

Table 1: Sponsored and Supporting Chemical Structures

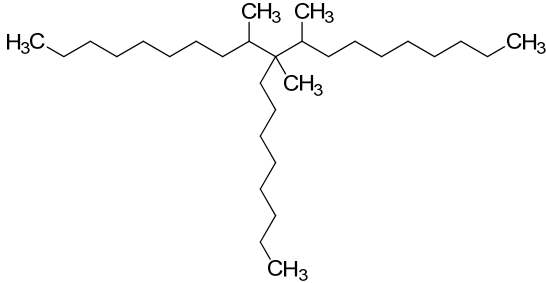
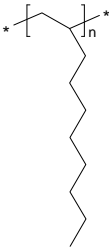
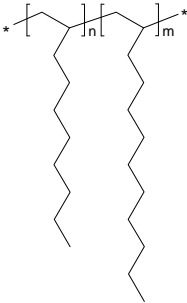
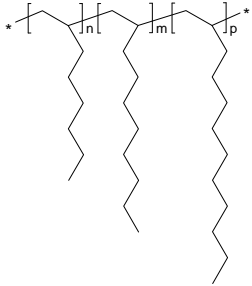
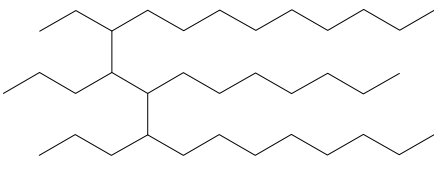
Chemical Abstract Index Name	CASRN	Structure
Sponsored Chemical		
1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated	68649-12-7	 <p style="text-align: center;">Representative trimer structure¹</p>
Supporting Chemicals		
1-Decene homopolymers, hydrogenated	68037-01-4	 <p style="text-align: center;">n is unknown</p>
1-Dodecene, polymer with 1-decene, hydrogenated	151006-60-9	 <p style="text-align: center;">n and m are unknown</p>
1-Dodecene, polymer with 1-decene and 1-octene, hydrogenated	163149-28-8	 <p style="text-align: center;">n, m and p are unknown</p>

Table 1: Sponsored and Supporting Chemical Structures

Chemical Abstract Index Name	CASRN	Structure
1-Dodecene trimer, hydrogenated	151006-62-1	

¹ 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated is a mixture of long chain branched alkanes prepared from hydrogenated oligomers of 1-decene (a hydrogenated polyalphaolefin [PAO]). The predominant and shortest oligomer present is a C30 trimer (~85%) with a C40 tetramer (~13%) and decene pentamers and higher (~2%) representing the remainder of the mixture. The representative structure used for 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated indicates the oligomerization reaction of 1-decene occurs at the beta position leaving secondary methyl groups. The SMILES notation used by the sponsor for estimation indicates the presence of 3 olefin bonds which is incorrect given the substance is hydrogenated. The sponsor does not provide a structure for the test substance elsewhere in the submitted documents.

1.2 Physical-Chemical Properties

The physical-chemical properties of 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated are summarized in Table 2.

1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated is a clear, colorless liquid mixture with a negligible water solubility and low vapor pressure.

Table 2. Physical-Chemical Properties of 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated ¹	
Property	Value
CASRN	68649-12-7
Molecular Weight	422.81
Physical State	Liquid, clear and colorless ²
Melting Point	-73°C (measured, pour point) ²
Boiling Point	>316°C (measured) ^{1,3} ; 414°C(measured) ²
Vapor Pressure	<0.1 mmHg at 20°C (measured); 1.7 mmHg at 177°C (measured) ²
Water Solubility	<0.1 parts per trillion (measured) ⁵ ; < 1.0×10 ⁻¹⁰ mg/L at 25°C (estimated) ⁴
Dissociation Constant (pK _a)	Not applicable
Henry's Law Constant	1.5×10 ³ atm·m ³ /mole (estimated) ⁴
Log K _{ow}	>7.0 (measured) ⁵ ; 14.82 (estimated) ⁴

Table 2. Physical-Chemical Properties of 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated¹

Property	Value
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¹ American Chemistry Council Higher Olefins Panel October 4, 2002. Revised Robust Summary and Test Plan for 1-Decene, Tetramer, Mixed with 1-Decene Trimer Hydrogenated. Available online from: <http://www.epa.gov/chemrtk/pubs/summaries/1dectmix/c13433tc.htm> as of May 20, 2010.

² Chevron Phillips Chemicals, Material Safety Data Sheet, Synfluid® 4 cSt PAO, CASRN 68649-12-7, Available online from: <http://www.dowpol.com/UploadFiles/2008610112842998.pdf> as of May 25, 2010.

³ The measured data submitted by the sponsor was generated using a test substance composed of decene trimers (85%), tetramers (13%), and pentamers and highr (2%).

⁴ U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online from: <http://www.epa.gov/opptintr/exposure/pubs/episuitedi.htm> as of May 20, 2010.

⁵ Sponsor cites as read across value for an analogous chemical, 1-dodecene trimer, hydrogenated (CASRN 151006-62-1)

2. General Information on Exposure

2.1 Production Volume and Exposure

CASRN 68649-12-7 had an aggregated production and/or import volume in the United States between 50 and 100 million pounds during calendar year 2005.

Industrial processing and use information as well as commercial and consumer use information of the chemical are claimed confidential in the 2006 IUR.

2.2 Environmental Exposure and Fate

The environmental fate properties of 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated are summarized in Table 3.

1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated is expected to have low mobility in soil. 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated was found not readily biodegradable using EPA Shake Flask Method (EPA 560/6-82-003, CG-2000) with unacclimated sewage/soil inoculum. Activated sludge was used as the inoculum at a concentration of 30 mg/L. Test substance concentrations of 10 and 20 mg/L were found to biodegrade 54% and 49% respectively after 28 days. Although these data do not meet the criteria to be considered readily biodegradable, the data show that 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated can biodegrade to an appreciable extent, which suggests that it will not persist in the environment. The rate of hydrolysis is considered negligible due to the lack of hydrolysable functional groups present in the representative structure. The potential for volatilization is considered high based on its Henry's Law constant; however, adsorption to suspended solids and sediment is expected to attenuate the rate at which this substance volatilizes. 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated is expected to have low persistence (P1) and low bioaccumulation potential (B1).

Table 3. Environmental Fate Characteristics of 1-Decene, tetramer, mixed with 1-decene trimer, hydrogenated¹	
Property	Value
Photodegradation Half-life	3.6 hours (estimated) ²
Hydrolysis Half-life	Stable
Biodegradation	49-54% degradation after 28 days (not readily biodegradable)
Bioaccumulation Factor	BAF = 6.2(estimated) ²
Log K _{oc}	8.2 (estimated) ²
Fugacity (Level III Model) ²	
Air (%)	2.0
Water (%)	45.8
Soil (%)	52.1
Sediment (%)	<0.1
Persistence ³	P1 (low)
Bioaccumulation ³	B1(low)

¹American Chemistry Council Higher Olefins Panel October 4, 2002. Revised Robust Summary and Test Plan for 1-Decene, Tetramer, Mixed with 1-Decene Trimer, Hydrogenated. Available online from: <http://www.epa.gov/chemrtk/pubs/summaries/1dectmix/c13433tc.htm> as of May 20, 2010.

²U.S. EPA. 2010. Estimation Programs Interface Suite™ for Microsoft® Windows, v4.00. U.S. Environmental Protection Agency, Washington, DC, USA. Available online from: <http://www.epa.gov/opptintr/exposure/pubs/episuite.dll.htm> as of May 25, 2010.

³Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

Conclusion: CASRN 68649-12-7 is a clear, colorless liquid mixture with low vapor pressure and negligible water solubility. It is expected to have low mobility in soil. Volatilization of CASRN 68649-12-7 is considered high based on its Henry's Law constant; however, adsorption to suspended solids and sediment is expected to attenuate the rate of volatilization. The rate of hydrolysis is considered negligible due to the lack of hydrolyzable functional groups. The rate of atmospheric photooxidation is considered moderate. CASRN 68649-12-7 is expected to have low persistence (P1) and low bioaccumulation potential (B1).

3. Human Health Hazard

No health effects data were submitted for the sponsored substance. A summary of health effects data submitted for SIDS endpoints is provided in Table 4.

Acute Oral Toxicity

1-Decene/1-dodecene copolymer, hydrogenated (CASRN 151006-60-9, supporting chemical)
Sprague-Dawley rats (5/sex/dose) were administered 1-decene/1-dodecene copolymer, hydrogenated via gavage at 5000 mg/kg-bw and observed for 14 days. There were no mortalities.

LD₅₀ > 5000 mg/kg-bw

1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CASRN 163149-28-8, supporting chemical)

Sprague-Dawley rats (5/sex/dose) were administered 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated via gavage at 2000 mg/kg-bw and observed for 14 days. There were no mortalities.

LD₅₀ > 2000 mg/kg-bw

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

Sprague-Dawley rats (5/sex/dose) were administered 1-dodecene trimer, hydrogenated via gavage at 5000 mg/kg-bw and observed for 14 days. There were no mortalities.

LD₅₀ > 5000 mg/kg-bw

Acute Dermal Toxicity

1-Decene/1-dodecene copolymer, hydrogenated (CASRN 151006-60-9, supporting chemical)

Sprague-Dawley rats (5/sex/dose) were administered 1-decene/1-dodecene copolymer, hydrogenated via the dermal route at 2000 mg/kg-bw under semi-occlusive conditions for 24 hours and observed for 14 days. There were no mortalities.

LD₅₀ > 2000 mg/kg-bw

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

Sprague-Dawley rats (5/sex/dose) were administered 1-dodecene trimer, hydrogenated via the dermal route at 2000 mg/kg-bw under semi-occlusive conditions for 24 hours and observed 14 days. There were no mortalities.

LD₅₀ > 2000 mg/kg-bw

Acute Inhalation Toxicity

1-Decene homopolymer, hydrogenated (CASRN 68037-01-4, supporting chemical)

Sprague-Dawley rats (10/sex/concentration) were exposed to 1-decene homopolymer, hydrogenated at mean aerosol (mass median aerodynamic diameter of 1.1 µm) concentrations of 0, 0.48 or 2.5 mg/L for 4 hours. Half of the animals in each group were sacrificed the day after exposure and necropsied; the remaining animals were observed for 14 days and then sacrificed. There were no mortalities.

LC₅₀ > 2.5 mg/L

1-Decene/1-dodecene copolymer, hydrogenated (CASRN 151006-60-9, supporting chemical)

Sprague-Dawley rats (5/sex/concentration) were exposed (nose-only) to 1-decene/1-dodecene copolymer, hydrogenated at an aerosol (mass median aerodynamic diameter of 1.3 µm) at a single concentration of 5.0 mg/L for 4 hours and observed for 14 days. There were no mortalities.

LC₅₀ > 5.0 mg/L

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

Sprague-Dawley rats (5/sex/concentration) were exposed (nose-only) to 1-dodecene trimer, hydrogenated at an aerosol (mass median aerodynamic diameter of 1.2 µm) concentration of

5.06 mg/L for 4 hours and observed for 14 days. There were no mortalities.

LC₅₀ > 5.06 mg/L

Repeated-Dose Toxicity

1-Decene homopolymer, hydrogenated (CASRN 68037-01-4, supporting chemical)

(1) In a 4-week range-finding study, female Sprague-Dawley rats (5/dose) were administered 1-decene homopolymer, hydrogenated via gavage at 0, 500, 2500 or 5000 mg/kg-day, 5 days/week. No deaths occurred and no changes in body weight were observed. The only clinical signs that could be attributed treatment were oily staining around the anus and soft stool. No gross pathological changes were observed in any group. Histological evaluations of the liver revealed no adverse effects.

NOAEL = 5000 mg/kg-day (highest dose tested)

(2) In a 90-day study, Sprague-Dawley rats (20/sex/dose) were administered 1-decene homopolymer, hydrogenated via the diet at 0, 500, 5000 or 20,000 ppm (~ 0, 25, 250 and 1000 mg/kg-day). No mortality or clinical signs indicative of toxicity were observed. 1-Decene homopolymer, hydrogenated did not adversely affect body weight gain, food consumption, urinalysis, ophthalmology or hematology. A linear relationship was found between dose and serum level for albumin/globulin ratio in males and between dose and inorganic phosphorus level in females, which was considered statistically significant. The biological significance of this finding is not clear. There were no changes in organ weights and no changes on the enteric tract were observed. None of the major organs or major organ systems, including male and female reproductive organs, showed any treatment-related changes.

NOAEL ~ 1000 mg/kg-day (highest dose tested)

(3) In a 90-day study, Fischer 344 rats (10/sex/dose) were administered 1-decene homopolymer, hydrogenated via the diet at 0, 200 or 20,000 ppm (~ 0, 10 or 1000 mg/kg-day). Aside from two animals that died during the 13-week blood collection, all animals survived until the end of the study. No clinical signs or changes in food consumption, body weight gain, ophthalmology or hematology were observed. Statistically significant differences in the serum chemistry data (glucose in males and sodium, phosphorus and calcium in females) were observed with treatment (level of significance not stated). The differences were considered marginal and the biological significance was unclear. There were no treatment-related changes in the liver or mesenteric lymph nodes.

NOAEL ~ 1000 mg/kg-day (highest dose tested)

(4) In a combined repeated-dose/reproductive toxicity screening test, Sprague-Dawley rats (30/sex/dose for F0 and 20/sex/dose for F1) were administered 1-decene homopolymer, hydrogenated in polyethylene glycol 400 via gavage at 0, 100, 500 or 1000 mg/kg-day, 7 days/week. F0 males were dosed for 4 weeks prior to mating and through the 15-day mating period and F0 females were dosed from 4 weeks prior to mating, through pregnancy and until day 20 post-partum. Offspring were dosed for 91 days starting on day 22 post-partum. No treatment-related toxicity was observed in the F0 rats. The F1 pups did not demonstrate any treatment-related toxicity during parturition and lactation. In the F1 rats during the 91-day toxicity phase, clinical observations representing minor gastrointestinal disturbances were seen

in all groups and were judged to be vehicle-related. No treatment-related clinical observations were noted. A significant increase in prothrombin time was seen in high-dose males; however, this change did not correlate with a decrease in platelets, gross necropsy findings or any histopathological lesions. There was no evidence of any adverse effects on clinical observations, organ weights, gross toxicity or histopathology, clinical chemistry or hematology endpoints.
NOAEL = 1000 mg/kg-day (highest dose tested)

1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CASRN 163149-28-8, supporting chemical)

In a 4-week study, Sprague-Dawley rats (10/sex/dose) were administered 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated via the dermal route at 0, 125, 500 or 2000 mg/kg-day, under unocclusive conditions 5 days/week. Two additional groups, one control and one high-dose, were included and allowed a 2-week recovery period. No dermal irritation was observed at exposure sites. There were no effects on food consumption during the study. During the fourth week of the study, male rats had significantly decreased body weight, higher neutrophil counts (level of significance not stated) and changes in 7 of 20 serum chemistry parameters (satellite group only). Following the recovery period, no changes in hematological parameters were observed in control or treated animals: females showed statistical differences between controls and treated animals for two serum chemistry parameters. No macroscopic findings were noted at necropsy in the treated groups or groups allowed recovery periods. Microscopic changes were limited to the skin, which showed an increased incidence of hyperplasia and hyperkeratosis in treated and control animals.

NOAEL = 2000 mg/kg-day (highest dose tested)

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

In a 28-day study, Sprague-Dawley rats (5/sex/dose) were administered 1-dodecene trimer, hydrogenated via gavage at 0 or 1000 mg/kg-day for 28 days. Two additional groups, one control and one high-dose, were included and allowed a 2-week recovery period following the dosing period. There were no deaths, clinical signs of toxicity or effects on body weight, food consumption, water consumption, hematology, blood chemistry or organ weights. No treatment-related effects were observed at necropsy and no histopathological effects were observed.

NOAEL = 1000 mg/kg-day (highest dose tested)

Reproductive Toxicity

1-Decene homopolymer, hydrogenated (CASRN 68037-01-4, supporting chemical)

In the combined repeated-dose/reproductive toxicity screening test previously described, there were no treatment-related effects on any of the reproductive parameters evaluated, including reproductive performance (mating, conception and fertility, time to mating, gestation length, litter size), offspring survival (gestation and postnatal survival indices, percent pre- and post-implantation loss), pup body weight and pup sex ratio. No treatment-related effects on reproductive organ weight or histopathology were seen in the 91-day toxicity study with F1 animals.

NOAEL (reproductive toxicity) = 1000 mg/kg-day (highest dose tested)

Developmental Toxicity

1-Decene homopolymer, hydrogenated (CASRN 68037-01-4, supporting chemical)

Pregnant Sprague-Dawley rats (15/dose) were administered 1-decene homopolymer, hydrogenated via the dermal route at 0, 800 or 2000 mg/kg-day on gestation days 0 – 19. Rats in the treatment groups showed minimal, if any, irritation at the site of application. There were no treatment-related effects on food consumption during gestation. There was a significant (significance not stated) smaller weight gain during gestation days 13 – 16 at 2000 mg/kg-day; however, the overall weight gain during gestation was not significantly different between controls and treated animals. Serum triglycerides and albumin showed significant (significance not stated) changes between control and treated groups; the significance of which is not clear. At necropsy, there were no findings attributable to exposure. Reproductive performance, *in utero* survival and development of the offspring were not affected by treatment. Individual body weights and crown-rump lengths of the fetuses were not altered by treatment. External, visceral and skeletal examinations of the fetuses did not reveal any remarkable findings.

NOAEL (maternal and developmental toxicity) = 2000 mg/kg-day (highest dose tested)

Genetic Toxicity - Gene mutation

In vitro

1-Decene/1-dodecene copolymer, hydrogenated (CASRN 151006-60-9, supporting chemical)

In a reverse-mutation assay, *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 and *Escherichia coli* strain WP2uvrA- were exposed to 1-decene/1-dodecene copolymer, hydrogenated in 25% w/w Pluronic F127 in ethanol at 0, 15, 50, 150, 500, 1500 or 5000 µg/plate in the presence or absence of metabolic activation. Vehicle, negative and positive controls were tested concurrently and responded appropriately. The cytotoxic concentration was > 5000 µg/plate. 1-Decene/1-dodecene copolymer, hydrogenated did not induce increased frequency of revertant colonies either with or without metabolic activation.

CASRN 151006-60-9 was not mutagenic in this assay.

1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CASRN 163149-28-8, supporting chemical)

In a reverse-mutation assay, *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98 and TA100 were exposed to 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated at 0.1, 0.3, 1.0, 3.0 or 10.0 µL/50 µL tetrahydrofuran (THF) vehicle per plate in the presence or absence of metabolic activation. Vehicle and positive controls were tested concurrently and responded appropriately. Cytotoxicity was not observed. None of the strains exhibited reversion frequencies that were substantially different from spontaneous or solvent controls in two independent assays.

CASRN 163149-28-8 was not mutagenic in this assay.

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

(1) *Salmonella typhimurium* strains TA1535, TA1537, TA98 and TA100 and *Escherichia coli* strain WP2uvrA- were exposed to 1-dodecene trimer, hydrogenated in 25% w/w Pluronic F127 in ethanol at 0, 15, 50, 150, 500, 1500 or 5000 µg/plate in the presence and absence of metabolic activation. Vehicle, negative and positive controls were tested concurrently and responded

appropriately. Precipitation occurred at or above 1500 µg/plate. The cytotoxic concentration was greater than 5000 µg/plate. No increase in the frequency of revertant colonies was recorded for any of the bacterial strains tested at any concentration of the test substance with or without metabolic activation.

CASRN 151006-62-1 was not mutagenic in this assay.

(2) Chinese hamster ovary (CHO) cells were exposed to 1-dodecene trimer, hydrogenated in ethanol, at 313, 625, 1250, 2500 or 5000 µg/mL for 4 hours in the presence or absence of metabolic activation. The cytotoxic concentration was greater than 5000 µg/mL. Positive and vehicle controls were conducted concurrently and responded appropriately. A significant increase in mutant frequency was observed at 625 and 2500 µg/mL with activation, but was not dose-dependent and was within historical control range.

CASRN 151006-62-1 was not mutagenic in this assay.

Genetic Toxicity - Chromosomal aberrations

In vitro

1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CASRN 163149-28-8, supporting chemical)

CHO cells were exposed to 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated in tetrahydrofuran (THF) at 0.1, 0.2 or 0.4 µL/mL in the presence or absence of metabolic activation. Cells were exposed to 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated for 2 hours in the presence of metabolic activation and harvested after 16 hours. Cells that were not exposed to metabolic activation were continually exposed to 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated in THF until cell harvest. A confirmatory test was conducted with delayed (40-hour) harvest. No increase in the proportion of cells with chromosomal aberrations was observed compared to controls. Positive and vehicle controls were tested concurrently and responded appropriately.

CASRN 163149-28-8 did not induce chromosomal aberrations in this assay.

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

Human lymphocytes were exposed to 1-dodecene trimer, hydrogenated in ethanol at 39, 78.1, 156.25, 312.5, 625, 1250, 2500 or 5000 µg/mL in the presence or absence of metabolic activation. Cultures with metabolic activation were treated for 4 hours and harvested after 16 additional hours. Cultures without activation were exposed continuously for 20 hours. In a confirmatory experiment, cultures with activation were exposed for 4 hours and harvested 16 and 40 hours later. Positive and vehicle controls were conducted concurrently and responded appropriately. 1-Dodecene trimer, hydrogenated did not induce increased frequency of chromosomal aberrations in any of the tests either with or without metabolic activation.

CASRN 151006-62-1 did not induce chromosomal aberrations in this assay.

In vivo

1-Decene homopolymer, hydrogenated (CASRN 68037-01-4, supporting chemical)

Rats (15/sex/dose; strain not specified) were administered 1-decene homopolymer, hydrogenated via the dermal route at 0, 800 or 2000 mg/kg-day, 5 days/week for 13 weeks. At the end of the 13-week period, tissues were harvested for micronucleus evaluation. Femurs were taken from

five rats/sex/dose and peripheral blood smears were made. 1-Decene homopolymer, hydrogenated was not cytotoxic to red blood cell formation. 1-Decene homopolymer, hydrogenated did not induce increases in micronucleated polychromatic or normochromatic erythrocytes at either dose level.

CASRN 68037-01-4 did not induce formation of micronuclei in this assay.

1-Decene/1-dodecene copolymer, hydrogenated (CASRN 151006-60-9, supporting chemical)

CD-1 mice (5/sex/dose) were administered 1-decene/1-dodecene copolymer, hydrogenated (in arachis oil vehicle) via the intraperitoneal route at 1250, 2500 or 5000 mg/kg-bw and sacrificed at 24, 48 and 72 hours after dosing. There were no premature deaths or clinical signs of toxicity observed at any dose level. Positive and vehicle controls were tested concurrently and responded appropriately. A significant increase in the frequency of micronucleated polychromatic erythrocytes was recorded in the 5000 mg/kg dose group sacrificed at 24 hours; however, this increase was within the range of historical controls. 1-Decene/1-dodecene copolymer, hydrogenated did not increase the frequency of micronucleated polychromatic erythrocytes.

CASRN 151006-60-9 did not induce formation of micronuclei in this assay.

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

CD-1 mice (5/sex/dose) were administered 1-dodecene trimer, hydrogenated (in arachis oil vehicle) via the intraperitoneal route at 1250, 2500 or 5000 mg/kg-bw and sacrificed at 24, 48 and 72 hours after dosing. No premature deaths or clinical signs of toxicity were observed at any dose. Positive and vehicle controls were tested concurrently and responded appropriately. A significant increase in the frequency of micronuclei occurred in the 24-hour 5000 mg/kg-bw test group, but this value was within the range of historical controls and therefore not considered to be dose-related.

CASRN 151006-62-1 did not induce formation of micronuclei in this assay.

Additional Information

Carcinogenicity

1-Decene homopolymer, hydrogenated (CASRN 68037-01-4, supporting chemical)

Male C3H mice (50/group) were administered 1-decene homopolymer, hydrogenated via the dermal route at a dose of 50 μ L/application to the interscapular skin twice weekly for 104 weeks. Negative and positive controls were tested concurrently. No treatment-related tumors were seen. In the negative control group, no primary skin tumors developed. The summary indicated that changes in the skin were minimal and nonspecific. Some hyperplasia was observed and deemed to be due to repeated hair removal. In the positive controls, 47 of 50 mice developed skin tumors. Survival in the treated group (56%) was higher than in the control group (42%). In the treated group, skin changes were similar to the negative controls.

CASRN 68037-01-4 did not increase the incidence of tumors in this study.

Conclusion: No data are available for the sponsored substance. Acute oral, inhalation and dermal toxicities of the supporting chemicals, CASRN 151006-60-9 and CASRN 151006-62-1 are low in rats. Acute oral toxicity of the supporting chemical, CASRN 163149-28-8, and acute inhalation toxicity of the supporting chemical, CASRN 68037-01-4, are low in rats. Repeated

oral exposure to the supporting chemical, CASRN 68037-01-4, to rats for periods of 4 weeks (gavage) or 90 days (dietary and gavage administration), showed no significant systemic effects. The NOAEL for systemic toxicity is 5000 mg/kg-day (4-week) and 1000 mg/kg-day (90-day) (highest dose tested). Repeated oral exposure to the supporting chemical, CASRN 151006-62-1, for 28 days, showed no significant treatment-related effects in rats. The NOAEL for systemic toxicity is 1000 mg/kg-day (highest dose tested). Repeated dermal exposures of the supporting chemical, CASRN 163149-28-8, for 4 weeks, showed no significant effects in rats up to 2000 mg/kg-day; the NOAEL for systemic toxicity is 2000 mg/kg-day (highest dose tested). In a combined oral repeated-dose/reproductive toxicity study in rats with the supporting chemical CASRN 68037-01-4, no reproductive toxicity was observed up to 1000 mg/kg-day; the NOAEL for reproductive toxicity is 1000 mg/kg-day. In a dermal prenatal developmental toxicity study in rats with the supporting chemical, CASRN 68037-01-4, no treatment-related effects were observed up to 2000 mg/kg-day. The NOAEL for maternal and developmental toxicity is 2000 mg/kg-day (highest dose tested). Available data for the supporting chemicals indicate negative results for genotoxicity. The supporting chemicals, CASRNs 151006-60-9, 163149-28-8 and 151006-62-1, were negative for gene mutations in bacteria *in vitro*. The supporting chemicals, CASRNs 163149-28-8 and 151006-62-1, were negative for chromosomal aberrations in mammalian cells *in vitro*. The supporting chemicals, CASRN 68037-01-4, CASRN 151006-60-9 and CASRN 151006-62-1, were negative for the induction of micronuclei *in vivo*.

**Table 4. Summary Table of the Screening Information Data Set
as submitted under the U.S. HPV Challenge Program – Human Health Data**

Endpoints	SPONSORED CHEMICAL Decene, tetramer, mixed with 1 decene trimer, hydrogenated (68649-12-7)	SUPPORTING CHEMICAL 1-Decene homopolymer, hydrogenated (68037-01-4)	SUPPORTING CHEMICAL 1-Decene/1- dodecene copolymer, hydrogenated (151006-60-9)	SUPPORTING CHEMICAL 1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (163149-28-8)	SUPPORTING CHEMICAL 1-Dodecene trimer, hydrogenated (151006-62-1)
Acute Oral Toxicity LD₅₀ (mg/kg-bw)	No Data >2000 (RA)	–	> 5000	> 2000	> 5000
Acute Dermal Toxicity LD₅₀ (mg/kg-bw)	No Data >2000 (RA)	–	> 2000	–	> 2000
Acute Inhalation Toxicity LC₅₀ (mg/L)	No Data >2.5 (RA)	> 2.5	> 5.0	–	> 5.06

**Table 4. Summary Table of the Screening Information Data Set
as submitted under the U.S. HPV Challenge Program – Human Health Data**

Endpoints	SPONSORED CHEMICAL Decene, tetramer, mixed with 1 decene trimer, hydrogenated (68649-12-7)	SUPPORTING CHEMICAL 1-Decene homopolymer, hydrogenated (68037-01-4)	SUPPORTING CHEMICAL 1-Decene/1- dodecene copolymer, hydrogenated (151006-60-9)	SUPPORTING CHEMICAL 1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (163149-28-8)	SUPPORTING CHEMICAL 1-Dodecene trimer, hydrogenated (151006-62-1)
Repeated-Dose Toxicity NOAEL/LOAEL Rat Oral (mg/kg-day)	No Data NOAEL = 1000 (RA)	(28-day gavage) NOAEL = 5000 (highest dose tested) (90-day gavage) NOAEL = 1000 (highest dose tested) (90-day diet) NOAEL ~ 1000 (highest dose tested)	–	–	(28-day gavage) NOAEL = 1000 (highest dose tested)
Repeated-Dose Toxicity NOAEL/LOAEL Dermal (mg/kg-day)	No Data NOAEL = 2000 (RA)	–	–	(28-day) NOAEL = 2000 (highest dose tested)	–
Reproductive Toxicity Oral (mg/kg-day) Reproductive and Systemic Toxicity	No Data NOAEL = 1000 (RA)	NOAEL = 1000 (highest dose tested)	–	–	–

**Table 4. Summary Table of the Screening Information Data Set
as submitted under the U.S. HPV Challenge Program – Human Health Data**

Endpoints	SPONSORED CHEMICAL Decene, tetramer, mixed with 1 decene trimer, hydrogenated (68649-12-7)	SUPPORTING CHEMICAL 1-Decene homopolymer, hydrogenated (68037-01-4)	SUPPORTING CHEMICAL 1-Decene/1- dodecene copolymer, hydrogenated (151006-60-9)	SUPPORTING CHEMICAL 1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (163149-28-8)	SUPPORTING CHEMICAL 1-Dodecene trimer, hydrogenated (151006-62-1)
Developmental Toxicity Dermal (mg/kg-day) Developmental and Maternal Toxicity	No Data NOAEL = 2000 (RA)	NOAEL = 2000 (highest dose tested)	–	–	–
Genetic Toxicity – Gene Mutation <i>In vitro</i>	No Data Negative (RA)	–	Negative	Negative	Negative
Genetic Toxicity – Chromosomal Aberrations <i>In vitro</i>	No Data Negative (RA)	–	–	Negative	Negative
Genetic Toxicity – Chromosomal Aberrations <i>In vivo</i>	No Data Negative (RA)	Negative	Negative	–	Negative
Additional Information Carcinogenicity	–	Negative (male mice)	–	–	–

Measured data in bold text; – indicates that endpoint was not addressed for this chemical; (RA) = read across

4. Hazard to the Environment

No data were submitted for the sponsor substance, 1-decene, tetramer, mixed with 1-decene trimer, hydrogenated. A summary of aquatic toxicity data submitted for SIDS endpoints is provided in Table 5.

Acute Toxicity to Fish

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

Rainbow trout (*Oncorhynchus mykiss*) were exposed to 1-dodecene trimer, hydrogenated as water accommodated fractions (WAFs) under semi-static conditions for 96 hours. In a range-finding study, no mortalities were observed at loading rates of 100 or 1000 mg/L. In the definitive study, the loading rate was 1000 mg/L and total organic carbon (TOC) analysis of the WAF showed no significant levels of carbon compared to controls. No effects were noted at the 1000 mg/L loading rate.

No effects at saturation.

Acute Toxicity to Aquatic Invertebrates

1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CASRN 163149-28-8, supporting chemical)

Water fleas (*Daphnia magna*) were exposed to 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated as WAFs under static conditions for 48 hours. The loading rates were of 0, 360, 630, 1350, 2610 or 5220 mg/L and analytical measurements were below the limit of quantitation (2 mg/L). No effects were noted at any of the WAF loading rates.

No effects at saturation.

1-Dodecene trimer, hydrogenated (CASRN 151006-62-1, supporting chemical)

Water fleas (*Daphnia magna*) were exposed to 1-dodecene trimer, hydrogenated as WAFs under static conditions for 48 hours. In a range-finding study, no mortalities were observed at loading rates of 100 or 1000 mg/L. In the definitive study, the loading rate was 1000 mg/L and TOC analysis of the WAF showed no significant levels of carbon compared to the controls. No effects were noted at the 1000 mg/L loading rate.

No effects at saturation.

Toxicity to Aquatic Plants

1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (CASRN 163149-28-8, supporting chemical)

Green algae (*Pseudokirchneriella subcapitata*) were exposed to 1-octene, 1-decene, 1-dodecene copolymer, hydrogenated as WAFs under static conditions for 72 hours. The loading rates were 0, 360, 630, 1350, 2610 or 5220 mg/L and mean measured concentrations were below the limit of quantitation (2 mg/L). No effects were noted at any of the WAF loading rates and a stimulatory response was seen at ≥ 630 mg/L.

No effects at saturation.

Conclusion: No data are available for the sponsored substance. However, the low water solubility and high Log K_{ow} CASRN 68649-12-7 is not expected to have any toxic effects on aquatic organisms.

Table 5. Summary Table of the Screening Information Data Set as submitted under the U.S. HPV Challenge Program – Aquatic Toxicity Data			
Endpoints	SPONSORED CHEMICAL Decene, tetramer, mixed with 1 decene trimer, hydrogenated (68649-12-7)	SUPPORTING CHEMICAL 1-Octene, 1-decene, 1-dodecene copolymer, hydrogenated (163149-28-8)	SUPPORTING CHEMICAL 1-Dodecene trimer, hydrogenated (151006-62-1)
Fish 96-h LC₅₀ (mg/L)	No Data NES (RA)	–	NES
Aquatic Invertebrates 48-h EC₅₀ (mg/L)	No Data NES (RA)	NES	NES
Aquatic Plants 72-h EC₅₀ (mg/L) (growth) (biomass)	No Data NES NES (RA)	NES	–

– indicates that endpoint was not addressed for this chemical; (RA) = read across; NES = no effects at saturation