High Production Volume (HPV) Challenge Program

Revised Test Plan
for

Petroleum Oxidates and Derivatives Thereof
Category

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1.0 Introduction

On November 30, 2000, the Lubrizol Corporation committed to provide basic toxicity information on chemicals listed under the Environmental Protection Agency (EPA) High Production Volume (HPV) Chemical Challenge Program. The eight sponsored chemicals addressed in this test plan are:

- 64742-98-9 Distillates (petroleum), oxidized light
- 64743-00-6 Hydrocarbon waxes (petroleum), oxidized
- 64743-01-7 Petrolatum (petroleum), oxidized
- 68425-34-3 Petrolatum (petroleum), oxidized, Ca salt
- 68602-85-7 Hydrocarbon waxes (petroleum), oxidized, Me esters
- 68603-10-1 Hydrocarbon waxes (petroleum), oxidized, Me esters, Ba salts
- 68603-11-2 Hydrocarbon waxes (petroleum), oxidized, Me esters, Ca salts
- 68603-12-3 Hydrocarbon waxes (petroleum), oxidized, Me esters, Na salts

The process of evaluating the members of the "Petroleum Oxidates and Derivatives Thereof" category entailed the following stepwise process:

- grouping of chemicals into a putative category
- gathering relevant data for each member of the category
- evaluating the physico-chemical, environmental, aquatic, and health effect patterns to confirm adequacy of category
- construction of a matrix of SIDS endpoints for category members
- identification of data gaps for critical endpoints within the category

2.0 Development of Oxidates and Derivatives thereof Category

The HPV Challenge Program encourages the development of chemical categories as an economic, animal sparing, and efficient way to complete the program goals. The EPA guidance document, Development of Chemical categories states, "a chemical category is a group of chemicals whose physicochemical and toxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity. The similarities should be based on a common functional group, common precursors or breakdown products (resulting in structurally similar chemical) and an incremental and constant change across the category." A goal of this category analysis document is to use interpolation and/or extrapolation to untested members to reduce the amount of additional testing needed to complete the SIDS requirements.

2.1 Chemical identity

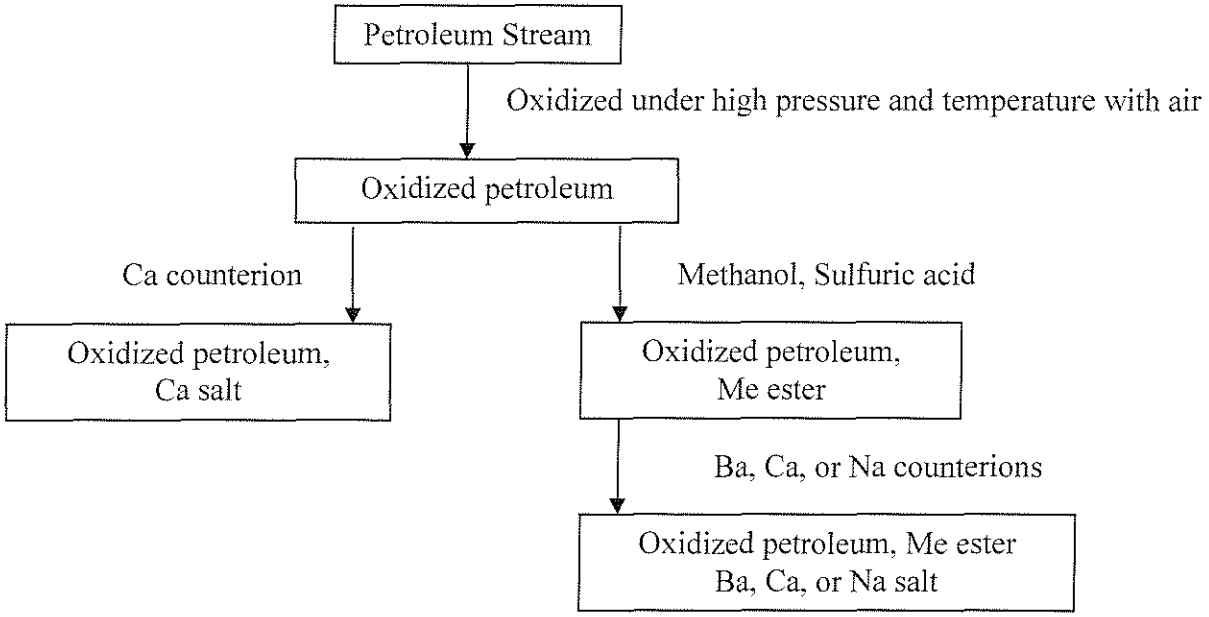
The members of this test plan are petroleum oxidates, oxidized methyl esters, and their salts, which are derived from aliphatic hydrocarbons. The petroleum oxidates vary in molecular weight, which is determined by the starting raw material and the extent of oxidation. The petroleum oxidates described in this test plan are derived from slack wax, petrolatum, or petroleum distillate. The slack wax and petrolatum starting materials range in chain length from C33 to C43 while the petroleum distillate starting material ranges in chain length from C9-C16. There are distinct differences between the petroleum oxidates derived from the slack wax or petrolatum and the light petroleum distillate. These differences

become apparent when comparing their physicochemical properties. Due to the apparent differences in physicochemical properties between the oxidates derived from the slack wax or petrolatum and the oxidates derived from the petroleum distillate, the members of this test plan are divided into two subcategories. Subcategory 1 contains the light oxidized distillate (64742-98-9) derived from the lower molecular weight petroleum distillate. Subcategory 2 contains the petroleum oxidates and derivatives (64743-00-6, 64743-01-7, 68425-34-3, 68602-85-7, 68603-10-1, 68603-11-2, 68603-12-3) derived from the higher molecular weight slack wax and petrolatum.

All of the petroleum oxidates described in this test plan are produced by controlled, liquid phase, partial oxidation using atmospheric air as the oxygen source. Oxidation of the petroleum hydrocarbon is an exothermic reaction, performed under high temperature and pressure.

The typical composition of the petroleum oxidate in subcategory 1 is 50% unreacted petroleum starting material, 10% carboxylic acid (mono- and di-), 25% ketone, the remainder of the composition consists of oxyacids, aldehydes, and methyl ester. The typical composition of the petroleum oxidates in subcategory 2 (64743-01-7 and 64743-00-6) is 40-50% unreacted petroleum starting material, 30-35% monocarboxylic acid, the remainder of the composition consists of dicarboxylic acids, oxyacids, aldehydes, and ketones. The oxidized methyl ester, 68602-85-7, is created by an esterification reaction of the petroleum oxidate using methanol and sulfuric acid. The product of this reaction is a mixture of methyl esters, unreacted starting material, mono and di- carboxylic acids, oxyacids, aldehydes, and ketones. The oxidized petroleum or the oxidized methyl ester intermediates are reacted with Ba, Ca, and Na counterions to form the oxidized salt. The counterions act to neutralize the carboxylic acid functional groups. The typical production process is shown in figure 1.

Figure 1 Production process for oxidate derivatives



2.2 Uses of Petroleum Oxidates and Derivatives Thereof

The properties of the oxidates and their derivatives that make them useful are their ability to repel and displace water. They have excellent lubricity and corrosion protection properties. The oxidates 64742-98-9, 64743-01-7, and 64743-00-6 are used primarily as intermediates. The salt derivatives and the methyl ester derivatives are useful in preparing oil soluble and water dispersing soaps. These soaps are applied to coiled steel and steel sheets to prevent corrosion before receiving a final paint. They are also used as rust preventatives in a variety of other applications. The petroleum oxidates can be used to replace natural fats and oils in the formulation of cutting, drawing, and rolling oils.

3.0 Physical and Chemical Properties

The light petroleum oxidate in subcategory 1 is a liquid at room temperature. The petroleum oxidates and derivatives in subcategory 2 are solids or waxy solids at room temperature. The difference in the physical state of the member in subcategory 1 is due to its variation in carbon chain length of the starting material and the oxidation products. This also accounts for its difference in melting point, boiling point, vapor pressure, octanol water partition coefficient, and water solubility in comparison to the members in subcategory 2. The differences in the physicochemical properties between the members of subcategory 1 and 2 justifies separating these materials into two separate subcategories.

3.1 Melting Point

There is melting point data available for seven of the eight members of this test plan (Table 1). The melting point for the light petroleum oxidate in subcategory 1 is - 31.03 deg C. The melting point for the petroleum oxidates and derivatives in subcategory 2 range from 33.64 to 49.87 deg. C. The untested member 68603-12-3, oxidized Me ester Na salt, is expected to have a melting point similar to 68603-10-1 and 38603-11-2, the oxidized Me ester Ba salt and Ca salt respectively. There is sufficient melting point data available for the members of this test plan; therefore, additional testing is not required.

3.2 Boiling Point Range

There is boiling point range data available for seven of the eight members of this test plan (Table 1). The petroleum oxidate in subcategory 1 has a boiling point range of 196 to 842 deg F. The petroleum oxidates and derivatives in subcategory 2 have a boiling point range from 379 to >1200 deg F. The untested member 68603-12-3, oxidized Me ester Na salt, is expected to have a boiling point range similar to 68603-10-1 and 38603-11-2, the oxidized Me ester Ba salt and Ca salt respectively. There is sufficient boiling point data available for the members of this test plan; therefore, additional testing is not required.

3.3 Vapor Pressure

There is vapor pressure data available for seven of the eight members of this test plan (Table 1). The petroleum oxidate in subcategory 1 has a vapor pressure of 69 Pa at 25 deg C. The petroleum oxidates and derivatives in subcategory 2 have a

vapor pressure less than 1Pa at 25 deg C. The untested member 68603-12-3, oxidized Me ester Na salt, is expected to have a vapor pressure similar to 68603-10-1 and 38603-11-2, the oxidized Me ester Ba salt and Ca salt respectively. There is sufficient vapor pressure data available for the members of this test plan; therefore, additional testing is not required.

3.4 Partition Coefficient

The octanol water partition coefficient could not be measured for the members of this test plan using OECD guideline 107. This test method would not accurately depict the octanol water partition coefficient of the members of this category because they are Class 2 substances containing a mixture of hydrophilic and hydrophobic materials. The hydrophilic acids partitioned into the water phase while the hydrophobic, aliphatic hydrocarbons and methyl esters partitioned into the octanol phase giving a distorted value for the octanol water partition coefficient. Due to the complex composition of these materials, a definitive octanol water partition coefficient value can not be made. The calculated octanol water coefficient for the raw material, light petroleum distillate, is 3.3 to 7.06 (ASTDR, 1995). The petroleum oxidate in subcategory 1 is expected to have a similar octanol water partition coefficient to this starting raw material. The members in subcategory 2 are expected to have an octanol water partition coefficient similar to that of their starting materials. The HPV test plan for waxes and related materials indicates that petrolatum and slack wax have an octanol water coefficient greater than 4.9 (The Petroleum HPV Testing Group, 2002).

3.5 Water Solubility

There is water solubility data available for seven of the eight members of this test plan (Table 1). The petroleum oxidate in subcategory 1 has a water solubility of 59.34 ppm at 25 deg C. The petroleum oxidates and derivatives in subcategory 2 have very low water solubilities that range from 0.35 to 1.29 ppm at 25 deg C. The untested member 68603-12-3, oxidized Me ester Na salt, is expected to have a water solubility similar to 68603-10-1 and 38603-11-2, the oxidized Me ester Ba salt and Ca salt respectively. There is sufficient water solubility data available for the members of this test plan; therefore, additional testing is not required.

Table 1 Physicochemical Properties

CAS #	Avg. MW	Melting Point deg C	Boiling Point Range deg F	Vapor Pressure at 25 C	Partition Coefficient	Water Solubility at 25 C
Subcategory 1						
64742-98-9	285	-31.03	196 to 842	69 Pa	Estimated 3.3 – 7.06	59.34 ppm
Subcategory 2						
64743-00-6	744	33.64	393 to >1200	<1Pa	Estimated >4.9	1.25 ppm
64743-01-7	2037	38.93	417 to >1200	<1Pa	Estimated >4.9	3.47 ppm
68425-34-3	2260	49.87	665 to >1200	<1Pa	Estimated >4.9	0.35 ppm
68602-85-7	1294	38.02	400 to >1200	<1Pa	Estimated >4.9	0.54 ppm
68603-10-1	1189	42.86	380 to >1200	<1Pa	Estimated >4.9	0.50 ppm
68603-11-2	ND	41.84	379 to >1200	<1Pa	Estimated >4.9	1.29 ppm
68603-12-3	ND	ND	ND	ND	Estimated >4.9	ND

ND – No data available.

4.0 Environmental Fate

4.1 Photodegradation

Photodegradation is the degradation of a chemical compound as a result of absorption of solar radiation. Chemicals having the potential to photolyze have ultraviolet (UV) absorption in the range of 290 to 800 nm. The tendency of representative chemicals of each subcategory were evaluated by using the modeling program EPIWIN which includes calculation of atmospheric oxidation potential (AOPWIN). This program calculates a chemical half-life based on an overall OH- reaction rate constant, a 12-hr day, and a given OH-concentration. Atmospheric oxidation half-lives were calculated for various molecular weight constituent hydrocarbons in the petroleum oxidate category. AOP half-lives for oxidized petroleum constituents exhibited oxidation half-lives of one day or less (12 hours). The modeled data represent a potential range of photodegradation half-lives for hydrocarbon constituents expected to occur in the members of test plan.

4.2 Hydrolysis

Hydrolysis of a chemical is a transformation process in which an organic chemical reacts with water, forms a new carbon oxygen bond, and cleaves a carbon-X bond in the original molecule, where X is the leaving group. In order for hydrolysis to occur, the chemical must contain a suitable leaving group. Chemicals that have the potential to hydrolyze include alkyl halides, amides, carbamates, carboxylic acid esters and lactones, epoxides, phosphate esters, and sulfonic acid esters (Neely, 1985).

The complex mixture and low water solubility of the materials in this test plan limits the ability to estimate or measure hydrolysis rates. However, the materials in this test plan do not contain hydrolyzable functional groups therefore hydrolysis if any is expected to be slow. Based on the information available, the members of this test plan will not undergo significant hydrolysis and no additional testing is required.

4.3 Fugacity

Fugacity modeling compares the distribution of chemicals between environmental compartments (i.e., air, soil sediment, suspended sediment, water, biota). In the document "Determining the Adequacy of Existing Data" the US EPA acknowledges that it accepts data from the widely use Equilibrium Criterion Model (EQC) (Mackay, 1996). Based on the physicochemical characteristics of the constituents of the petroleum oxidates the lower molecular weight constituents are expected to have the highest vapor pressures and water solubilities, and the lowest octanol water partition coefficients. These factors enhance the potential for distribution in the environment. To gain an understanding of the potential transport and distribution of the petroleum oxidate constituents, the EPIWIN EQC model Level III was used to characterize the environmental distribution of constituents of the petroleum oxidates. Various C11 to C39 compounds representing the different classes of hydrocarbons found in the petroleum oxidate derivatives category were modeled. The partitioning behavior of constituent hydrocarbons of substances in the petroleum oxidate category indicate that the majority of the constituents will partition primarily to soil and sediment.

4.4 Biodegradation

Biodegradation data is available for three members of this test plan (Table 2). The oxidized light distillate, 64742-98-9, of subcategory 1 attained 59% biodegradation in a manometric respirometry test following OECD guideline 301F. The oxidized petroleum, 64743-00-6, and the oxidized Me ester Ca salt, 68603-11-2 attained biodegradation rates of 55% and 48%, respectively in a manometric respirometry test following OECD guideline 301F. The data generated on these materials will be extrapolated to the other members of the subcategory. Due to the similarities between the members of this subcategory, extrapolation to the untested members is appropriate. Based on available data, all

members of the category can be characterized as having moderate biodegradation; therefore, no additional testing is required.

Table 2 Environmental Fate

CAS #	Photodegradation	Hydrolysis	Fugacity	Biodegradation
Subcategory 1				
64742-98-9	≤1 day	Slow	>70% to soil and sediment	59 %
Subcategory 2				
64743-00-6	≤1 day	Slow	>70% to soil and sediment	55%
64743-01-7	≤1 day	Slow	>70% to soil and sediment	ND
68425-34-3	≤1 day	Slow	>70% to soil and sediment	ND
68602-85-7	≤1 day	Slow	>70% to soil and sediment	ND
68603-10-1	≤1 day	Slow	>70% to soil and sediment	ND
68603-11-2	≤1 day	Slow	>70% to soil and sediment	48%
68603-12-3	≤1 day	Slow	>70% to soil and sediment	ND

ND – No data available.

5.0 Ecotoxicology Data

5.1 Acute Fish

Acute fish toxicity data is available for two members of the category (Table 3). The oxidized light distillate, 64742-98-9, (subcategory 1) gave a 96 hr LL50 of 38 mg/L using rainbow trout following OECD guideline 203. The , oxidized methyl ester Ca salt, 68603-11-2, (subcategory 2) gave a 96 hr LL50 of 3540 mg/L using rainbow trout following OECD guideline 203. Due to the similarities between the members of this test plan, extrapolation to the untested members is appropriate. Based on available data, all members of the category can be characterized as having moderate to low toxicity to fish; therefore, no additional testing is required.

5.2 Acute Algae

Acute algae toxicity data is available for two members of the category (Table 3). The oxidized light distillate, 64742-98-9, (subcategory 1) gave a 72 hr EL50 > 100 mg/L using *Scenedesmus subspicatus* following OECD guideline 201 The, oxidized methyl ester Ca salt, 68603-11-2 (subcategory 2) gave a 72hr EL50 of 3860mg/L using *Selenastrum capricornutum* following OECD guideline 201. Due to the similarities between the members of this test plan, extrapolation to the untested members is appropriate. Based on available data, all members of the

category can be characterized as having low toxicity to algae; therefore, no additional testing is required.

5.3 Acute Invertebrate

Acute Daphnia toxicity data is available for two members of the category (Table 3). The oxidized light distillate, 64742-98-9, (subcategory 1) gave a 48 hr EL50 of 29 mg/l using *Daphnia magna* following OECD guideline 202. The, oxidized methyl ester Ca salt, 68603-11-2, (subcategory 2) gave a 48hr LL50 of 7070mg/L using *Daphnia magna* following OECD guideline 202. Due to the similarities between the members of this test plan, extrapolation to the untested members is appropriate. Based on available data, all members of the category can be characterized as having moderate to low toxicity to invertebrate; therefore, no additional testing is required.

Table 3 Ecotoxicology

CAS #	Acute Fish	Acute Algae	Acute Daphnia
Subcategory 1			
64742-98-9	96hr LL50= 38mg/L	72hr EL50 >100 mg/L	48hr EL50= 29 mg/L
Subcategory 2			
64743-00-6	ND	ND	ND
64743-01-7	ND	ND	ND
68425-34-3	ND	ND	ND
68602-85-7	ND	ND	ND
68603-10-1	ND	ND	ND
68603-11-2	96hr LL50= 3540mg/L	72hr EL50 =3860 mg/L	48hr LL50= 7070mg/L
68603-12-3	ND	ND	ND

ND- No data available.

6.0 Mammalian Toxicology Data

6.1 Acute Mammalian Toxicity

Acute oral toxicity data is available for four members of subcategory 2 (Table 4). The chemicals tested show a low acute oral toxicity with a LD_{50} greater than 2000 mg/kg. Due to the similarities between the members of this subcategory, read across to the untested members is appropriate. Acute oral toxicity data is not available for the member of subcategory 1. However, data generated from the repeated-dose toxicity, reproduction-developmental toxicity test will be sufficient to fill this data gap.

6.2 Genetic Toxicity

6.2.1 Bacterial Mutagenicity

There is mutagenicity data available for three members of this test plan (Table 4). One member of subcategory 1 and two members of subcategory

2 were tested using the ASTM E1687-98 test method. In addition, two members of this test plan were tested following OECD guideline 471. The oxidized light distillate, 64742-98-9, was tested for subcategory 1 and the oxidized petroleum, 64743-00-6, was tested for subcategory 2. These materials were not mutagenic in five strains of *Salmonella typhimurium* or in one strain of *Escherchia coli* with or without metabolic activation. Due to the similarities between the members of this test plan, extrapolation to the untested members is appropriate. Based on available data, all members of the category can be characterized as being non-mutagenic therefore, no additional testing is required.

6.2.2 Chromosomal Aberration

Chromosomal aberration data is available for two members of the test plan. The oxidized light distillate, 64742-98-9, (subcategory 1) and the oxidized petroleum, 64743-00-6, (subcategory 2) were tested following OECD guideline 473. These materials were non-clasotgenic to human lymphocytes. Due to the similarities between the members of this test plan, extrapolation to the untested members is appropriate. Based on available data, all members of the category can be characterized as being non-clastogenic therefore, no additional testing is required.

6.3 Repeated Dose Toxicity

The member of subcategory 1, 64742-98-9 was evaluated for chronic toxicity using OECD guideline 422. The oxidized light distillate was administered to rats by oral gavage at 100, 300, or 1000mg/kg/day for 54 consecutive days. Treatment related microscopic changes were detected in the kidneys, thyroid, and forestomach at all treatment levels. The renal changes observed were considered a consequence of protein accumulation, a phenomenon exclusive to the male rat. The changes in the thyroid glands and forestomach were minimal and considered to be adaptive in nature. The 'No Observed Adverse Effect Level' (NOAEL) for systemic toxicity was 1000 mg/kg/day. This member was chosen for testing because it is projected to be the upper boundary of toxicity based upon its physicochemical properties. This material has the lowest molecular weight, which indicates it will be more bioavailable than the other members of the category. This material also has a higher degree of water solubility relative to the other members of the category, which indicates that the material will be more readily bioavailable. The results from the repeated dose toxicity test are bridged to the other members of the category. Due to the similarities between the members of this category, read across to the untested members is appropriate.

6.4 Reproductive and Developmental Toxicity

The member of subcategory 1, 64742-98-9 was tested using OECD guideline 422. The oxidized light distillate was administered to rats by oral gavage at 100, 300, or 1000 mg/kg/day for 54 consecutive days. There was no effect of treatment on

reproduction or offspring development. The 'No Obsevered Effect Level' (NOEL) was 1000 mg/kg/day. This member was chosen for testing because it is projected to be the upper bound of toxicity based upon its physicochemical properties. This material has the lowest molecular weight, which indicates it will be more bioavailable than the other members of category. This material also has a higher degree of water solubility relative to the other members of the category, which indicates that the material will be more readily bioavailable. The results from the reproductive/developmental toxicity test are bridged to the other members of the category. Due to the similarities between the members of this category, read across to the untested members is appropriate.

Table 4 Mammalian Toxicology

CAS #	Acute Health	Bacterial Mutagenicity	Chromosomal Aberration	Repeated dose	Reproductive/ Developmental
Subcategory 1					
64742-98-9	ND	Non-mutagenic	Non-clastogenic	NOAEL 1000mg/kg /day	NOEL 1000mg/kg/day
Subcategory 2					
64743-00-6	LD50 >5000mg/kg	Non-mutagenic	Non-clastogenic	ND	ND
64743-01-7	LD50 5000mg/kg	NA	ND	ND	ND
68425-34-3	ND	ND	ND	ND	ND
68602-85-7	ND	ND	ND	ND	ND
68603-10-1	LD50 >2000mg/kg	ND	ND	ND	ND
68603-11-2	LD50 >15mL/kg	ND	ND	ND	ND
68603-12-3	ND	ND	ND	ND	ND

ND – No data available.

NA – Data available but not adequate for purposes of the HPV Challenge Program

7.0 Test Plan Summary (Table 5)

7.1 Physical and Chemical Properties

- The physical and chemical properties for the untested member 68603-12-3, oxidized Me ester Na salt, are bridged from 68603-10-1, oxidized Me ester Ba salt and 68603-11-2, oxidized Me ester Ca salt. Adequate data is available for all physical and chemical parameters. No additional testing is required.

7.2 Environmental Fate

- Photodegradation was calculated for representative chemical components for the materials in subcategory 1 and 2. Adequate data is available for photodegradation. No additional testing is required.
- Hydrolysis is expected to be slow for the materials in this test plan and no additional testing is required
- Fugacity data was calculated for representative chemical components for the materials in subcategory 1 and 2. Adequate data is available for fugacity. No additional testing is required.
- Biodegradation data was generated using OECD guideline 301F for the member of subcategory 1 (64742-98-9) and for (64743-00-6) and (68603-11-2 in subcategory 2. Data generated for the members of subcategory 2 will be bridged to the other members of subcategory 2.

7.3 Ecotoxicology Data

- Acute fish toxicity data was generated for the member of subcategory 1. Adequate data is available for acute fish toxicity. No additional testing is required.
- Acute algae toxicity data was generated for the member of subcategory 1. Adequate data is available for acute algae toxicity. No additional testing is required
- Acute invertebrate toxicity data was generated for the member of subcategory 1. Adequate data is available for acute algae toxicity. No additional testing is required

7.4 Mammalian Toxicity Data

- Adequate data is available for acute mammalian No additional testing is required.
- Bacterial mutagenicity data was generated for the member of subcategory 1 (64742-98-9) and for (64743-00-6) in subcategory 2. Adequate data is available for bacterial mutagenicity. No additional testing is required.
- Chromosomal aberration data was generated for the member of subcategory 1 (64742-98-9) and for (64743-00-6) in subcategory 2. Adequate data is available for chromosomal aberration. No additional testing is required
- Repeated dose toxicity data was generated for the member of subcategory 1 (64742-98-9) following OECD guideline 422. Adequate data is available for repeated dose toxicity. No additional testing is required
- Reproductive and developmental toxicity data was generated for the member of subcategory 1 (64742-98-9) following OECD guideline 422.

Adequate data is available for repeated dose toxicity. No additional testing is required

Table 5 Test Plan Summary

	Subcategory 1	Subcategory 2						
	64742-98-9	64743-00-6	64743-01-7	68425-34-3	68602-85-7	68603-10-1	68603-11-2	68603-12-3
Melting Point	√	√	√	√	√	√	√	RA
Boiling Point Range	√	√	√	√	√	√	√	RA
Vapor Pressure	√	√	√	√	√	√	√	RA
Partition Coefficient	√	√	√	√	√	√	√	√
Water Solubility	√	√	√	√	√	√	√	RA
Photodegradation	√	√	√	√	√	√	√	√
Hydrolysis	√	√	√	√	√	√	√	√
Fugacity	√	√	√	√	√	√	√	√
Biodegradation	√	√	RA	RA	RA	RA	√	RA
Acute Fish Toxicity	√	RA	RA	RA	RA	RA	√	RA
Acute Algae Toxicity	√	RA	RA	RA	RA	RA	√	RA
Acute Daphnia Toxicity	√	RA	RA	RA	RA	RA	√	RA
Acute Oral Toxicity	RA	√	√	RA	RA	√	√	RA
Bacterial Mutagenicity	√	√	RA	RA	RA	RA	RA	RA
Chromosomal Aberration	√	√	RA	RA	RA	RA	RA	RA
Repeated dose Toxicity	√	√	RA	RA	RA	RA	RA	RA
Reproductive/ Developmental Toxicity	√	√	RA	RA	RA	RA	RA	RA

T= Test; RA= Readacross; √ = adequate data exists

8.0 References

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