

Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals

Zinc Dialkyldithiophosphates (ZDDP) Category

| | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts | (CASRN 84605-29-8) |
| Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts | (CASRN 68457-79-4) |
| Phosphorodithioic acid, mixed O,O-bis(sec-Bu and 1,3-dimethylbutyl) esters, zinc salts | (CASRN 68784-31-6) |
| Phosphorodithioic acid, mixed O,O-bis(sec-Bu and isooctyl) esters, zinc salts | (CASRN 113706-15-3) |
| Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salts (CA Index Name: Zinc, bis[O-(2-ethylhexyl) O-(2-methylpropyl) phosphorodithioato-.kappa.S,.kappa.S']-, (T-4)-) | (CASRN 26566-95-0) |
| Phosphorodithioic acid, mixed O,O-bis(iso-Bu and isooctyl and pentyl) esters, zinc salts | (CASRN 68988-46-5) |
| Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt (CA Index Name: Zinc, bis[O,O-bis(1,3-dimethylbutyl) phosphorodithioato-.kappa.S,.kappa.S']-, (T-4)-) | (CASRN 2215-35-2) |
| Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt (CA Index Name: Zinc, bis[O,O-bis(2-ethylhexyl) phosphorodithioato-.kappa.S,.kappa.S'] -, (T-4)-) | (CASRN 4259-15-8) |
| Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt (CA Index Name: Zinc, bis(O,O-diisooctyl phosphorodithioato-.kappa.S,.kappa.S')-) | (CASRN 28629-66-5) |
| Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt (CA Index Name: Zinc, bis(O,O-diisodecyl phosphorodithioato-.kappa.S,.kappa.S')-) | (CASRN 25103-54-2) |
| Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt (CA Index Name: Zinc, bis[O,O-bis(dodecylphenyl) phosphorodithioato-.kappa.S,.kappa.S']-) | (CASRN 54261-67-5) |
| Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (CA Index Name: Zinc, bis[O,O-bis(tetrapropylenphenyl) phosphorodithioato-.kappa.S,.kappa.S']-) | (CASRN 11059-65-7) |

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BACKGROUND

Screening-level hazard, exposure and risk characterizations for high production volume chemicals (HPV) are important contributions to the chemicals cooperation work being done in North America¹ through the EPA Chemical Assessment and Management Program (ChAMP)². These screening-level characterizations are developed by EPA for individual chemicals or chemical categories to support initial Risk-Based Prioritizations (RBPs) for HPV chemicals. These screening-level characterizations are technical documents intended primarily to inform the Agency's internal decision-making process. Accordingly, they are written for assessment professionals and assume a degree of technical understanding. Each of the support documents is described below.

The Risk-Based Prioritizations are found in an accompanying document and are written for a general audience. They present EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed.

Hazard Characterizations for HPV Chemicals

EPA's screening-level hazard characterizations are based primarily on the review of the summaries of studies and other information submitted by the chemical sponsor(s) under the HPV Challenge Program³. These studies included in the scope of the HPV Challenge comprise the Screening Information Data Set (SIDS) of the Organization for Economic Cooperation and Development (OECD)⁴, an internationally recognized battery of tests that provides the basic data necessary to make an initial evaluation of a chemical's hazards and fate. In preparing the initial hazard characterizations, EPA also consulted a variety of reliable sources⁵ for additional relevant information and 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 an HPV submission, EPA also searched publicly available databases⁶ for information entered from one year prior to the HPV submission through May 2008. The screening-level hazard characterization is performed according to established EPA guidance⁷. A more detailed description of the hazard characterization process is available on the EPA website⁸.

With respect to chemicals for which internationally-accepted OECD SIDS Initial Assessment Profiles (SIAP) and Initial Assessment Reports (SIAR) were available, EPA did not generate its own screening-level hazard characterization, but did check for and incorporate updated information in the risk characterization.

Exposure Characterizations for HPV Chemicals

EPA recently received exposure-related data on chemicals submitted in accordance with the requirements of Inventory Update Reporting (IUR)⁹. The 2006 IUR submissions pertain to chemicals manufactured in

¹ U.S. EPA – U.S. Commitments to North American Chemicals Cooperation: <http://www.epa.gov/hpv/pubs/general/sppframework.htm>.

² U.S. EPA – ChAMP information: <http://www.epa.gov/champ/>.

³ U.S. EPA – HPV Challenge Program information: <http://www.epa.gov/hpv>.

⁴ U.S. EPA – Technical Guidance Document, OECD SIDS Manual Sections 3.4 and 3.5: <http://www.epa.gov/chemrtk/pubs/general/sidsappb.htm>.

⁵ U.S. EPA – Public Database Hazard Information: <http://www.epa.gov/hpvis/hazardinfo.htm>.

⁶ U.S. EPA – Public Database Update Information: <http://www.epa.gov/chemrtk/hpvis/updateinfo.htm>.

⁷ U.S. EPA – Risk Assessment Guidelines: <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>.

⁸ U.S. EPA – About HPV Chemical Hazard Characterizations: <http://www.epa.gov/hpvis/abouthc.htm>.

⁹ U.S. EPA – Basic IUR Information: <http://www.epa.gov/opptintr/iur/pubs/guidance/basic-information.htm>.

(including imported into) the U.S. during calendar year 2005 in quantities of 25,000 pounds or more at a single site. The reports include the identity, the quantity, and the physical form of the chemical manufactured or imported, and the number of workers reasonably likely to be exposed during manufacture of the chemical. For chemicals manufactured or imported in quantities of 300,000 pounds or more at a single site, additional reported information includes: the industrial processing and uses of the chemical; the number of industrial processing sites and workers reasonably likely to be exposed to the chemical at those sites; the consumer and commercial uses of the chemical; and an indication whether the chemical was used in products intended for use by children under 14 years of age.

EPA's screening-level exposure characterizations are based largely on the information submitted under the IUR reporting, although other exposure information submitted to the Agency (for example, in HPV submissions) or readily available through a limited set of publicly accessible databases¹⁰ was also considered. The screening-level exposure characterizations identify a potential (high, medium, or low) that each of five populations – the environment, the general population, workers, consumers, and children – might be exposed to the chemical. In most cases, this potential doesn't address the quantity, frequency, or duration of exposure, but refers only to the likelihood that an exposure could occur.

In many instances EPA is not able to fully disclose to the public all the IUR exposure-related data reviewed or relied upon in the development of the screening-level documents because some of the material was claimed as confidential business information (CBI) when it was submitted to the Agency. These CBI claims do limit the Agency's ability to be completely transparent in presenting some underlying exposure and use data for chemicals in public documents. EPA does consider all data, including data considered to be CBI, in the screening-level exposure and risk characterization process, and endeavors whenever possible to broadly characterize supporting materials claimed as confidential in ways that do not disclose actual CBI.

Risk Characterizations for HPV Chemicals

EPA combines the information from the screening-level exposure characterization with the screening-level hazard characterization to develop a qualitative screening-level risk characterization, as described in the Agency's guidance on drafting risk characterizations¹¹. These screening-level risk characterizations are technical documents intended to support subsequent priority-setting decisions and actions by OPPT. The purpose of the qualitative screening-level risk characterization is two-fold: to support initial risk-based decisions to prioritize chemicals, identify potential concerns, and inform risk management options; and to identify data needs for individual chemicals or chemical categories.

These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Recommended actions reflect EPA's relative judgment regarding this chemical or chemical category in comparison with others evaluated under this program, as well as the uncertainties presented by gaps that may exist in the available data.

¹⁰ U.S. EPA – Summary of Public Databases Routinely Searched: <http://www.epa.gov/chemrtk/hpvis/pubdtsum.htm>.

¹¹ U.S. EPA – Risk Characterization Program: <http://www.epa.gov/osa/spc/2riskchr.htm>.

**QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION
OF HIGH PRODUCTION VOLUME CHEMICALS**

CHEMICAL CATEGORY NAME

Zinc Dialkylthiophosphates

SPONSORED CHEMICALS

| | |
|---------------------------------------------------------------------------------------------|---------------------|
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts | CAS No. 84605-29-8 |
| Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts | CAS No. 68457-79-4 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts | CAS No. 68784-31-6 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts | CAS No. 113706-15-3 |
| Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt | CAS No. 26566-95-0 |
| Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isooctyl and pentyl) esters, zinc salts | CAS No. 68988-46-5 |
| Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt | CAS No. 2215-35-2 |
| Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt | CAS No. 4259-15-8 |
| Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt | CAS No. 28629-66-5 |
| Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt | CAS No. 25103-54-2 |
| Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt | CAS No. 54261-67-5 |
| Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt | CAS No. 11059-65-7 |

September 2008

Prepared by

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QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR Zinc Dialkyldithiophosphates Category

1. Category Justification

Zinc dialkyldithiophosphates (ZDDPs) consist of a phosphorodithioic acid structure with alkyl or alkaryl ester substituent groups. The alkyl groups are saturated hydrocarbon chains that vary in length (C3 – C10) and in the extent of branching. Zinc dialkyldithiophosphates are synthesized by reacting phosphorus pentasulfide (P₂S₅) with one or more primary or secondary C3 – C12 branched or linear alcohols to form the phosphorodithioic acid ester, which is further diluted with 10 – 15% highly refined lubricating base oil (typical CAS Nos. 64742-54-7 and 64741-88-4) before it is neutralized with zinc oxide. The lubricating base oil acts as a solvent in the reaction, manages the viscosity and improves consistency of the final product. The members of the ZDDP category are used as multi-functional anti-wear and anti-oxidants in passenger vehicle motor oils, diesel engine oils and industrial oils. The highly refined lubricating base oil used in the manufacture of the zinc dialkyldithiophosphates cannot be removed without altering the structural and physical-chemical character of the zinc dialkyldithiophosphate molecules. Therefore, many of the physical-chemical properties presented are qualitative estimates. These chemicals can be grouped and evaluated together as they are structurally similar, all consisting of alkyl (C3 – C10) or alkaryl (C12 alkylphenol) substituted phosphorodithioic acid structures complexed with zinc. Based on these characteristics data for the tested category members are extrapolated to provide estimates of similar properties for the untested members where appropriate. EPA considered this grouping acceptable for the purposes of the HPV Challenge Program and further accepts this category for prioritization in the Chemical Assessment and Management Program (ChAMP).

2. Physical-Chemical Properties and Environmental Fate

Zinc dialkyldithiophosphates are amber colored viscous liquids at ambient temperature that contain 10-15 weight % highly refined lubricating base oil. De-oiled zinc dialkyldithiophosphates are solid materials. Zinc dialkyldithiophosphates have low mobility and negligible volatilization. Atmospheric photooxidation is not an important environmental fate process since these compounds will exist in the particulate phase in the atmosphere. Biodegradation is slow and bioaccumulation is not expected. The persistence and bioaccumulation ranking for the members of this category are P3 (high) and B1 (low).

3. Hazard Characterization

Aquatic Organism Toxicity: The aquatic toxicity data submitted were generated using the Water Accommodated Fraction method. The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for C8 and higher ZDDPs indicates the potential acute hazard to aquatic organisms is low based on no effects observed at the water solubility limit (saturation) of two category members. The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for C3 to C8 ZDDPs indicates the potential acute hazard to fish is moderate and to aquatic invertebrates and aquatic plants is low, based on the one tested category member

(CAS No. 84605-29-8). The physical-chemical properties of the substances in this category also indicate they are soluble or miscible in water at concentrations that could be relevant to chronic effects.

Human Health Toxicity: Acute oral and dermal toxicity of ZDDP category members is low. Several repeated-dose dermal studies of ZDDP category chemicals showed moderate toxicity in rabbits. An oral repeated-dose study in rats of one ZDDP category member showed moderate systemic toxicity. An oral combined reproductive/developmental toxicity study in rats of one ZDDP category member showed moderate systemic toxicity in the adult animals and moderate postnatal developmental toxicity; there were no effects on reproductive parameters or reproductive organs. In contrast, dermal repeated-dose studies in rabbits of several ZDDP category members did show moderate toxicity to the male reproductive organs. ZDDP category members were not mutagenic in bacterial cells, but showed a positive response in mammalian cells. ZDDP category members did not induce chromosome aberrations when tested *in vivo*.

4. Exposure Characterization

Ten of the 12 zinc dialkyldithiophosphates category chemicals have aggregated production volumes in the ranges of 94 million to 340.5 million pounds. The other two category members - phosphorodithioic acid, mixed o,o-bis(iso-bu and isoctyl) (CAS#68988-46-5) and phosphorodithioic acid, o,o-diisodecyl ester, zinc salt (CAS#25103-54-2) - do not have IUR submissions. Non-confidential IUR information for many of the chemicals in the zinc dialkyldithiophosphates category indicates that these chemicals are used as lubricants in the manufacturing of other chemical products. Nine of the 12 chemicals in this category have IUR submissions that indicate uses in commercial settings or consumer uses.

Information submitted as part of the HPV Challenge Program indicates that zinc dialkyldithiophosphates are used to formulate finished lubricating oils including all types of automotive and diesel engine crankcase, industrial oils and hydraulic fluids. The Hazardous Substances Data Bank (HSDB) had information for two of the chemicals and list uses as hydraulic and transmission fluids (CAS#28629-66-5) or additives in lubricating oils (CAS#25103-54-2).

Potential Exposures to the General Population and the Environment: Based on the information considered, including known uses, and the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium potential that the general population and the environment might be exposed. Based on the predominant uses of zinc dialkyldithiophosphates in automotive and diesel crankcase oils, industrial oils, and hydraulic fluids, there may be potential releases to land via disposal or accidental spills and to air via incineration of spent oil. Persistence and bioaccumulation ratings for these chemicals are P3 and B1. These ratings suggest that these chemicals are very persistent in the environment; and are not bioaccumulative.

Potential Exposures to Workers: Based on the information considered, including IUR data and information from HPV Test Plan, and the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium relative ranking for potential worker exposure. This relative ranking is based on the potential for dermal exposure of a moderate

number of workers, information on uses of the chemical substances including commercial uses, and the production volume. Zinc dialkyldithiophosphates do not have OSHA Permissible Exposure Limits (PELs).

Potential Exposures to Consumers: EPA identifies, for the purposes of risk-based prioritization, a high potential that consumers might be exposed from products containing this chemical. Nine of the twelve chemicals in this category have IUR submissions that indicate uses in commercial settings or consumer uses. Information from public data sources indicate potential for exposure to consumers who may periodically add lubricating oil to automotive crankcases or change their own automotive engine oil.

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a low potential that children might be exposed. None of chemicals reported uses in products intended to be used by children. One chemical reported that such information was Not Readily Obtainable. It is unlikely that children will be exposed to automotive and diesel crankcase oils, industrial oils, and hydraulic fluids containing these chemicals.

5. Risk Characterization

The statements and rationale provided below are intended solely for the purpose of this screening-level and qualitative risk characterization and will be used for prioritizing substances for future work in the Chemical Assessment and Management Program (ChAMP).

Risk Statement and Rationale

Potential Risk to Aquatic Organism from Environmental Releases: (LOW/MEDIUM CONCERN) EPA identifies a medium potential that aquatic organisms might be exposed from environmental releases. Chemicals in the ZDDP category have high persistence and low bioaccumulation. These characteristics in combination with the low acute toxicity to aquatic invertebrates and aquatic plants for ZDDP category chemicals indicate a low concern for potential risk from environmental releases. These characteristics in combination with the moderate acute toxicity of one category member (CAS# 84605-29-8) indicate a medium concern for potential risk to fish from environmental releases of this category member and potentially other untested category members.

Potential Risk to the General Population from Environmental Releases: (MEDIUM CONCERN) EPA identifies a medium potential that the general population might be exposed from environmental releases. The potential human health hazard is moderate. Therefore, taken together, there is a medium concern for potential risk to the general population from environmental releases.

Potential Risk to Workers: (MEDIUM CONCERN) EPA identifies a medium relative ranking for potential worker exposure. ZDDP category chemicals do not have an OSHA Permissible Exposure Limit (PEL). The potential human health hazard is moderate. Therefore, taken together, the available information suggests a medium concern for potential risks to workers.

Potential Risk to Consumers: (MEDIUM CONCERN) EPA identifies a high potential that consumers might be exposed. This is based on the use of consumer products containing this chemical. The potential human health hazard is moderate. Therefore, taken together, the available information suggests a medium concern for potential risks to consumers.

Potential Risk to Children: (LOW CONCERN) EPA identifies a low potential that children might be exposed. There are no uses in products specifically intended to be used by children. It is unlikely that children will be exposed to finished lubricating oils used for automotive and diesel engine crankcases, industrial oils and hydraulic fluids. An animal study of one member of the ZDDP category showed moderate toxicity following exposure during early life stages. However, given the lack of exposure to children, the available information suggests a low concern for potential risks to children.

**SCREENING-LEVEL HAZARD CHARACTERIZATION
OF HIGH PRODUCTION VOLUME CHEMICALS**

CHEMICAL CATEGORY NAME

Zinc Dialkyldithiophosphates

SPONSORED CHEMICALS

| | |
|---------------------------------------------------------------------------------------------|---------------------|
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts | CAS No. 84605-29-8 |
| Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts | CAS No. 68457-79-4 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts | CAS No. 68784-31-6 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts | CAS No. 113706-15-3 |
| Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt | CAS No. 26566-95-0 |
| Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isooctyl and pentyl) esters, zinc salts | CAS No. 68988-46-5 |
| Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt | CAS No. 2215-35-2 |
| Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt | CAS No. 4259-15-8 |
| Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt | CAS No. 28629-66-5 |
| Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt | CAS No. 25103-54-2 |
| Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt | CAS No. 54261-67-5 |
| Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt | CAS No. 11059-65-7 |

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SCREENING-LEVEL HAZARD CHARACTERIZATION Zinc Dialkyldithiophosphates

Introduction

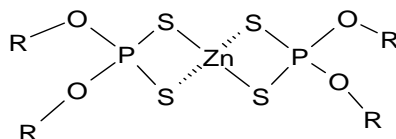
The sponsor, American Chemistry Council, submitted a Test Plan and Robust Summaries to EPA for the zinc dialkyldithiophosphate (ZDDP) category on November 11, 2002. EPA posted the submission on the ChemRTK HPV Challenge website on November 27, 2002 (<http://www.epa.gov/chemrtk/pubs/summaries/zincdial/c14066tc.htm>). EPA comments on the original submission were posted to the website on April 1, 2003. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on May 20, 2003 and April 19, 2005, which were posted to the ChemRTK website on June 24, 2003 and June 3, 2005 respectively. The zinc dialkyldithiophosphates category consists of the following chemicals:

| | |
|---------------------------------------------------------------------------------------------|---------------------|
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts | CAS No. 84605-29-8 |
| Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts | CAS No. 68457-79-4 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts | CAS No. 68784-31-6 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts | CAS No. 113706-15-3 |
| Phosphorodithioic acid, O-(-2-ethylhexyl) O-isobutyl ester, zinc salt | CAS No. 26566-95-0 |
| Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isooctyl and pentyl) esters, zinc salts | CAS No. 68988-46-5 |
| Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt | CAS No. 2215-35-2 |
| Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt | CAS No. 4259-15-8 |
| Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt | CAS No. 28629-66-5 |
| Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt | CAS No. 25103-54-2 |
| Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt | CAS No. 54261-67-5 |
| Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt | CAS No. 11059-65-7 |

This screening-level hazard characterization is based primarily on the review of the test plan and robust summaries of studies submitted by the sponsor(s) under the HPV Challenge Program. 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 2004 to June 2008: the NLM databases (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, ATSDR, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. Structure(s) of the sponsored chemical(s) is included in the appendix. The screening-level hazard characterization for environmental and human health toxicity is based largely on SIDS endpoints and is described according to established EPA or OECD effect level definitions and hazard assessment practices.

Category Justification

Zinc dialkyldithiophosphates (ZDDPs) consist of a phosphorodithioic acid structure with alkyl or alkaryl ester substituent groups. The alkyl groups are saturated hydrocarbon chains that vary in length (C3 – C10) and in the extent of branching. A typical structure for the zinc dialkyldithiophosphate component is shown below.



R = C3 – C10 (linear and/or branched) alkyl or C12 (branched) alkaryl

Zinc dialkyldithiophosphates are synthesized by reacting phosphorus pentasulfide (P₂S₅) with one or more primary or secondary C3 – C12 branched or linear alcohols to form the phosphorodithioic acid ester, which is further diluted with 10 – 15% highly refined lubricating base oil (typical CAS Nos. 64742-54-7 and 64741-88-4) before it is neutralized with zinc oxide. The lubricating base oil acts as a solvent in the reaction, manages the viscosity and improves consistency of the final product.

The members of the ZDDP category are used as multi-functional anti-wear and anti-oxidants in passenger vehicle motor oils, diesel engine oils and industrial oils. The highly refined lubricating base oil used in the manufacture of the zinc dialkyldithiophosphates cannot be removed without altering the structural and physical-chemical character of the zinc dialkyldithiophosphate molecules. Therefore, many of the physical-chemical properties presented are qualitative estimates.

Although in its test plan review EPA suggested presenting the category in three subgroups, following review of the updated/revised submission, EPA concluded that these chemicals can be grouped and evaluated together as they are structurally similar, all consisting of alkyl (C3 – C10) or alkaryl (C12 alkylphenol) substituted phosphorodithioic acid structures complexed with zinc. Based on these characteristics data for the tested category members are extrapolated to provide estimates of similar properties for the untested members where appropriate.

Hazard Characterization

Zinc dialkyldithiophosphates are amber colored viscous liquids at ambient temperature that contain 10-15 weight % highly refined lubricating base oil. De-oiled zinc dialkyldithiophosphates are solid materials. Zinc dialkyldithiophosphates have low mobility and negligible volatilization. Atmospheric photooxidation is not an important environmental fate process since these compounds will exist in the particulate phase in the atmosphere. Biodegradation is slow and bioaccumulation is not expected. The persistence and bioaccumulation ranking for the members of this category are P3 (high) and B1 (low).

The aquatic toxicity data submitted were generated using the Water Accommodated Fraction method. The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for C8 and higher ZDDPs indicates the potential acute hazard to aquatic organisms is low based on no effects observed at the water solubility limit (saturation) of two category members. The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for C3 to C8 ZDDPs indicates the potential acute hazard to fish is moderate and to aquatic invertebrates and aquatic plants is low, based on the one tested category member (CAS No. 84605-29-8). The physical-chemical properties of the substances in this category also indicate they are soluble or miscible in water at concentrations that could cause chronic effects.

Acute oral and dermal toxicity of ZDDP category members is low. Several repeated-dose dermal studies of ZDDP category chemicals showed moderate toxicity in rabbits. An oral repeated-dose study in rats of one ZDDP category member showed moderate systemic toxicity. An oral combined reproductive/developmental toxicity study in rats of one ZDDP category member showed moderate systemic toxicity in the adult animals and moderate postnatal developmental toxicity; there were no effects on reproductive parameters or reproductive organs. In contrast, dermal repeated-dose studies in rabbits of several ZDDP category members did show moderate toxicity to the male reproductive organs. ZDDP category members were not mutagenic in bacterial cells, but showed a positive response in mammalian cells. ZDDP category members did not induce chromosome aberrations when tested *in vivo*.

Chronic toxicity in aquatic organisms remains a data gap under the HPV Challenge Program.

1. Physical-Chemical Properties and Environmental Fate

The physical-chemical properties of the zinc dialkyldithiophosphates are summarized in Table 1a, while their environmental fate properties are given in Table 1b. The structures of the compounds are provided in the Appendix.

Physical-Chemical Properties Characterization

Zinc dialkyldithiophosphates are solid materials; however, the technical materials are manufactured and distributed in highly refined lubricant base oil. The vapor pressure of these materials is negligible and the solubility is low.

| Table 1a. Physical and Chemical Properties of Zinc Dialkyldithiophosphate Category ¹ | | | | | | | |
|-------------------------------------------------------------------------------------------------|-------------|------------------|-----------------|----------------------|-----------------------------|-------------------------|-------------------------|
| Chemical name | CAS No. | Molecular Weight | Melting Point | Boiling Point | Vapor Pressure ³ | Water Solubility (mg/L) | Log K _{ow} |
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts | 84605-29-8 | 578.1 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | 15.8 (measured) | NA ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(isobutyl and pentyl) esters, zinc salts | 68457-79-4 | 578.1 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 15.8 (RA) | NA ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts | 68784-31-6 | 606.2 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 15.8 (RA) | NA ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts | 113706-15-3 | 662.3 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 15.8 (RA) | NA ⁴ |
| Phosphorodithioic acid, mixed O-(2-ethylhexyl) O-(isobutyl) ester, zinc salts | 26566-95-0 | 648.3 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 15.8 (RA) | NA ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(isobutyl and isooctyl and pentyl) esters, zinc salts | 68988-46-5 | 634.2 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 15.8 (RA) | NA ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl) ester, zinc salt | 2215-35-2 | 662.3 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 15.8 (RA) | NA ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl) ester, zinc salt | 4259-15-8 | 774.5 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | 1.09 (measured) | 8.79 (est) ⁴ |
| Phosphorodithioic acid, mixed O,O-bis(isooctyl) ester, zinc salt | 28629-66-5 | 774.5 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 1.09 (RA) | 8.79 (est) ⁴ |
| Phosphorodithioic acid, mixed O,O-diisodecyl ester, zinc salt | 25103-54-2 | 886.7 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 1.09 (RA) | NA ⁴ |
| Phenol, dodecyl-,hydrogen phosphorodithioate, zinc salt | 54261-67-5 | 1303.3 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | No Data 1.09 (RA) | NA ⁴ |
| Phenol, tetrapropenyl-,hydrogen phosphorodithioate, zinc salt | 11059-65-7 | 1303.3 | NA ² | Decomposes at 120 °C | 1.7x10 ⁻⁴ Pa | 0.18 (measured) | NA ⁴ |

¹ Petroleum Additives Panel Health Environmental and Regulatory Task Group. 2005. Revised Robust Summaries for Zinc Dialkyldithiophosphates. <http://www.epa.gov/chemrtk/pubs/summaries/zincdial/c14066tc.htm>.

² Not applicable. ZDDP category members are manufactured in base oils, which have high viscosity at ambient temperature.

³ Vapor pressure of the lubricating base oil.

⁴ US EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v 3.20. United States Environmental Protection Agency, Washington, DC, USA. <http://www.epa.gov/opptintr/exposure/pubs/episuite.htm>. The model used to estimate log K_{ow} (KOWWIN v.1.67) has been demonstrated to be accurate in predicting log K_{ow} between -4 and 10. All but two of the members of the category are outside this range, so the values may not be reliable, but it is reasonable to conclude that these estimates indicate that the log K_{ow} values for these members of this category are high (> 4). The measurement of log K_{ow} for the ZDDP category members is not expected to provide useful information due to the presence of 10-15 % lubricating oil in the final product.

Environmental Fate Characterization

Zinc dialkyldithiophosphates have low mobility and negligible volatilization. Atmospheric photooxidation is not an important environmental fate process since these compounds will exist in the particulate phase in the atmosphere. Biodegradation is slow and bioaccumulation is not expected. The persistence and bioaccumulation ranking for the members of this category are P3 (high) and B1 (low).

Table 1b. Environmental Fate Properties of Zinc Dialkyldithiophosphate Category¹

| Chemical name | CAS No. | Photo-degradation Half-life | Hydrolysis Half-Life | Bio-degradation | BCF ⁴ | Log K _{oc} ⁴ | Fugacity | Persistence ⁵ | Bio-accumulation ⁵ |
|---------------------------------------------------------------------------------------------|-------------|-----------------------------|----------------------|----------------------------------------------------------|------------------|----------------------------------|----------------------|--------------------------|-------------------------------|
| Phosphorodithioic acid, mixed O,O-bis(1,3dimethylbutyl and isopropyl) esters, zinc salts | 84605-29-8 | No Data ² | No Data ³ | 5.9% at 28 days Not readily biodegradable | 22 | 6.3 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(isobutyl and pentyl) esters, zinc salts | 68457-79-4 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 6.6 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts | 68784-31-6 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 6.9 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isoocetyl) esters, zinc salts | 113706-15-3 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 7.9 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O-(2-ethylhexyl) O-(isobutyl) ester, zinc salts | 26566-95-0 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 8.1 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(isobutyl and isoocetyl and pentyl) esters, zinc salts | 68988-46-5 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 7.3 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl) ester, zinc salt | 2215-35-2 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 9.6 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(2-ethylhexyl) ester, zinc salt | 4259-15-8 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 7 | 5 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-bis(isoocetyl) ester, zinc salt | 28629-66-5 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 7 | 4.9 | No Data ³ | P3 | B1 |
| Phosphorodithioic acid, mixed O,O-diisodecyl ester, zinc salt | 25103-54-2 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 12 | No Data ³ | P3 | B1 |
| Phenol, dodecyl, hydrogen phosphorodithioate, zinc salt | 54261-67-5 | No Data ² | No Data ³ | 4.2-5.9% at 28 days Not readily biodegradable | 3 | 22 | No Data ³ | P3 | B1 |
| Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt | 11059-65-7 | No Data ² | No Data ³ | No Data Not readily biodegradable (RA) | 3 | 22 | No Data ³ | P3 | B1 |

¹Petroleum Additives Panel Health Environmental and Regulatory Task Group. 2005. Revised Robust Summaries for Zinc

| Table 1b. Environmental Fate Properties of Zinc Dialkyldithiophosphate Category ¹ | | | | | | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-----------------------------|----------------------|-----------------|------------------|----------------------------------|----------|--------------------------|-------------------------------|
| Chemical name | CAS No. | Photo-degradation Half-life | Hydrolysis Half-Life | Bio-degradation | BCF ⁴ | Log K _{oc} ⁴ | Fugacity | Persistence ⁵ | Bio-accumulation ⁵ |
| Dialkyldithiophosphates. http://www.epa.gov/chemrtk/pubs/summaries/zincdial/c14066tc.htm . ² Atmospheric photooxidation is not an important environmental fate process since these compounds are not volatile and will exist in the particulate phase in the atmosphere. ³ The measurement of hydrolysis and fugacity for the ZDDP category members is not expected to provide useful information due to the presence of 10-15 % lubricating oil in the final product. ⁴ US EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v 3.20. United States Environmental Protection Agency, Washington, DC, USA. http://www.epa.gov/opptintr/exposure/pubs/episuite.htm . ⁵ FR 1999, Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. <i>Federal Register</i> 64, Number 213 (November 4, 1999) Page 60194-60204. | | | | | | | | | |

Conclusion: Zinc dialkyldithiophosphates are amber colored viscous liquids at ambient temperature that contain 10-15 weight % highly refined lubricating base oil. De-oiled zinc dialkyldithiophosphates are solid materials. Zinc dialkyldithiophosphates have low mobility and negligible volatilization. Atmospheric photooxidation is not an important environmental fate process since these compounds will exist in the particulate phase in the atmosphere. Biodegradation is slow and bioaccumulation is not expected. The persistence and bioaccumulation ranking for the members of this category are P3 (high) and B1 (low).

2. Environmental Effects – Aquatic Toxicity

A summary of aquatic toxicity data submitted for SIDS endpoints is provided in Table 2. The table also indicates where data for tested category members are read-across (RA) to untested members of the category.

Acute Toxicity to Fish

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts (CAS No. 84605-29-8)
 Rainbow trout (*Oncorhynchus mykiss*) were exposed to nominal concentrations (loading rates) of 0, 1.0, 1.8, 3.2, 5.6 and 10 mg/L water accommodated fractions (WAFs) under semi-static conditions for 96 hours. Analytical monitoring was not conducted, but all the loading rates are below the reported measured water solubility of this chemical (15.8 mg/L). Increased pigmentation and morbidity were observed at 5.6 and 10 mg/L. Mortality was 20, 70 and 100% at 3.2, 5.6 and 10 mg/L, respectively. The 96 hour LL₅₀ (loading level likely to cause 50% mortality) was 4.5 mg/L WAF.
96-h LC₅₀ = 4.5 mg/L

Phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt (CAS No. 4259-15-8)
 Rainbow trout (*O. mykiss*) were exposed to nominal concentrations of 0, 10, 18, 32, 56 and 100 mg/L as WAFs under semi-static conditions for 96 hours. No analytical measurements were made on the WAFs. An LC₅₀ of 47 mg/L was provided in the test plan, but not in the robust summary. This implies effects were seen, but they are not described in the robust summaries. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming that exposure concentration in the WAF is the water solubility limit (saturation) for phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt, the no effect concentration would be approximately 1.09 mg/L.
No effects at saturation

Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (CAS No. 11059-65-7)

[In the robust summary, the chemical name is listed as *zinc, bis[O,O-bis(tetrapropylenophenyl) phosphorodithioata-S,S']*] Rainbow trout (*O. mykiss*) were exposed to phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt as WAFs under semi-static conditions for 96 hours. The loading rate was 100 mg/L and no analytical measurements were made on the WAFs. No effects were noted at any of the WAF loading rates. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming exposure concentration in the WAF is the water solubility limit (saturation) for phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt, the no effect concentration would be approximately 0.18 mg/L.

No effects at saturation

Acute Toxicity to Aquatic Invertebrates

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts (CAS No. 84605-29-8)

Water fleas (*Daphnia magna*) were exposed to phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts as WAFs under semi-static conditions for 48 hours. The loading rates were 0, 10, 18, 32, 56 and 100 mg/L and no analytical measurements were made on the WAFs. Results reported by the sponsor (48-h EL₅₀ of 23 mg/L) is greater than, but relatively close to the water solubility limit for this chemical (15.8 mg/L). The no observed effect level was reported as the 10 mg/L loading rate, which is below the chemical's solubility.

Low effects expected at saturation

Phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt (CAS No. 4259-15-8)

Water fleas (*D. magna*) were exposed to phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt as WAFs under semi-static conditions for 48 hours. The loading rate was 100 mg/L and no analytical measurements were made on the WAFs. No effects were noted at any of the WAF loading rates. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming that exposure concentration in the WAF is the water solubility limit (saturation) for phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt, the no effect concentration would be approximately 1.09 mg/L.

No effects at saturation

Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (CAS No. 11059-65-7)

[In the robust summary, the chemical name is listed as *zinc, bis[O,O-bis(tetrapropylenophenyl) phosphorodithioata-S,S.]*] Water fleas (*D. magna*) were exposed to phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt as WAFs under semi-static conditions for 48 hours. The loading rates were 0, 10, 18, 32, 56 and 100 mg/L and no analytical measurements were made on the WAFs. 100% mortality was observed at the 100 mg/L loading rate; no effects were noted at any other loading rates. The sponsor reported a 48-h EL₅₀ of 75 mg/L, which is several orders of magnitude above the reported measured water solubility for this chemical; hence this test/data is questionable. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming that exposure concentration in the WAF is the water solubility limit (saturation) for zinc, bis[O,O-bis(tetrapropylenophenyl)phosphorodithioate-S,S'], the no effect concentration would be approximately 0.18 mg/L.

No effects at saturation

Toxicity to Aquatic Plants

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts (CAS No. 84605-29-8)

Green algae (*Scenedesmus subspicatus*) were exposed to phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts as WAFs under semi-static conditions for 72 hours. The loading rates were 0, 10, 20, 40, 80 and 160 mg/L and no analytical measurements were made on the WAFs. The sponsor reported EL₅₀ for biomass of 21 mg/L and EL₅₀ for growth of 24 mg/L. These concentrations are greater than, but relatively close to the chemical's water solubility. The no observed effect level was reported as the 10 mg/L loading rate, which is below the chemical's solubility.

Low effects expected at saturation

Phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt (CAS No. 4259-15-8)

Green algae (*S. subspicatus*) were exposed to phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt as WAFs under semi-static conditions for 72 hours. The loading rates were 0, 10, 32, 220, 320 and 1000 mg/L and no analytical measurements were made on the WAFs. Growth was reduced at loading rates of 100 and 1000 mg/L; however these concentrations are well in excess of the chemical's water solubility; hence, these results are questionable and suggest possible physical effects. Assuming that exposure concentration in the WAF is the water solubility limit (saturation) for phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt, the no effect concentration would be approximately 1.09 mg/L.

No effects at saturation

Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (CAS No. 11059-65-7)

[In the robust summary, the chemical name is listed as *zinc, bis[O,O-bis(tetrapropylenephenyl)phosphorodithioate-S,S']*] Green algae (*S. subspicatus*) were exposed to phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt as WAFs under semi-static conditions for 72 hours. The loading rates were 0 or 1000 mg/L and no analytical measurements were made on the WAFs. No effects were noted at any of the WAF loading rates. EPA does not consider the loading rate as the no effect concentration when the concentration exceeds the water solubility of the substance. Assuming that exposure concentration in the WAF is the water solubility limit (saturation) for zinc, bis[O,Obis(tetrapropylenephenyl) phosphorodithioate-S,S'], the no effect concentration would be approximately 0.18 mg/L.

No effects at saturation

Conclusion: The aquatic toxicity data submitted were generated using the Water Accommodated Fraction method. The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for C8 and higher ZDDPs indicates the potential acute hazard to aquatic organisms is low based on no effects observed at the water solubility limit (saturation) of two category members. The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for C3 to C8 ZDDPs indicates the potential acute hazard to fish is moderate and to aquatic invertebrates and aquatic plants is low, based on the one tested category member (CAS No. 84605-29-8). The physical-chemical properties of the substances in this category also indicate they are soluble or miscible in water at concentrations that could cause chronic effects.

Table 2. Summary of Environmental Effects – Aquatic Toxicity Data¹

| Endpoint | Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts (84605-29-8) | Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts (68457-79-4) | Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (68784-31-6) | Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts (113706-15-3) | Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt (26566-95-0) | Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isooctyl) esters, zinc salts (68988-46-5) | Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt (2215-35-2) | Phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, zinc salt (4259-15-8) | Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt (28629-66-5) | Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt (25103-54-2) | Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt (51261-67-5) | Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (11059-65-7) |
|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Fish 96-h LC ₅₀ (mg/L) | 4.5 (m) | No Data 4.5 (RA) | No Data 4.5 (RA) | No Data 4.5 (RA) | No Data 4.5 (RA) | No Data 4.5 (RA) | No Data 4.5 (RA) | NES (m) | No Data NES (RA) | No Data NES (RA) | No Data NES (RA) | NES (m) |
| Aquatic Invertebrates 48-h EC ₅₀ (mg/L) | Low effects at saturation | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | NES (m) | No Data NES (RA) | No Data NES (RA) | No Data NES (RA) | NES (m) |
| Aquatic Plants 72-h EC ₅₀ (mg/L) | Low effects at saturation | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | No Data Low effects at saturation (RA) | NES (m) | No Data NES (RA) | No Data NES (RA) | No Data NES (RA) | NES (m) |

(m) = measured data (i.e., derived from testing); NES = No effects at saturation (water solubility limit); (RA) = read across; ¹All data generated from WAF are all nominal concentrations.

3. Human Health Effects

A summary of health effects data submitted for SIDS endpoints is provided in Table 3. The table also indicates where data for tested category members are read-across (RA) to untested members of the category.

Acute Oral Toxicity

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts (CAS No. 84605-29-8)

Sprague-Dawley rats (10/sex/dose) were administered single doses of phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts at 1500, 1825, 2221, 2702, 3288 or 4000 mg/kg-bw. Mortality occurred at ≥ 1825 mg/kg-bw within 93 hours of dosing. Other signs of toxicity included hypokinesia, ataxia and diarrhea at all dose levels; ataxia was reported in animals receiving doses > 1825 mg/kg-bw. No changes were seen during necropsy.

LD₅₀ = 3100 – 3200 mg/kg-bw

Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts (CAS No. 68457-79-4)

Wistar rats (10 males/dose) were administered single doses of phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts at 2000, 3500, 5000 or 8750 mg/kg-bw. Mortality was seen at ≥ 3500 mg/kg-bw within the first 5 days of exposure. Lethargy, diarrhea, ptosis, chromorhinorrhea, piloerection and chromodacryorrhea were reported findings at all doses. At necropsy, common findings among the animals that died were lung congestion, gastrointestinal findings and staining around the mouth, nose and anus.

LD₅₀ = 3600 mg/kg-bw

Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (CAS No. 68784-31-6)

Sprague-Dawley rats (5/sex/dose) were administered single doses of phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts via gavage at 0, 1800, 2700, 4000 or 6000 mg/kg-bw. Mortality occurred in males at ≥ 4000 and in females at ≥ 2700 mg/kg-bw. Other signs of toxicity included diarrhea, depression, reduced food consumption, weakness, salivation and blood in urine. No treatment-related necropsy findings were noted.

LD₅₀ (females) = 2900 mg/kg-bw

LD₅₀ (males) = 3400 mg/kg-bw

Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt (CAS No. 2215-35-2)

Sprague-Dawley rats (5/sex/dose) were administered single doses of phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt via gavage at 2000 or 5000 mg/kg-bw. Mortality occurred in both doses within 4 days of exposure. Other signs of toxicity included diarrhea, stained and/or ruffled fur and hypoactivity. Necropsy of animals that died revealed gastrointestinal effects along with bloody oral and nasal discharge.

2000 mg/kg-bw < LD₅₀ < 5000 mg/kg-bw

Phosphorodithioic acid, O,O-bis(2-ethylhexyl) esters, zinc salt (CAS No. 4259-15-8)

Sprague-Dawley rats (10 males/dose) were administered single doses of phosphorodithioic acid, O,O-bis(2-ethylhexyl) esters, zinc salt via gavage at 0, 2200, 3300 or 7500 mg/kg-bw. Mortality was seen at all doses. Other signs of toxicity included diarrhea, depression and reduced food consumption.

LD₅₀ = 3100 mg/kg-bw

Acute Dermal Toxicity

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts (CAS No. 84605-29-8)

New Zealand White rabbits (2/sex) were exposed to a single dose of phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and isopropyl) esters, zinc salts via the dermal route at 2000 mg/kg-bw for 24 hours. No mortality was reported. Erythema in one animal and peeling of the skin in all animals were noted as a result of exposure.

LD₅₀ > 2000 mg/kg-bw

Phosphorodithioic acid, mixed O,O-bis(isobutyl and pentyl) esters, zinc salts (CAS No. 68457-79-4)

New Zealand White rabbits (2/sex) were exposed to a single dose of phosphorodithioic acid, mixed O,O-bis(isobutyl and pentyl) esters, zinc salts at 20,000 mg/kg-bw to the abraded skin under semi-occlusive conditions for 24 hours. No mortality was reported. Lethargy, diarrhea, ataxia, emaciation and ptosis were reported as a result of exposure.

LD₅₀ > 20,000 mg/kg-bw

Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (CAS No. 68784-31-6)

New Zealand White rabbits (5/sex) were exposed to a single exposure of mixed phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts at 5000 mg/kg-bw to the abraded skin under semi-occluded conditions for 24 hours. No mortality was reported. Weight loss and sub-acute dermatitis were reported as a result of exposure.

LD₅₀ > 5000 mg/kg-bw

Phosphorodithioic acid, mixed O,O-bis(isobutyl and isooctyl and pentyl) esters, zinc salts (CAS No. 68988-46-5)

New Zealand White rabbits (5/sex) were exposed to a single exposure of phosphorodithioic acid, mixed O,O-bis(isobutyl and isooctyl and pentyl) esters, zinc salts via dermal route at of 2000 mg/kg-bw for 24 hours. No mortality was reported. Cyanosis, decreased motor coordination and loss of righting reflex were noted. Dermal reactions, necrosis, edema and ulceration persisted through study termination. At necropsy, pitted kidney was seen in one female.

LD₅₀ > 2000 mg/kg-bw

Phosphorodithioic acid, O,O-bis(2-ethylhexyl) esters, zinc salt (CAS No. 4259-15-8)

New Zealand White rabbits (6 males) were exposed to a single dose of phosphorodithioic acid, O,O-bis(2-ethylhexyl) esters, zinc salt at 5000 mg/kg-bw to abraded and non-abraded skin for 24 hours. One animal in the abraded skin group died during the 14-day observation period. Other signs of toxicity were reduced food consumption, muscular weakness and gross lesions in the liver and lungs.

LD₅₀ > 5000 mg/kg-bw

Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt (CAS No. 84605-29-8)

New Zealand White rabbits (5/sex) were exposed to a single dose of phosphorodithioic acid, O,O-diisodecyl ester, zinc salt at 8000 mg/kg-bw to abraded skin under semi-occlusive conditions for 24 hours. No mortality was reported. Clinical signs of toxicity included moderate erythema and edema, decreased activity, abnormal gait, fissuring and sloughing of the skin. Necropsy revealed white nodules in lung and stomach of one animal following exposure.

LD₅₀ > 8000 mg/kg-bw

Repeated-Dose Toxicity

Phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt (CAS No. 4259-15-8)

Sprague-Dawley rats (5/sex/dose) were exposed to phosphorodithioic acid O,O-bis (2-ethylhexyl) ester, zinc salt daily via gavage at 0 (corn oil), 10, 50, 125, 250 and 500 mg/kg-bw/day for 7 days/week for 28 days. Mortality was seen at 500 mg/kg-bw/day. Clinical signs included changes in fecal consistency and coloration, staining of various body surfaces, rales, salivation and aggressive behavior at 125, 250 and 500 mg/kg-bw/day in both sexes. Rales and salivation were also observed in the 50 mg/kg-bw/day males. Decreased body weight gains were seen in males at \geq 250 mg/kg-bw/day and in females at 500 mg/kg-bw/day. At necropsy, a thickened mucosa of the nonglandular stomach was observed at 250 and 500 mg/kg-bw/day. Submucosal edema of the glandular and/or non-glandular portions of the stomach was seen in one 250 mg/kg-bw/day male and all high-dose females. Three high-dose females also had suppurative inflammation, primarily in the non-glandular portion of the stomach. Mean absolute and relative adrenal weights in the 250 and 500 mg/kg-bw/day groups were increased in both sexes. No histopathological lesions were seen associated with these increases.

LOAEL = 50 mg/kg-bw/day (based on rales and salivation)

NOAEL = 10 mg/kg-bw/day

Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts (CAS No. 113706-15-3)

New Zealand White rabbits (10/sex/dose) were administered phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts via the dermal route at 0, 5 or 25% (w/v) (approximately 0, 100 and 500 mg/kg-bw/day¹², respectively) for 5 days/week for 4 weeks. The vehicle control was Primol 185. Treatment-related mortality was seen at the high dose. Emaciation, dermal thickening, lacrimation and ano-genital staining were among the observed clinical signs. Marked, dose-related increases in the incidence and severity of erythema, edema, atonia, desquamation, fissuring, eschar formation and exfoliation were seen at both dose levels. Many of these observations were moderate to extreme in severity, particularly those in the high-dose group. Dermal irritation was observed in the vehicle control and treatment groups, but occurred with greater incidence and severity in the treatment groups. The mean body weights of the high-dose males and females were markedly reduced compared to vehicle control throughout the study. A slight reduction in body weight was also seen in the low-dose animals. A marked reduction in mean hemoglobin, hematocrit and erythrocyte counts was seen in the high-dose animals compared to vehicle control. In addition, there were increases in mean platelet count in the high-dose males and slight (low dose) to marked (high dose) increases in mean cholesterol levels. Marked decreases in the mean albumin levels were seen in the high-dose animals. The mean plasma, erythrocyte and brain cholinesterase values of the high-dose animals and low-dose females were decreased compared to the vehicle control. The mean absolute and relative (to body weight) testes and epididymal weights were markedly lower than vehicle control in the high-dose group. The mean absolute and relative (to body weight) adrenal weights of the high-dose males and females were increased compared to vehicle control. Dose-related increases in mean absolute and relative kidney weights were evident in both sexes at both doses.

Subchronic inflammatory changes consisting of multifocal pneumonitis were present in some vehicle control and treated animals. Macroscopic dermal changes included atonia, alopecia, exfoliation, fissuring and eschar formation. Compound-related microscopic changes in the skin of low- and high-dose animals consisted of slight to moderately severe hyperkeratosis, parakeratosis and epithelial hyperplasia. In some rabbits, these changes were accompanied by an increase in the amount of collagen present in the dermis and/or focal to multifocal areas of suppurative dermatitis. The severity of these lesions was greater at the high dose. In addition, the testes of the high-dose animals were observed to be markedly smaller than those of the vehicle control males. Microscopic examination of the testes revealed the presence of morphologic abnormalities in the seminiferous tubules of the testes of the high-dose animals that were characterized by aspermatogenesis, diffuse tubular hypoplasia and a reduced mitotic activity. **LOAEL = 100 mg/kg-bw/day** (based on clinical signs, dermal effects, and significant reductions in plasma, erythrocyte and brain cholinesterase)

NOAEL = Not established

Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt (CAS No. 28629-66-5)

New Zealand White rabbits (10/sex/dose) were administered phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt via the dermal route at 0, 5 or 25% (w/v) (approximately 100 and 500 mg/kg-bw/day) for 5 days/week for a total of 20 exposures. Mortality was seen at the high-dose. Dose-related emaciation was a common finding at both doses in both sexes with greater severity in females. Dermal thickening was observed in most of the treated animals during the last 2 weeks of the study. Ano-genital staining, nasal discharge and lacrimation were frequently observed in the treated animals at both doses. Treated animals exhibited marked, dose-related increases in the incidence and severity of erythema, edema, atonia desquamation, fissuring, eschar formation and exfoliation. The severity of these observations was moderate to extreme in the high-dose group. Dermal irritation was also observed in the vehicle control group with low incidence and severity. The mean body weights of males and females at both doses were decreased throughout the study. Mean hemoglobin, hematocrit and erythrocyte counts were slightly to markedly reduced compared to vehicle control. Decreased alkaline phosphatase, decreased albumin, increased blood urea nitrogen, increased cholesterol and increased total and direct bilirubin were seen at both doses. In addition, mean brain cholinesterase levels were slightly reduced in the treated animals. Dermal changes consisted of slight to moderately severe hyperkeratosis, parakeratosis and epithelial hyperplasia. In some rabbits, these changes were accompanied by an increase in the amount of collagen in the dermis and/or focal to multifocal areas of suppurative dermatitis. The severity of these lesions was greater at the high-dose level. In treated males, there was a dose-related, marked decrease in the absolute and relative testes and epididymides weights. Microscopic examination of the testes from both dose groups revealed the presence of morphologic abnormalities in the seminiferous tubules of the testes that were characterized by aspermatogenesis, diffuse tubular hypoplasia and a reduced mitotic activity.

¹² Approximate conversion to mg/kg-bw/day is based on assumption of 100% absorption throughout this section.

LOAEL = 100 mg/kg-bw/day (based on clinical signs, changes in clinical chemistry parameters, decreased body weight, dermal effects and effects on testes)

NOAEL = Not established

Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts (CAS No. 68457-79-4)

Rabbits (15 males/dose) were administered phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts via dermal route at 0 (vehicle) or 25% (w/v) (approximately 500 mg/kg-bw/day) for 5 days/week for 4 weeks. Mortality, decreased body weights, emaciation, decreased food consumption, fissuring and exfoliation of the skin, and higher incidence and/or severity of ano-genital staining were seen in treated animals when compared to controls. Erythema, atonia and desquamation were observed in animals from both groups; however, the incidence and severity was higher in animals exposed to phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts. Hematological parameters were lower and clinical chemistry parameters (cholesterol, triglycerides and blood urea nitrogen) were elevated in treated animals. Absolute and relative organ weights (epididymides, testes, prostate) of exposed animals were reduced and kidney weights were increased when compared to control animals; these changes remained following a 9-week extension period without treatment. Microscopic examination revealed that treated animals had slight to moderately severe changes in the skin and testicular changes (moderate to severe diffuse tubular hypoplasia and aspermatogenesis).

LOAEL = 500 mg/kg-bw/day (based on mortality, reduced body weight, dermal effects, clinical signs)

NOAEL = Not established

Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt (CAS No. 26566-95-0)

New Zealand White rabbits (5/sex/dose) were administered phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt at 0, 210, 430 and 860 mg/kg-bw/day to the abraded skin for 5 days/week for 3 weeks. Mortality was seen at 430 and 860 mg/kg-bw/day. Decreased body weight, lethargy, anorexia, adipsia, emaciation and diarrhea were noted prior to death. The survivors in the treated groups expressed signs of nasal and ocular discharge and gastrointestinal effects. These effects increased in frequency over the course of the study. In some cases, lethargy, ptosis, anorexia and adipsia accompanied by emaciation were also seen. Severe dermal reactions were observed in all treated animals by the ninth dose. Decreased body weights were seen in all mid- and high-dose animals. Leukocyte counts were increased slightly in all treated groups at termination. Dose-related moderate to severe epithelial hyperplasia with surface exudate was observed in the treated skin of all treated rabbits. Ulceration and necrosis were seen among the high-dose animals. Four of five high-dose and two of five mid-dose males exhibited suppression of sperm formation. One control animal had severely reduced spermatogenesis. The high-dose animals exhibited aspermia.

LOAEL = 210 mg/kg-bw/day (based on dermal effects, increased leukocyte counts and suppressed sperm formation)

NOAEL = Not established

Phosphorodithioic acid mixed O,O-bis(iso-butyl and isooctyl, and pentyl) esters, zinc salts (CAS No. 68988-46-5)

Rabbits (18 males/dose) were administered phosphorodithioic acid mixed O,O-bis(iso-butyl and isooctyl, and pentyl) esters, zinc salts via dermal route at 3, 5, 25 and 100% (approximately, 60, 100, 500 and 2000 mg/kg-bw/day) or the vehicle control (base oil) for 5 days/week for 3 weeks. Untreated and sham controls were included. A 6-week recovery period followed the exposure period. All animals treated at the 100% dose level, 15 of 18 in the 25% and 1 of 18 in the vehicle and 5% dose groups died or were sacrificed moribund. No deaths occurred in the 3%, sham or untreated control groups. During recovery, three animals in the vehicle control and one at 5% were sacrificed moribund. Erythema and edema were observed in all treated rabbits within 24 hours of the first application. Severity was proportional to phosphorodithioic acid mixed O,O-bis(iso-butyl and isooctyl, and pentyl) esters, zinc salts concentration and duration of exposure. Severe erythema and/or eschar formation were observed at later scoring periods in test and vehicle control animals. Other findings included hyperirritability, diarrhea, decreased motor activity, ataxia, loss of righting reflex, ocular discharge, redness in the genital area and rippling of skin. Severe body weight losses were seen at the 25 and 100% dose levels. Marked decreases in body weight of the vehicle control, 3 and 5% groups were noted throughout the study. Recovery from body weight losses began following termination of treatment with the vehicle or phosphorodithioic acid mixed O,O-bis(iso-butyl and isooctyl, and pentyl) esters, zinc salts. Reductions in several hematology parameters were noted in the vehicle and treated groups at the termination of treatment. Increases in the percentages of mature heterophiles and corresponding decreases in lymphocytes were detected. Mean absolute weights of testes, prostate and epididymis were markedly lower in the vehicle and treated groups than in the sham or untreated control groups, but there were no significant

differences when the vehicle controls were compared to the treated groups. Vehicle and test material related effects noted on the skin, hematology parameters and weights of reproductive organs observed during treatment were no longer different at the end of the 6-week recovery period. Gross necropsy findings included discoloration, scaling, scabbing, hair loss and skin thickening at the dosing site. Treated animals also exhibited enlargement of the prefemoral lymph node, discoloration of the lungs and liver red foci in the gastric mucosa and trichobezoars in the stomach. One animal in each of the 5%, 25% and vehicle control groups had small soft testes. Necropsy observations following recovery noted less frequent and less severe skin lesions, enlargement of the prefemoral and respiratory lymph nodes and heart, lung and liver discoloration. In general, vehicle (base oil) treated animals had a higher incidence of lesions following recovery than did the treated animals. The skin of the vehicle and treated animals had acanthosis and acute and severe inflammation with pus formation at the treatment site. In treated animals, the acanthosis was followed by escharotic dermatitis, which involved the deeper layers of the skin and resulted in blood and fluid loss. Following the 6-week recovery period, the lesions of the epidermis had abated. A low incidence of orchitis (testicular inflammation) and maturation arrest at the primary spermatocyte level was observed in the testes of vehicle and treated animals following the treatment and recovery periods. Effects noted at 3 and 5% of phosphorodithioic acid mixed O,O-bis(iso-butyl and isoctyl, and pentyl) esters, zinc salts were similar to those observed with the vehicle, suggesting that toxic effects observed at these dose levels were principally due to the vehicle.

LOAEL = 500 mg/kg-bw/day (based on mortality, dermal effects, decreased body weights, clinical signs and effect on hematological parameters)

NOAEL = 100 mg/kg-bw/day

Reproductive/Developmental Toxicity

Phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, zinc salt (CAS No. 4259-15-8)

In a combined reproductive/developmental toxicity screening test, Sprague-Dawley rats (12/sex/dose) were administered phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, zinc salt via gavage at 0, 30, 100 or 200 mg/kg-bw/day. Dosing regimens were as follows: F0 males, 28 days total (14 days pre-mating, 14-day mating period); F0 females, at least 43 days total (14 days pre-mating, mating; 25 days of gestation and 4 days of lactation). Mortality was seen in males at the high dose. Two females in the mid-dose group and one female in the high-dose group were euthanized on lactation days 1 or 2 due to total litter loss. All other animals survived to their scheduled sacrifice. Clinical signs noted in the dead or sacrificed animals included staining, matting of fur, respiratory distress, hunched appearance and mucoid diarrhea. Clinical signs in the surviving mid- and high-dose males and females included post-dosing salivation, brown staining, respiratory distress and diarrhea. No treatment-related clinical findings were observed in the low-dose animals. A microscopic examination of the reproductive organs of these animals did not reveal any treatment-related effects. Other reproductive parameters (mating and fertility indices, days between pairing and coitus, gestation length and parturition) were unremarkable in all treated groups. The pre-mating (weeks 1 – 4) mean body weight gain of the high-dose males was reduced compared to control. The mean body weights of the low- and mid-dose males and all treated female groups were unremarkable during the pre-mating period. Gestation and lactation body weights were unremarkable in all treated groups. There was no effect on food consumption in any treated groups during the pre-mating, gestation and lactation periods. With the exception of the gastric irritation noted above in several unscheduled deaths, the macroscopic and microscopic findings were unremarkable.

F1 pup body weights, live litter size and sex ratios were not affected by treatment. An increased number of dead pups were noted in the mid-dose group on day 0 of lactation. Pup viability indices were reduced in the mid-dose (during lactation days 1 and 4) and high-dose (lactation day 4) groups. This was attributed to total litter loss by three females (two mid-dose and one high-dose females). Increased pup deaths were observed in the mid- and high-dose groups during the post-natal period. An increased incidence of pups without milk in the stomach was noted in the 100 mg/kg-bw/day group. No treatment-related effects were evident during necropsy of the pups found dead and scheduled pup necropsies.

LOAEL (systemic toxicity) = 100 mg/kg-bw/day (based on mortality, clinical signs)

NOAEL (systemic toxicity) = 30 mg/kg-bw/day

LOAEL (reproductive/developmental toxicity) = 100 mg/kg-bw/day (based on increased postnatal mortality)

NOAEL (reproductive/developmental toxicity) = 30 mg/kg-bw/day

Genetic Toxicity – Gene Mutation

In vitro

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts (CAS No. 84605-29-8)

Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (CAS No. 68784-31-6)

Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt (CAS No. 26566-95-0)

Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt (CAS No. 4259-15-8)

Salmonella typhimurium strains TA98, TA100, TA1535, TA1537 or TA1538 and *Escherichia coli* WP2uvrA were exposed to the above-listed zinc dialkyldithiophosphates in separate assays at concentrations of 1 – 10,000 µg/plate in the presence and absence of metabolic activation. Cytotoxicity was evaluated in each assay. Solvent (ethanol or acetone) and positive controls showed appropriate responses. None of the tested substances showed mutagenic activity in the presence or absence of metabolic activation.

The above-listed chemicals were not mutagenic in these assays.

Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts (CAS No. 68457-79-4)

Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts (CAS No. 113706-15-3)

Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt (CAS No. 4259-15-8)

Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isooctyl and pentyl) esters, zinc salts (CAS No. 68988-46-5)

Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt (CAS No. 26566-95-0)

Mouse lymphoma cells (strain L5178Y) were exposed to the above-listed zinc dialkyldithiophosphates in separate assays at concentrations of 0.0013 – 0.024 µL/mL in the presence and absence of metabolic activation. All chemicals showed negative mutagenic activity without metabolic activation. Two chemicals, phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts (CAS No. 113706-15-3) and phosphorodithioic acid, mixed O,O-bis(iso-butyl and isooctyl and pentyl) esters, zinc salts (CAS No. 68988-46-5), tested positive for gene mutation in the presence of metabolic activation. The remaining chemicals showed equivocal evidence (considered positive) for gene mutations in the presence of metabolic activation.

The above-listed chemicals were mutagenic in these assays.

Genetic Toxicity – Chromosomal Aberrations

In vivo

Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts (CAS No. 84605-29-8)

Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (CAS No. 68784-31-6)

Phosphorodithioic acid, O-(2-ethylhexyl) O-(2-methylpropyl) esters, zinc salt (CAS No. 26566-95-0)

Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt (CAS No. 4259-15-8)

Swiss Albino CrI:CD-1 (male and female) were administered the above listed zinc dialkyldithiophosphates via intraperitoneal route in separate assays at doses ranging from 6 to 50 mg/kg-bw. Several animals showed clinical signs including mortality, piloerection, tremors and hypoactivity and were prostrate prior to death. Bone marrow was sampled at 24, 48 and/or 72 hours post-treatment. Erythrocytes were harvested, washed, stained and evaluated for the presence of micronuclei. None of the chemicals induced micronuclei in bone marrow erythrocytes.

The above-listed chemicals did not induce micronuclei in these assays.

Conclusion: Acute oral and dermal toxicity of ZDDP category members is low. Several repeated dose dermal studies of ZDDP category chemicals showed moderate toxicity in rabbits. An oral repeated-dose study in rats of one ZDDP category member showed moderate systemic toxicity. An oral combined reproductive/developmental toxicity study in rats of one ZDDP category member showed moderate systemic toxicity in the adult animals and moderate postnatal developmental toxicity; there were no effects on reproductive parameters or reproductive organs. In contrast, dermal repeated-dose studies in rabbits of several ZDDP category members did show moderate toxicity to the male reproductive organs. ZDDP category members were not mutagenic in bacterial cells, but showed a positive response in mammalian cells. ZDDP category members did not induce chromosome aberrations when tested *in vivo*.

Table 3. Summary of Human Health Data

| Endpoints | Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts (84605-29-8) | Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts (68457-79-4) | Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (68784-31-6) | Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isoocetyl) esters, zinc salts (113706-15-3) | Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt (26566-95-0) | Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isoocetyl and pentyl) esters, zinc salts (68988-46-5) | Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt (2215-35-2) | Phosphorodithioic acid, O,O-bis(2-ethylhexyl) ester, zinc salt (4259-15-8) | Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt (28629-66-5) | Phosphorodithioic acid, O,O-diisodecyl ester, zinc salt (25103-54-2) | Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt (51261-67-5) | Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (11059-65-7) |
|-------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Acute Oral Toxicity (mg/kg-bw) | 3100 | 3600 | 2900 | No Data 2900 (RA) | No Data 2900 (RA) | No Data 2900 (RA) | > 2000 < 5000 | 3100 | No Data 3100 (RA) | No Data 3100 (RA) | No Data 3100 (RA) | No Data 3100 (RA) |
| Acute Dermal Toxicity (mg/kg-bw) | > 2000 | > 2000 | > 5000 | No Data > 2000 (RA) | No Data > 2000 (RA) | > 2000 | No Data > 2000 (RA) | > 5000 | No Data > 5000 (RA) | > 8000 | No Data > 8000 (RA) | No Data > 8000 (RA) |
| Repeated-dose Toxicity-Oral (NOAEL/LOAEL (mg/kg-bw/day)) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | NOAEL = 10 LOAEL = 50 | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) | No Data NOAEL = 10 LOAEL = 50 (RA) |
| Repeated-dose Toxicity- Dermal (NOAEL/LOAEL (mg/kg-bw/day)) | No Data NOAEL = NE LOAEL = 500 (RA) | NOAEL = NE LOAEL = 500 | No Data NOAEL = NE LOAEL = 500 (RA) | NOAEL = NE LOAEL = 100 | NOAEL = NE LOAEL = 210 | NOAEL = 100 LOAEL = 500 | NOAEL = NE LOAEL = 800 | No Data NOAEL = NE LOAEL = 100 (RA) | NOAEL = NE LOAEL = 100 | No Data NOAEL = NE LOAEL = 100 (RA) | No Data NOAEL = NE LOAEL = 100 (RA) | No Data NOAEL = NE LOAEL = 100 (RA) |

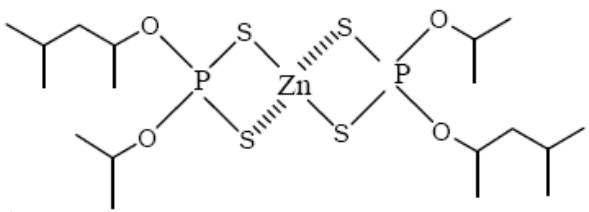
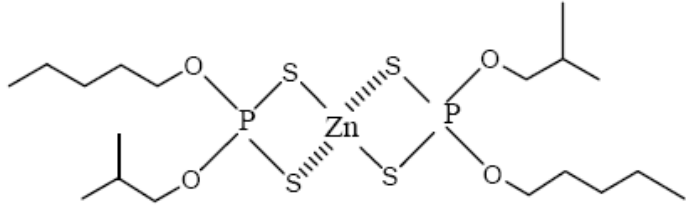
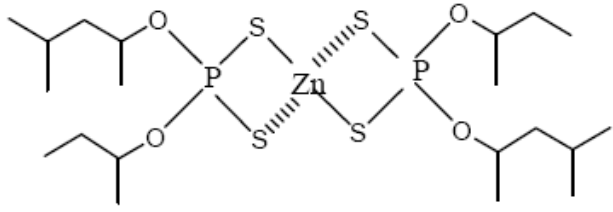
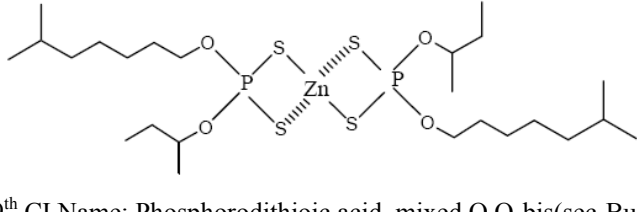
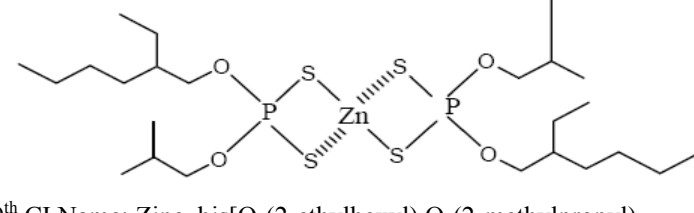
Bold = measured data; (RA) = Read Across; NE = Not established

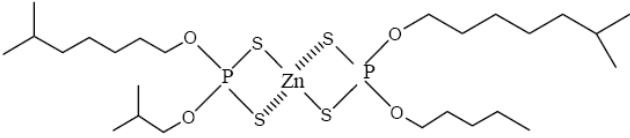
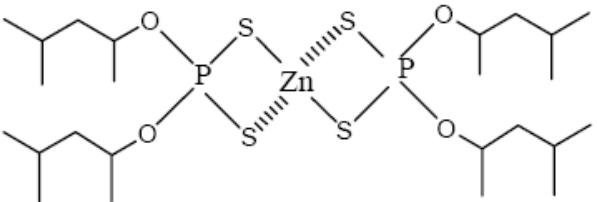
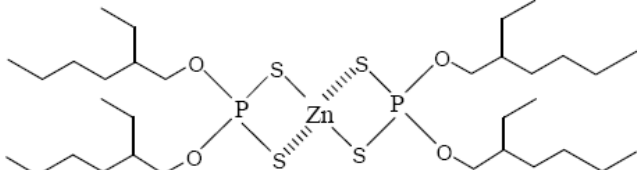
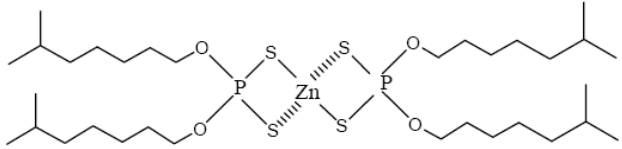
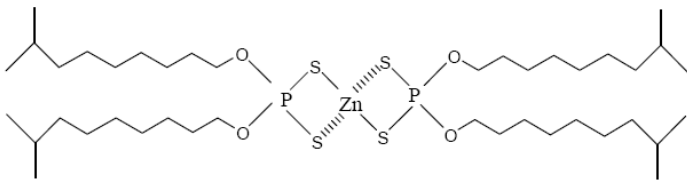
Table 3. Summary of Human Health Data

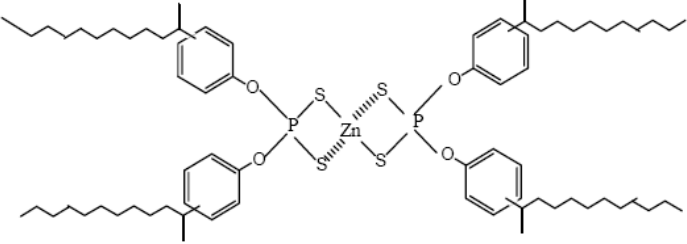
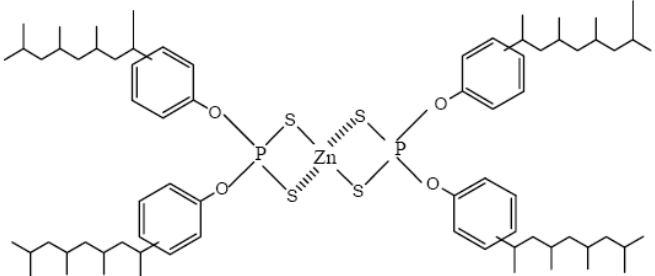
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|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|----------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Reproductive/ Developmental Toxicity NOAEL/ LOAEL (mg/kg-bw/day) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | NOAEL = 30 LOAEL = 100 | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) | No Data NOAEL = 30 LOAEL = 100 (RA) |
| Genetic Toxicity–Gene Mutation | Negative | Positive (Equivocal) | Negative | Positive | Positive (mammalian cell) Negative (bacteria) | Positive | Positive | Positive (mammalian cell) Negative (bacteria) | No Data Positive (RA) | No Data Positive (RA) | No Data Positive (RA) | No Data Positive (RA) |
| Genetic Toxicity–Chromosomal Aberrations | Negative | No Data Negative (RA) | Negative | No Data Negative (RA) | Negative | No Data Negative (RA) | No Data Negative (RA) | Negative | No Data Negative (RA) | No Data Negative (RA) | No Data Negative (RA) | No Data Negative (RA) |

Bold = measured data; (RA) = Read Across; NE = Not established

Appendix

| Zinc Dialkyldithiophosphates | | |
|------------------------------|---------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CAS No. | Chemical Name | Structure |
| SPONSORED CHEMICALS | | |
| 84605-29-8 | Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts |  <p>9th CI Name: Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-Pr) esters, zinc salts</p> |
| 68457-79-4 | Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts |  <p>9th CI Name: Phosphorodithioic acid, mixed O,O-bis(iso-Bu and pentyl) esters, zinc salts</p> |
| 68784-31-6 | Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts |  <p>9th CI Name: Phosphorodithioic acid, mixed O,O-bis(sec-Bu and 1,3-dimethylbutyl) esters, zinc salts</p> |
| 113707-15-3 | Phosphorodithioic acid, mixed O,O-bis(sec-butyl and iso-octyl) esters, zinc salts |  <p>9th CI Name: Phosphorodithioic acid, mixed O,O-bis(sec-Bu and iso-octyl) esters, zinc salts</p> |
| 26566-95-0 | Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salts |  <p>9th CI Name: Zinc, bis[O-(2-ethylhexyl) O-(2-methylpropyl) phosphorodithioato-κ.S,κ.S']-, (T-4)-</p> |

| Zinc Dialkyldithiophosphates | | |
|------------------------------|---------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CAS No. | Chemical Name | Structure |
| SPONSORED CHEMICALS | | |
| 68988-46-5 | Phosphorodithioic acid, mixed O,O-bis(iso-butyl and isoctyl and pentyl) esters, zinc salts |  <p>9th CI Name: Phosphorodithioic acid, mixed O,O-bis(iso-Bu and isoctyl and pentyl) esters, zinc salts</p> |
| 2215-35-2 | Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salts |  <p>9th CI Name: Zinc, bis[O,O-bis(1,3-dimethylbutyl) phosphorodithioato-κ.S,κ.S']-, (T-4)-</p> |
| 4259-15-8 | Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salts |  <p>9th CI Name: Zinc, bis[O,O-bis(2-ethylhexyl) phosphorodithioato-κ.S,κ.S']-, (T-4)-</p> |
| 28629-66-5 | Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt |  <p>9th CI Name: Zinc, bis(O,O-diisooctyl phosphorodithioato-κ.S,κ.S')-</p> |
| 25103-54-2 | Phosphorodithioic acid, O,O-diisodecyl ester, zinc salts |  <p>9th CI Name: Zinc, bis(O,O-diisodecyl phosphorodithioato-κ.S,κ.S')-</p> |

| Zinc Dialkyldithiophosphates | | |
|------------------------------|------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CAS No. | Chemical Name | Structure |
| SPONSORED CHEMICALS | | |
| 54261-67-5 | Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salts |  <p>9th CI Name: Zinc, bis[O,O-bis(dodecylphenyl)phosphorodithioato-κ.S,κ.S']-</p> |
| 11059-65-7 | Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salts |  <p>9th CI Name: Zinc, bis[O,O-bis(tetrapropenylphenyl)phosphorodithioato-κ.S,κ.S']-</p> |

Screening Level Exposure Characterization for HPV Challenge Chemical

Zinc Dialkyldithiophosphates Category

CAS #(s): 113706-15-3; 4259-15-8; 68988-46-5; 26566-95-0;
68457-79-4; 28629-66-5; 68784-31-6; 25103-54-2;
11059-65-7; 84605-29-8; 54261-67-5; 2215-35-2

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Screening Level Exposure Characterization Zinc Dialkyldithiophosphates Category

Non-CBI Executive Summary

The 12 zinc dialkyldithiophosphates category chemicals have aggregated production/ import volumes in the range of 94 million to 340.5 million pounds.¹³ The aggregated production/ import volumes exclude two of the twelve chemicals, phosphorodithioic acid, mixed O,O-bis(iso-bu and isoctyl) (CAS#68988-46-5) and zinc, bis (O,O-diisodecyl phosphorodithioato-.kappa.S,.kappa) (CAS#25103-54-2), which do not have Inventory Update Reporting (IUR) submissions. Non-confidential IUR information indicates that these chemicals were manufactured and/or imported at the following companies and sites:

CAS#113706-15-3:

- Infineum USA, L.P. / Linden, NJ

CAS#4259-15-8:

- Rhein Chemie Corporation / Trenton, NJ

CAS#26566-95-0:

- Confidential

CAS#68457-79-4:

- Infineum USA, L.P. / Linden, NJ

CAS#28629-66-5:

- Infineum USA, L.P. / Linden, NJ

CAS#68784-31-6:

- Confidential

CAS#11059-65-7:

- Confidential

CAS#84605-29-8:

- Infineum USA, L.P. / Linden, NJ

CAS#54261-67-5:

- Confidential

CAS#2215-35-2:

- BP AMERICA INC. / Wayne, NJ

¹³ USEPA, 2006 Partial Updating of TSCA Chemical Inventory

There may be other companies and sites that are claimed confidential. Non-confidential IUR information for many of the chemicals in the zinc dialkyldithiophosphates category indicates that these chemicals are used as lubricants in the manufacturing of other chemical products. Nine of the twelve chemicals in this category have IUR submissions that indicate uses in commercial settings, or consumer uses.

Information submitted as part of the HPV Challenge Program indicates that zinc dialkyldithiophosphates are used to formulate finished lubricating oils, including all types of automotive and diesel engine crankcase, industrial oils and hydraulic fluids.¹⁴ The Hazardous Substances Data Bank (HSDB) has information for two of the chemicals and lists the uses as hydraulic and transmission fluids (CAS#28629-66-5) or additives in lubricating oils (CAS#25103-54-2).¹⁵

Potential Exposures to the General Population and the Environment: Based on the information considered, including known uses, and the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium potential that the general population and the environment might be exposed.

Based on the predominant uses of zinc dialkyldithiophosphates in automotive and diesel crankcase oils, industrial oils, and hydraulic fluids, there may be potential releases to land via disposal, or accidental, spills and to air via incineration of spent oil.

Persistence and bioaccumulation ratings for these chemicals are P3 and B1. These ratings suggest that these chemicals are very persistent in the environment; and are not bioaccumulative.

Potential Exposures to Workers: Based on the information considered, including IUR data and information from HPV Test Plan, and the Agency's professional judgment, EPA identifies, for the purposes of risk-based prioritization, a medium relative ranking for potential worker exposure. This relative ranking is based on the potential for dermal exposure of a moderate number of workers, information on uses of the chemical substances including commercial uses, and the production volume. Zinc dialkyldithiophosphates do not have OSHA Permissible Exposure Limits (PELs).¹⁶

Potential Exposures to Consumers: EPA identifies, for the purposes of risk-based prioritization, a high potential that consumers might be exposed from products containing this chemical. Nine of the twelve chemicals in this category have IUR submissions that indicate uses in commercial settings or consumer uses. Information from public data sources indicate potential for exposure to consumers who may periodically add lubricating oil to automotive crankcases or change their own automotive engine oil.¹⁷

¹⁴ ACCPAP, 2002. HPV Test Plan for Zinc Dialkyldithiophosphates. American Chemistry Council Petroleum Additives Panel. Accessed, 6/16/08. <http://www.epa.gov/chemrtk/pubs/summaries/zincdial/c14066tp.pdf>

¹⁵ HSDB, 2008. Hazardous Substances Data Bank. Accessed, 6/16/08. <http://toxnet.nlm.nih.gov/>.

¹⁶ NIOSH, 1988. OSHA PEL Project Documentation. <http://www.cdc.gov/niosh/pel88/npelcas.html> Accessed, 6/17/08.

¹⁷ ACCPAP, 2002. HPV Test Plan for Zinc Dialkyldithiophosphates. American Chemistry Council Petroleum Additives Panel. Accessed, 6/16/08. <http://www.epa.gov/chemrtk/pubs/summaries/zincdial/c14066tp.pdf>

Potential Exposures to Children: EPA identifies, for the purposes of risk-based prioritization, a low potential that children might be exposed. None of chemicals reported uses in products intended to be used by children. One chemical reported that such information was Not Readily Obtainable. It is unlikely that children will be exposed to automotive and diesel crankcase oils, industrial oils, and hydraulic fluids containing these chemicals.

Below are tables summarizing non-confidential processing and use information in the IUR for each of the individual chemicals in this category.

This exposure characterization was completed using both public, non-confidential sources, and one or more IUR submissions that were available as of this writing.

Non Confidential IUR Data Summary: Phosphorodithioic acid, mixed O,O-bis(sec-butyl and isooctyl) esters, zinc salts (CAS#113706-15-3)

Manufacturing/Import Information

Production and import volume: 10 million to 50 million pounds
 List of non-CBI companies/ sites*: Infineum USA, L.P. / Linden, NJ
 Maximum number of exposed workers**: less than 100 (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration*: up to 90% by weight
 Non-CBI physical forms*: liquid

* There may be other companies/sites, concentrations, and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 31% - 60% | NRO |
| Additional line item(s) may be claimed as CBI | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, O,O-bis(2-ethylhexyl)ester, zinc salt (CAS#4259-15-8)

Manufacturing/Import Information

Production and import volume: 10 million to 50 million pounds
 List of non-CBI companies/ sites*: Rhein Chemie Corporation / Trenton, NJ
 Maximum number of exposed workers**: 1,000 or greater (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration*: up to 90% by weight
 Non-CBI physical forms*: pellets or large crystals; liquid

* There may be other companies/sites, concentrations, and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 1% - 30% | Confidential |
| Additional line item(s) may be claimed as CBI | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, O-(2-ethylhexyl) O-isobutyl ester, zinc salt (CAS#26566-95-0)

Manufacturing/Import Information

Production and import volume: <500,000 pounds
 List of non-CBI companies/ sites: confidential
 Maximum number of exposed workers*: less than 100 (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration: confidential
 Non-CBI physical forms: confidential

* There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|--------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| None reported | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| None reported | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, mixed O,O-bis(iso-butyl and pentyl) esters, zinc salts (CAS#68457-79-4)

Manufacturing/Import Information

Production and import volume: 10 million to 50 million pounds
 List of non-CBI companies/ sites*: Infineum USA, L.P. / Linden, NJ
 Maximum number of exposed workers**: between 100 and 999 (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration*: up to 90% by weight
 Non-CBI physical forms*: liquid

* There may be other companies/sites, concentrations, and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 1% - 30% | No |
| Additional line item(s) may be claimed as CBI | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, O,O-bis(isooctyl) ester, zinc salt (CAS#28629-66-5)

Manufacturing/Import Information

Production and import volume: 1 million to 10 million pounds
 List of non-CBI companies/ sites*: Infineum USA, L.P. / Linden, NJ
 Maximum number of exposed workers**:
 between 100 and 999 (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration*: up to 90% by weight
 Non-CBI physical forms*: liquid

* There may be other companies/sites, concentrations, and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 61% - 90% | No |
| Additional line item(s) may be claimed as CBI | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, mixed O,O-bis(sec-butyl and 1,3-dimethylbutyl) esters, zinc salts (CAS#68784-31-6)

Manufacturing/Import Information

Production and import volume: 1 million to 10 million pounds
 List of non-CBI companies/ sites: confidential
 Maximum number of exposed workers*: 1,000 or greater (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration: confidential
 Non-CBI physical forms: confidential

* There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|--------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Claimed as CBI | | |

Non Confidential IUR Data Summary: Phenol, tetrapropenyl-, hydrogen phosphorodithioate, zinc salt (CAS#11059-65-7)

Manufacturing/Import Information

Production and import volume: 1 million to 10 million pounds
 List of non-CBI companies/ sites: confidential
 Maximum number of exposed workers*: 1,000 or greater (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration: confidential
 Non-CBI physical forms: confidential

* There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|--------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Claimed as CBI | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, mixed O,O-bis(1,3-dimethylbutyl and iso-propyl) esters, zinc salts (CAS#84605-29-8)

Manufacturing/Import Information

Production and import volume: 50 million to 100 million pounds
 List of non-CBI companies/ sites*: Infineum USA, L.P. / Linden, NJ
 Maximum number of exposed workers***: 1,000 or greater (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration*: up to 100% by weight
 Non-CBI physical forms*: liquid

* There may be other companies/sites, concentrations, and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Processing--incorporation into formulation, mixture, or reaction product | Other Basic Organic Chemical Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 1% - 30% | confidential |
| Additional line item(s) may be claimed as CBI | | |

Non Confidential IUR Data Summary: Phenol, dodecyl-, hydrogen phosphorodithioate, zinc salt (CAS#54261-67-5)

Manufacturing/Import Information

Production and import volume: 1 million to 10 million pounds
 List of non-CBI companies/ sites: confidential
 Maximum number of exposed workers*: between 100 and 999 (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration: confidential
 Non-CBI physical forms**: liquid

* There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

** There may be other physical forms that are claimed confidential.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 1% - 30% | No |
| Additional line item(s) may be claimed as CBI | | |

Non Confidential IUR Data Summary: Phosphorodithioic acid, O,O-bis(1,3-dimethylbutyl) ester, zinc salt (CAS#2215-35-2)

Manufacturing/Import Information

Production and import volume: 10 million to 50 million pounds
 List of non-CBI companies/ sites*: BP AMERICA INC. / Wayne, NJ
 Maximum number of exposed workers**: 1,000 or greater (including those of manufacturing, industrial processing and use)
 Highest non-CBI maximum concentration*: up to 60% by weight
 Non-CBI physical forms*: liquid

* There may be other companies/sites, concentrations, and physical forms that are claimed confidential.

** There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there may be at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions.

| Table 1 Industrial Processing and Use Information Reported in 2006 IUR | | |
|---------------------------------------------------------------------------------------|----------------------------------------------------------|--------------------------------|
| Processing Activity | Industrial Sector | Function in Ind. Sector |
| Processing--incorporation into formulation, mixture, or reaction product | All Other Chemical Product and Preparation Manufacturing | Lubricants |
| Additional line item(s) may be claimed as CBI | | |

| Table 2 Commercial/ Consumer Uses Reported in 2006 IUR | | |
|-----------------------------------------------------------------------|--------------------------------------------|-----------------------------------|
| Commercial/ Consumer Product Category Description | Highest maximum concentration range | Use in Children's Products |
| Lubricants, greases and fuel additives | 1% - 30% | confidential |
| Additional line item(s) may be claimed as CBI | | |