

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 salts (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(tetrapropylenephenyl) phosphorodithioato-.kappa.S,.kappa.S']-)	(CASRN 11059-65-7)

This document is based on screening-level characterizations done by EPA on the environmental fate, hazard, and exposure of the listed chemicals. The information used by EPA includes data submitted under the HPV Challenge Program¹ and the 2006 Inventory Update Reporting (IUR)², and data publicly available through other selected sources³. This screening-level prioritization presents EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed. These initial characterization and prioritization

¹ US EPA, HPV Challenge Program information: <http://epa.gov/hpv/>.

² US EPA, IUR information: <http://www.epa.gov/oppt/iur/index.htm>.

³ US EPA, Information on additional public databases used: <http://www.epa.gov/hpvis/pubdtsum.htm>.

documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Rather, they are interim evaluations. Recommended actions may be considered by EPA in the future based on a relative judgment regarding these chemicals in comparison with others evaluated under this program, and in light of the uncertainties presented by gaps in the available data that may be determined to exist. These evaluations contribute to meeting U.S. commitments under the chemicals cooperation work being done in North America⁴ through the EPA Chemical Assessment and Management Program (ChAMP)⁵.

Hazard and Fate Summary:

- **Human Health:** Acute oral and dermal toxicity of members of this category is low. Several repeat dose dermal studies of members of this category showed moderate toxicity in rabbits. An oral repeated dose study in rats of one category member showed moderate systemic toxicity. An oral combined reproductive/developmental toxicity study in rats of one 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 category members did show moderate toxicity to the male reproductive organs. Category members were not mutagenic in bacterial cells, but showed a positive response in mammalian cells. Category members did not induce chromosomal aberrations when tested *in vivo*.
- **Environment:** The evaluation of available toxicity data for fish, aquatic invertebrates and aquatic plants for the C8 and higher chemicals in this category 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 the C3 to C8 range chemicals in this category 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 (CASRN 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.
- **Persistence and Bioaccumulation:**
 - Available information indicates that chemicals in this category are very persistent in the environment.
 - Available information indicates that these chemicals are not bioaccumulative.

Exposure Summary:

- Both Confidential Business Information (CBI) and non-confidential information from IUR and other sources were used in developing this initial prioritization.
- **Production Volume:** The ranges reported below are based on 2006 IUR submissions.
 - Nine category members are HPV chemicals:
 - CASRN 84605-29-8: ≥ 50 million and < 100 million lbs.

⁴ US EPA, U.S. Commitments to North American Chemicals Cooperation:
<http://www.epa.gov/hpv/pubs/general/sppframework.htm>.

⁵ US EPA, ChAMP information: <http://www.epa.gov/champ/>.

- CASRN 2215-35-2, 4259-15-8, 68457-79-4, 113706-15-3: ≥ 10 million and < 50 million lbs.
- CASRN 11059-65-7, 28629-66-5, 54261-67-5, and 68784-31-6: ≥ 1 million and < 10 million lbs.
- One category member is a Moderate Production Volume (MPV) chemical:
 - CASRN 26566-95-0: $< 500,000$ lbs.
- Two category members did not have 2006 IUR submissions:
 - CASRN 25103-54-2 and 68988-46-5.
- Uses: Non-confidential IUR information for many of the chemicals in this category indicates that they are used as lubricants in the manufacture of other chemical products and preparations. 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 chemicals in this category are used to formulate finished lubricating oils including all types of automotive and diesel engine crankcase oils, industrial oils, and hydraulic fluids. The Hazardous Substances Data Bank (HSDB) lists uses for CASRN 28629-66-5 as hydraulic and transmission fluids, and for CASRN 25103-54-2 as an additive in lubricating oils.
- General Population and Environment: EPA identifies a medium potential that the general population and the environment may be exposed. Based on the predominant uses of these chemicals 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.
- Workers: EPA identifies a medium relative ranking for potential worker exposure. This 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. These chemicals do not have OSHA Permissible Exposure Limits (PELs).
- Consumers: EPA identifies a high potential that consumers may be exposed through the use of products containing these chemicals. 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 indicates that consumers who may periodically add lubricating oil to automotive crankcases or change their own automotive engine oil may be exposed.
- Children: EPA identifies a low potential that children might be exposed to the chemicals in this category from consumer products. None of the chemicals had reported uses in products intended to be used by children. One submission reported that such information was Not Readily Obtainable. EPA believes that children are unlikely to be exposed to lubricating oils or hydraulic fluids containing these chemicals.

Risk Characterization Summary:

- Potential Risk to Aquatic Organisms from Environmental Releases: *LOW/MEDIUM CONCERN*. EPA identifies a medium potential that aquatic organisms might be exposed from environmental releases. Chemicals in the this category have high persistence and low bioaccumulation. These characteristics in combination with the low acute toxicity to aquatic invertebrates and aquatic plants of members of this category indicate a low concern for potential risk to those organisms from environmental releases. These

characteristics in combination with the moderate acute toxicity of one category member (CASRN 84605-29-8) indicate a medium concern for potential risk to fish from environmental releases of this chemical and potentially from other untested category members.

- Potential Risk to the General Population from Environmental Releases: *MEDIUM CONCERN*. EPA identifies a medium potential that the general population may be exposed from environmental releases. The potential human health hazard is moderate. Therefore, 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. The potential human health hazard is medium. These chemicals do not have PELs that would be presumed to limit exposures. Therefore, the available information suggests a medium concern for potential risk to workers.
- Potential Risk to Consumers from Known Uses: *MEDIUM CONCERN*. EPA identifies a high potential that consumers might be exposed based on the use of products containing these chemicals, and the potential human health hazard is medium. Therefore, 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 considered unlikely that children will be exposed to lubricating oils or hydraulic fluids containing these chemicals. An animal study of one member of the category showed moderate toxicity following exposure during early life stages. However, given the lack of expected exposure to children, the available information suggests a low concern for potential risk to children.

Regulatory and Related Information Summary:

- The category chemicals are listed in the TSCA inventory; they are not otherwise regulated under TSCA.
- Canada, as a result of initial categorization of their Domestic Substances List (DSL), has designated one member (CASRN 2215-35-2) of this category as persistent, bioaccumulative and inherently toxic (PBiT) and has prioritized it for further consideration. The toxicity concern is for aquatic organisms. The analysis supporting the Canadian decision will be published in batch 8 in November 2008. EPA has reached a different conclusion concerning the bioaccumulation potential of these chemicals. EPA will share the information supporting its decision with Canada.
- Regulations implementing the Clean Air Act (40 CFR 86.1805-04: Useful Life) require that auto manufacturers guarantee catalytic converter life spans of 15 years or 150,000 miles by 2009. Engine oil standards have been revised to limit use of chemicals such as members of this category which contain phosphorus or other substances that reduce the effectiveness and life span of catalytic converters.

Assumptions and Uncertainties:

- EPA has no information on releases of these chemicals, and assumes potential exposures based on reported uses.

- There is uncertainty regarding the extent, frequency, and duration of dermal exposure of workers and consumers to members of this category associated with their current use as motor oil components, and the extent to which that exposure may change as the use of chemicals in this category is reduced to protect catalytic converters.
- There is uncertainty regarding the potential for these chemicals to cause chronic toxicity to aquatic organisms. Additional information on environmental releases to water and environmental exposures could be useful in determining whether conducting chronic aquatic toxicity studies would be appropriate.
- Information is not available on the potential dissociation of these chemicals in the aquatic environment into related chemicals without the zinc structure that are used as pesticides. While EPA considers this unlikely based on professional judgment combined with limited data on hydrolysis and biodegradation, there is uncertainty about this potential.
- There is uncertainty regarding the extent of human exposure to members of the category associated with uses not affected by regulations designed to protect catalytic converters.

Rationale Leading To Prioritization Decision:

- Available data suggest a medium concern for potential risk to general population, workers, and consumers, and a low to medium concern for risk to aquatic organisms.
- Hazard communication and standard industrial hygiene practices, if properly followed, may be sufficient to address eye and skin irritation concerns for occupational exposures.

Prioritization Decision:

- **MEDIUM PRIORITY, POTENTIAL CONCERN:** In order to further evaluate the medium concern for potential risk to fish, the general population, workers and consumers from these chemicals, EPA has identified possible next steps involving efforts to develop a better understanding of exposure to and uses of these chemicals. Examples of information that would assist EPA in its analysis include, but are not limited to:
 - Information concerning potential releases to water from manufacturing, use and disposal of these chemicals and products containing these chemicals;
 - Information concerning the extent and rate of dissociation of members of this chemical category under environmental conditions;
 - Information concerning exposure associated with use of these chemicals in consumer and commercial products; and
 - Other information pertinent to exposures to these chemicals.

As an initial step in developing this understanding, companies that manufacture, process, or use these chemicals are encouraged to provide available information on a voluntary and non-confidential basis.

Supporting Documentation:

Screening-Level Risk Characterization: September 2008

Screening-Level Hazard Characterization: September 2008

Screening-Level Exposure Characterizations: September 2008