Registration Decision RD2010-17

Tetrakis (Hydroxymethyl) Phosphonium Sulfate

(publié aussi en français)

3 December 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0932 (print)
1925-0940 (online)

Catalogue number: H113-25/2010-17E (print version)
H113-25/2010-17E-PDF (PDF version)

Registration Decision for Tetrakis (hydroxymethyl) Phosphonium Sulfate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act,* and Regulations, is granting a renewal of the conditional registration for the sale and use of the technical product Tolcide® PS75, as well as the end-use products Tolcide® PS200 and Tolcide® PS75LT, all containing the active ingredient tetrakis (hydroxymethyl) phosphonium sulfate, to control microbial slime formation in oilfield operations and evaporative cooling towers.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were proposed for renewal of the conditional registration in the consultation document[1] Proposed Registration Decision PRD2010-14, *Tetrakis (hydroxymethyl) Phosphonium Sulfate*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for tetrakis (hydroxymethyl) phosphonium sulfate and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2010-14. This decision is consistent with the proposed registration decision stated in PRD2010-14, which includes the requirement to submit additional scientific information as a condition of registration.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-14, *Tetrakis (hydroxymethyl) Phosphonium Sulfate* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act.*

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act.*

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act.*

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Tetrakis (Hydroxymethyl) Phosphonium Sulfate?

Tetrakis (hydroxymethyl) phosphonium sulfate is an antimicrobial biocide that provides effective prevention of microbial slimes in process waters against a range of slime-forming microbes. Tetrakis (hydroxymethyl) phosphonium sulfate acts primarily to increase the permeability of the outer membrane of the microbial cell envelope which causes protein and other cellular materials to be rapidly released from the cells. In addition, tetrakis (hydroxymethyl) phosphonium sulfate inhibits the sulfate reduction process within sulfate reducing bacteria.

Tolcide® PS75 is a technical product containing 75% tetrakis (hydroxymethyl) phosphonium sulfate. Tolcide® PS75 is used to manufacture the end use products Tolcide® PS75LT and Tolcide® PS200. Tolcide® PS75LT is used to control microbial slime formation in oilfield operations. Tolcide® PS200 is used to control microbial slimes in evaporative cooling towers and in oilfield operations.

Tolcide® PS200 was proposed for use in pulp and paper processing facilities. Workers in the pulp and paper processing facilities may be exposed to mist downstream of the site of application. No data were submitted for the characterization of the level of worker exposure to mist and to tetrakis (hydroxymethyl) phosphonium sulphate and its by-products in pulp and paper facilities. Therefore, a risk assessment for this scenario could not be conducted, and the use in pulp and paper processing facilities was not accepted to appear on the Tolcide® PS200 label.

Health Considerations

Can Approved Uses of Tetrakis (Hydroxymethyl) Phosphonium Sulfate Affect Human Health?

Tetrakis (hydroxymethyl) phosphonium sulfate is unlikely to affect your health when used according to label directions.

Exposure to tetrakis (hydroxymethyl) phosphonium sulfate may occur when handling and applying the products. When assessing health risks, two key factors are considered: the levels where no health effects occur; and the levels to which people may be exposed.

The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). The risk assessment is conducted to ensure that the level of human exposure is well below the lowest dose at which effects occurred in animal tests. Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical, and identify the dose where no effects are observed.

The technical product Tolcide® PS75 was of high toxicity when given as a single oral dose to rats and was of slight toxicity after a single dose was inhaled. It also caused eye and skin irritation in animals, and is considered to be a potential skin sensitizer. Consequently, the statements "Danger Poison", "Eye and Skin Irritant", and "Potential Skin Sensitizer", as well as the skull and crossbones symbol are required on the label. The end-use products Tolcide® PS75LT and Tolcide® PS200 are considered to have the same acute toxicity profile as Tolcide® PS75. Therefore, the same statements and symbols will be required on the labels of Tolcide® PS75LT and Tolcide® PS200.

Tolcide® PS75 was found to be genotoxic in some studies and to cause cancer in the uterus and adrenal gland. Health effects in animals given daily doses of Tolcide® PS75 over longer periods of time included effects on the liver, lung, testes, uterus and bone marrow as well as lymphoid depletion of spleen and thymus. Some animals died when higher doses of Tolcide® PS75 were given or when Tolcide® PS75 was given for longer periods of time. There was no indication that Tolcide® PS75 caused damage to the nervous system. When Tolcide® PS75 was given to pregnant animals, effects on the developing fetus were generally observed at doses that were also toxic to the mother, which suggests that the fetus is not more sensitive to Tolcide® PS75 than the adult animal. There were limitations with the study that tests for reproductive effects. Therefore, the study was considered to be unacceptable for use in assessing human risk of Tolcide® PS75.

A complete toxicology data package was not submitted to support Tolcide® PS75. Therefore, the hazard characterization for this chemical could not be completed. As the exposure was determined to be negligible based on the products use in cooling towers and oilfields, no further studies were required to complete the current assessment. However, for any future use expansions, the PMRA will reconsider the need to address these data concerns.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Based on the use pattern for tetrakis (hydroxymethyl) phosphonium sulfate, dietary risk from food and water are not of concern.

Occupational Risks From Handling Tolcide® PS200 and Tolcide® PS75LT SC

Occupational risks are not of concern when Tolcide® PS200 and Tolcide® PS75LT is used according to label directions, which include protective measures.

A qualitative risk assessment conducted for individuals handling Tolcide® PS75LT or Tolcide® PS200 products, indicated that the risk for adults is not of concern when these products are used according to label directions.

Workers mixing, loading and applying Tolcide® PS75LT or Tolcide® PS200 can come in direct contact with tetrakis (hydroxymethyl) phosphonium sulfate on the skin or through inhalation. Therefore, the label will specify that workers must wear coveralls over long sleeved shirt and long pants, chemical resistant gloves, socks, chemical resistant footwear, a respirator and goggles or a face shield when mixing, loading, and applying Tolcide® PS75LT or Tolcide® PS200, or during cleanup and repair.

Environmental Considerations

What Happens When Tetrakis (Hydroxymethyl) Phosphonium Sulfate is Introduced Into the Environment?

Tetrakis (hydroxymethyl) phosphonium sulfate is toxic to freshwater alga and freshwater invertebrates. Therefore, label instructions are required to protect these organisms and to minimize exposure to the aquatic environment.

Tetrakis (hydroxymethyl) phosphonium sulfate may enter the environment after it is used as a slimicide in oilfield operations and evaporative cooling towers. Tetrakis (hydroxymethyl) phosphonium sulfate is not persistent in water and is rapidly mineralized into carbon dioxide.

Tetrakis (hydroxymethyl) phosphonium sulfate is not expected to be present in air. Based on the use pattern, very little is anticipated to reach the environment and once there it rapidly transforms into carbon dioxide so is not expected to be persistent. Tetrakis (hydroxymethyl) phosphonium sulfate has limited potential to partition into sediment or organic matter and is non-persistent in the aquatic system. Under actual use conditions, tetrakis (hydroxymethyl) phosphonium sulfate residues were found to be below the detection limit (0.5 mg a.i./L) at the point of discharge into the watercourse. Tetrakis (hydroxymethyl) phosphonium sulfate residues are not expected to enter the soil and is, therefore, not expected to be found in the terrestrial environment.

Tetrakis (hydroxymethyl) phosphonium sulfate presents a low risk to mysid shrimp, fish, eastern oyster, and vascular plants. Tetrakis (hydroxymethyl) phosphonium sulfate is expected to adversely affect daphnids and freshwater green algae. Therefore, specific instructions on its toxicity to aquatic organisms and to minimize exposure to the aquatic environment are provided on the product labels.

Value Considerations

What is the Value of Tolcide® PS75LT and Tolcide® PS200?

Tolcide® PS75LT controls microbial slime formation in oilfield operations. Tolcide® PS200 controls microbial slimes in evaporative cooling towers and in oilfield operations.

Tolcide® PS75LT and Tolcide® PS200 provide effective prevention of microbial slimes in process waters against a range of slime-forming microbes. These products are compatible with current slime-management practices in oilfield operations and evaporative cooling towers. These products provide an alternative biocide for industrial process waters with a completely new chemistry and are valuable alternative biocides in industries where the common practice is to regularly alternate slimicides.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

Key Risk-Reduction Measures

Human Health

To avoid direct contact with Tolcide® PS200 or Tolcide® PS75LT, loading and transfer is permitted only with a closed system. In addition, anyone handling these products must wear all the personal protective equipment stated on the labels.

Environment

As tetrakis (hydroxymethyl) phosphonium sulfate is toxic to freshwater algae and freshwater invertebrates, specific instructions to minimize exposure to the aquatic environment are provided on the product labels.

What Additional Scientific Information Is Being Requested?

Although the risks and value have been found acceptable when all risk-reduction measures are followed, the applicant must submit additional scientific information as a condition of registration. More details are presented in the Science Evaluation of ERC2010-02, or in the Section 12 Notice associated with the renewal of these conditional registrations. The applicant must submit the following information within the time frames indicated.

Chemistry

The following studies are required to complete the chemistry database for this product:

- Oxidizing and reducing properties of Tolcide® PS75LT. Submission of this information to the PMRA must be made no later than December 1, 2011.
- Storage stability data of Tolcide® PS200 stored at ambient temperature for one year. Submission of this information to the PMRA must be made no later than December 1, 2011.

Environment

Representative chromatograms of unfortified and fortified surface and drinking water samples generated from the analysis of tetrakis (hydroxymethyl) phosphonium sulphate as well data demonstrating linearity of the ion chromatographic method used to determine tetrakis (hydroxymethyl) phosphonium sulphate in drinking and surface water are required for the residue methods. Submission of this information to the PMRA must be made no later than December 1, 2011.

Develop and validate analytical methodology for tetrakis (hydroxymethyl) phosphonium sulphate and its transformation products using aquatic plant and animal tissues (preferably fish or bird tissue, but mammal tissues are also acceptable). The studies should be conducted using non-labelled tetrakis (hydroxymethyl) phosphonium sulphate and transformation products. Tissue samples should be spiked with the non-labelled compounds, extracted and subsequently analysed. Validation data should include precision, accuracy, recovery, LOQ and linear range. Submission of this information to the PMRA must be made no later than December 1, 2011.

Value

The following studies are required to ensure that the lowest effective rates are being used:

Operational trials are needed to determine the appropriate frequency of application in the oilfield water flooding and evaporative recirculating cooling tower uses. Submission of this information to the PMRA must be made no later than December 1, 2011.

Other Information

The relevant test data on which the decision is based are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[5] As per subsection 35(1) of the *Pest Control Products Act.*