Potassium dihydrogen phosphate (076413) Fact Sheet

1. Description of the Chemical

- **Generic Name(s) of the Active Ingredient(s):** Potassium dihydrogen phosphate; also known as potassium monophosphate
- **OPP Chemical Code:** 076413
- **Year of Initial Registration:** 1998
- **Trade name of end-use product:** eKsPunge
- **Type of Pesticide:** Fungicide
- **Basic Producers:**

  Lidochem, Inc.
  20 Village Court
  Hazlet, NJ 07730

2. Use Sites, Application Timing & Target Pests

- **Formulation Types:** Soluble crystalline powder.
- **Target Pests:** Powdery mildew.
- **Registered Uses:** Apples, grapes, cucumbers, melons, summer and winter squash, watermelons, mangoes, peaches, nectarines, plums, cherries, peppers, tomatoes, and roses.
- **Application Timing:** As needed. Applications should be repeated at 7-14 day interval, depending upon the intensity of infestation.

3. Food Clearances / Tolerances

The Agency, on its own initiative, proposed to establish an exemption from the requirement of a tolerance for residues of potassium dihydrogen phosphate in or on all food commodities when used as a fungicide to control powdery mildew in fruits and vegetables. This proposed rule was published on March 3, 1998 with a 60-day comment period (63FR10352). The final rule was published on August 12, 1998. Safety factors from the Food Quality Protection Act of 1996 (FQPA) were considered.

4. Science Findings

A. Chemical Description

The active ingredient, potassium dihydrogen phosphate (also referred to as monopotassium phosphate) is a synthesized active ingredient (a.i.). The end-use product is a crystalline powder containing 100% active ingredient. The chemical abstract service (CAS) number for monopotassium phosphate (KH_2PO_4) is 7778-77-0.

B. Biochemical Classification

Potassium dihydrogen phosphate is naturally occurring, has had widespread use with no adverse effects, but has a toxic mode of action on fungi. OPP's Biochemical Classification Committee has determined that potassium dihydrogen phosphate is not a biochemical, but is eligible for reduced data requirements akin to those established for biochemical pesticides because of the simple inorganic structure and natural occurrence of this compound.

C. Toxicology

The required acute mammalian toxicology studies have been submitted except for those which the Agency has waived. The submitted data indicates that the product has an acute oral LD_{50} >5000 mg/kg in male rats, >500 mg/kg in female rats and a combined LD_{50} >500 mg/kg in male and female rats (Toxicity Category III), and an acute dermal LD_{50} >2000 mg/kg in rabbits (Toxicity Category III). Additionally, primary skin irritation studies reveal that the product is a non-irritant (Toxicity Category IV), and primary eye irritation studies reveal that it is a mild eye irritant (Toxicity Category III).

EPA waived the acute inhalation study, dermal sensitization study (guinea pig), mutagenicity, cellular immune response, and developmental toxicity data based on low acute mammalian toxicity of the active ingredient and the fact that potassium dihydrogen phosphate has been exempt from requirement of a tolerance when used in accordance with good agricultural practice as an inert ingredient in pesticide formulations as a buffering agent.

D. Food Quality Protection Act Requirements

Safety factors from FQPA were evaluated. EPA has considered, among other factors, available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. Given the low toxicity of potassium dihydrogen phosphate as indicated by toxicity data, and a history of safe use as a fertilizer and pesticide inert ingredient, a determination of reasonable certainty of no harm for the general population, as well as subgroups including infants and children, was made.

E. Human Health Effects

1. **Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children**

   Dietary risk from potassium dihydrogen phosphate is difficult to estimate due to its being ubiquitous in nature, and its use as a pesticide inert ingredient and fertilizer.

In the absence of any toxicological endpoints, risk from the consumption of residues is not expected for both the general population and infants and children from all uses of potassium dihydrogen phosphate. Furthermore, results from mammalian toxicity studies as discussed in unit III B, Human Health Assessment, indicate a lack of toxicity, adding further weight to the lack of risk from exposure. EPA has concluded that there is a reasonable certainty that no harm will result from use of potassium dihydrogen phosphate, and due to the lack of mammalian toxicity, the ten-fold exposure (safety) factor does not need to be considered.

2. **Common Mode of Action**

Potassium dihydrogen phosphate does not share any common mechanisms of toxicity with other pesticide active ingredients. Potassium dihydrogen phosphate is used as an agricultural fertilizer and a buffering agent in pesticide formulations. There are no reported adverse effects from these uses and toxicology studies submitted indicated low mammalian toxicity. Therefore, no impact on the potential for toxic effects from the pesticidal use is expected when added to the other uses of potassium dihydrogen phosphate.

3. **Risks Posed by Potential Residential, School or Day Care Exposure**

No indoor residential, school or day care uses currently appear on the label. Therefore, an assumption of no risk due to lack of exposure is made.

4. **Drinking Water Exposure and Risk Characterization**

There is no expected human exposure to potassium dihydrogen phosphate in drinking water. When the end-use product is applied to plants, most of it is absorbed. The potential exists for a minimal amount of potassium dihydrogen phosphate to enter ground water or other drinking water sources if, after application, weather patterns are such that significant rainfall and surface water runoff occur. But residues are not expected to be significantly above background levels due to the naturally occurring and ubiquitous nature of the compound. Health risk to humans is considered negligible based on the evaluations of the submitted toxicity information, and low application rate of the active ingredient.

5. **Aggregate Exposure**

The Agency has considered the various routes of exposure (dietary, drinking water, and exposure from non-occupational sources), and potential risks of the subject compound and determined that the proposed use of the active ingredient does not pose significant risk over a lifetime to populations including infants and

children even when the extra ten-fold safety factor is considered. This is demonstrated by low acute mammalian toxicity, and a history of safe use of the compound as a fertilizer and a pesticide inert ingredient without reported adverse effects.

F. Occupational and Residential Expsoure and Risk Characterization

Because of low mammalian acute toxicity, low application rates, and a history of safe use as a fertilizer and pesticide inert ingredient without reported adverse effects, occupational exposure data are not required at this time. Risks from occupational exposure will be mitigated through appropriate precautionary labeling.

G. Environmental Assessment

The ecological database for eKsPunge is adequate and will support registration. All guideline requirements for potassium dihydrogen phosphate have been satisfied.

H. Ecological Effects

Data waivers for ecological effects studies were requested and supported based on the current use as a pesticide inert ingredient and fertilizer, and low acute mammalian toxicity. In addition, monopotassium phosphate is ubiquitous in nature, and no adverse effects have been reported on nontarget species with current uses. Risk to nontarget species is minimal due to the use pattern, application methods, and mitigation of nontarget aquatic organism toxicity with appropriate precautionary label statements under "Environmental Hazards."

I. Environmental Fate and Ground Water Data

The environmental fate data requirements were not triggered because no human health or ecological effects issues were manifested in the acute toxicity (Tier I) studies.

J. Ecological Risk Assessment

A potential for exposure exists to nontarget insects, fish, and other wildlife with foliar spray applications. However, test results indicate that the compound is practically nontoxic to birds and freshwater fish, and, at most, slightly toxic to aquatic invertebrates. Low toxicity, the proposed rate of application, and mitigating label language present minimal to nonexistent risk to wildlife.

REQUIRED ENVIRONMENTAL HAZARDS STATEMENT ON THE END-USE PRODUCT LABEL

"Do not contaminate water when disposing of rinsate or equipment washwaters. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark."

5. Summary of Required Data

All hypersensitivity incidents must be reported to the Agency when/if they occur.

6. Regulatory Actions

7. Additional Contact Information

Ombudsman, Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460