US EPA ARCHIVE DOCUMENT

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EPA R.E.D. FACTS

2,4-DB

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA (the Agency), based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides, which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then registers pesticides that meet current health and safety standards and can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision with the Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document.

Use Profile

2,4-DB is manufactured as an acid (2,4-DB) and an amine salt (2,4-DB-DMAS). 2,4-DB and 2,4-DB-DMAS are systemic herbicides used to control broadleaf weeds in alfalfa, clover, peanuts, soybeans, peppermint, spearmint, and birdsfoot trefoil. There are no registered residential uses. Approximately 375,000 pounds of 2,4-DB and 2,4-DB-DMAS are used annually. Applications are made aerially or by ground equipment. There are six products containing 2,4-DB (four technical products and two end-use-products) and 15 products containing 2,4-DB-DMAS (one formulation intermediate and fourteen end-use-products). There is one Section 24C Special Local Need registration for 2,4-DB-DMAS use on mint in Idaho. All end-use product formulations are liquids.

Regulatory History

2,4-DB and 2,4-DB-DMAS have been registered for use on broadleaf weeds since 1958.

EPA completed the tolerance reassessment for 2,4-DB and 2,4-DB-DMAS on January 31, 2005. The Agency concluded that there is a reasonable certainty of no harm to any population subgroup from aggregate exposure to 2,4-DB or 2,4-DB-DMAS from dietary (food and water) exposure and all other non-occupational sources for which there is reliable information.

Human Health Assessment

Toxicity

Both 2,4-DB and 2,4-DB-DMAS are considered to have low acute toxicity, with the exception of 2,4-DB-DMAS being a Toxicity Category I eye irritant (Category I being the most severe). 2,4-DB is placed in the following acute Toxicity Categories: oral III; dermal III; inhalation IV; eye irritation III; and, dermal irritation IV. 2,4-DB-DMAS is placed in the following acute Toxicity Categories: oral III; dermal III; inhalation IV; eye irritation I; and, dermal irritation IV. 2,4-DB and 2,4-DB-DMAS are classified as "not likely to be a human carcinogen".

Dietary Risks

EPA determined that there is reasonable certainty that no harm to any population subgroup will result from aggregate exposure to 2,4-DB or 2,4-DB-DMAS when considering dietary (food and water) exposure. Both acute and chronic exposures are below the Agency's level of concern. For acute dietary exposure, the most sensitive group, females 13-49, was less than 1% of the acute Population Adjusted Dose (aPAD). For chronic dietary exposure the general U.S. population was less than 1% of the chronic Population Adjusted Dose (cPAD). Tolerance level residues and 100% crop treated assumptions were used to determine the above acute and chronic screening level risk estimates. 2,4-DB and 2,4-DB-DMAS are not expected to accumulate in drinking water. Drinking water models showed that the Estimated Drinking Water Concentrations (EDWCs) for ground water and surface water are below the Agency's level of concern. Both the acute ground water EDWC of 0.51 µg/L and the acute surface water EDWC of 318.68 µg/L are less than the acute drinking water level of concern (DWLOC) of 18,000 µg/L for females 13-49. In addition, both the chronic ground water EDWC of 209 µg/L and the chronic surface water EDWC of 72.40 µg/L are below the chronic DWLOC of 290 µg/L for infants less than one year of age and 1,050 µg/L for the general population. Therefore, exposure from drinking water is not of concern to the Agency.

Residential and Other Non-Occupational Risks

There are no registered residential uses for 2,4-DB and thus residential exposure is not expected.

FQPA Considerations

EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to 2,4-DB and 2,4-DB-DMAS when considering dietary (food and water) exposure and all other non-occupational sources of pesticide exposure for which there is reliable information.

EPA did not perform a cumulative risk assessment as part of this reassessment of 2,4-DB and 2,4-DB-DMAS because the Agency has not determined that there are any other chemical substances that have a similar mechanism of toxicity.

Worker Risks

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of 2,4-DB and 2,4-DB-DMAS includes the following: individuals who mix, load, and/or apply pesticides with aerial or ground equipment. Non-cancer risks for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) taken from an animal study. For 2,4-DB and 2,4-DB-DMAS, MOEs greater than 100 do not exceed the Agency's level of concern. All short-term and intermediate-term MOEs are not of concern to the Agency when applicators are wearing baseline personal protective equipment (PPE) and mixers/loaders are wearing baseline PPE and chemical resistant gloves. Post-application exposure to re-entry workers is possible. Since 2,4-DB and 2,4-DB-DMAS are applied only once or twice a season it is anticipated that exposure will be primarily short-term. No toxicity endpoint for short-term dermal exposures was identified, therefore, short-term post-application risks were not assessed. 2,4-DB-DMAS is a Toxicity Category I eye irritant and protective eye-wear is required for early re-entry post-application activities.

Environmental Assessment

Ecological Fate

Available data indicates that 2,4-DB-DMAS rapidly dissociates in moist soils and aquatic environments, therefore, ecological risks were only assessed for 2,4-DB. In soil environments 2,4-DB dissipation is dependent on leaching and on oxidative microbial-mediated degradation. 2,4-DB's metabolism half-life is 24.5 days in mineral soils, and ranges from 6.3 - 17.2 days in aquatic environments. The primary route of dissipation is transformation with the major transformation product being 2,4-D. 2,4-DB is not expected to bioaccumulate in the environment.

Ecological Risks

The ecological risk assessment shows that terrestrial plants are at the greatest risk from 2,4-DB and 2,4-DB-DMAS applications. Potential effects to non-target terrestrial plants are most likely to occur as a result of spray drift and runoff from aerial and ground applications. All acute freshwater risk quotients (RQs) are not of

concern to the Agency. The Agency is requiring additional studies to better understand the potential risk to estuarine and marine invertebrates. The Agency is not concerned with chronic risks to freshwater organisms. Both acute and chronic risks to birds are not of concern to the Agency. Predicted residues from all uses of 2,4-DB and 2,4-DB-DMAS are below the acute level of concern for mammals. No mammalian chronic levels of concern were exceeded for scenarios when considering one or two applications at average labeled rates and a default half-life of 35 days.

The risk assessment for threatened and endangered species indicates that 2,4-DB and 2,4-DB-DMAS exceed the threatened and endangered species levels of concern for the following use sites: freshwater fish (Texas alfalfa scenario); small mammals feeding (soybean, alfalfa, and peanut scenarios); medium size mammals (alfalfa); small and medium size birds (Texas alfalfa scenario); and, terrestrial plants (at highest application rates). These findings are based solely on the Agency's screening level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Risk Mitigation

Dietary Risk

For all supported commodities, the acute and chronic dietary exposure estimates (food and drinking water) are below the Agency's level of concern. Therefore, no risk mitigation measures are required to address exposure to from food and drinking water.

Occupational Risk

Currently, not all 2,4-DB and 2,4-DB-DMAS labels require mixers and loaders wear chemical resistant gloves. Based on toxicity studies, the Agency is requiring mixers and loaders to wear gloves made from chemically resistant material. Because 2,4-DB-DMAS is a Toxicity Category I eye irritant, protective eyewear should be worn by early re-entry workers and a re-entry interval of 48 hours will be established for 2,4-DB-DMAS products.

Ecological Risk

The major contributing factor of risk associated with 2,4-DB and 2,4-DB-DMAS is spray drift. To mitigate risk associated with spray drift, the registrant has agreed to include droplet size restrictions on 2,4-DB and 2,4-DB-DMAS labels. Labels must specify medium to coarse droplet size or a volume mean diameter of 300 microns or greater for spinning atomizer nozzles and prohibit fine sprays. Additionally, for aerial applications, the boom length must not exceed 75% of the wingspan or 90% of the rotor blade diameter to reduce spray drift. The Agency has concluded that risks posed by 2,4-DB and 2,4-DB-DMAS to most mammalian, avian, plant, and aquatic species will be substantially reduced by adhering to best management practices for aerial applications.

Additional Data Required

The generic database supporting the reregistration of 2,4-DB and 2,4-DB-DMAS has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and are listed below. Additionally, responses to outstanding data requirements regarding spray drift and droplet size spectrum (OPPTS GLN 201-1) are currently outstanding.

OPPTS GLN 850.4100/4500	Seedling Emergence and Vegetative Vigor
OPPTS GLN 850.1075	Estuarine/Marine Fish Acute Toxicity
OPPTS GLN 850.1025	Estuarine/Marine Invertebrate Acute Toxicity

Regulatory Conclusion

The use of currently registered products containing 2,4-DB and 2,4-DB-DMAS in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment if the risk mitigation measures and label changes outlined in the RED are implemented. Therefore, all uses of these products are eligible for reregistration. These products will be reregistered once the required product specific data, confidential statements of formula (CSFs), and revised labeling are received and accepted by EPA. Products which contain ingredients in addition to 2,4-DB and 2,4-DB-DMAS will be reregistered when all of their other active ingredients also are reregistered.

For More Information

To obtain a copy of the 2,4-DB RED document, please contact the OPP Public Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460-0001, telephone: (703) 305-5805. Electronic copies of the 2,4-DB RED and all supporting documents are also available on the Agency's electronic docket at http://www.epa.gov/edocket.

For more information about EPA's pesticide reregistration program or the 2,4-DB RED, please contact the U.S. EPA, OPP, Special Review and Reregistration Division (7508C), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, telephone (703) 308-8000.

For more information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticide Information Center (NPIC). Call toll-free (800) 858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is http://www/npic.orst.edu.

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