

United States **Environmental Protection** Adencv

Prevention, Pesticides And Toxic Substances (7508C)

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# SEPA R.E.D. FACTS **MCPA**

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, 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 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 reregisters pesticides that meet the safety standard of the FQPA 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 in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0017, MCPA.

## **Use Profile**

MCPA is an herbicide in the phenoxy or phenoxyacetic acid family that is used post-emergence for selective control of broadleaf weeds. MCPA is registered for use on alfalfa, barley, clover, flax, lespedeza, oats, pasture and rangeland grass, peas, rye, trefoil, triticale, and wheat, as well as grass grown for seed, to control a wide spectrum of broadleaf weeds. MCPA is also registered for use on turf, lawns, vines, rights-of-way, and forestry applications. Residential homeowners may use MCPA on lawns.

Approximately 4.6 million pounds of MCPA active ingredient are applied annually to approximately 12 million acres (including both agricultural and non-agricultural use). Approximately 1.2 million pounds of active ingredient are used annually on residential and commercial turf.

There are four active ingredients associated with MCPA: MCPA acid, MCPA sodium salt, MCPA dimethylamine salt (MCPA DMAS), and MCPA 2-ethylhexyl ester (MCPA 2-EHE). Formulation types registered include solids, soluble concentrate/solid, water dispersible granules (dry flowable), and wettable powder. MCPA is usually applied in combination with other phenoxy class chemicals, such as 2,4-D, 2,4-DB, MCPP-p, and MCPB. MCPA can be applied anytime, but is recommended for best efficacy in early spring and early fall.

## Regulatory History

MCPA was first registered in the United States in 1973. In the early 1980s, EPA conducted a thorough review of the scientific database on MCPA and reassessed the Agency's earlier regulatory position. A Registration Standard for MCPA was issued in July 10, 1981, and an MCPA Guidance Document was issued in March 1982. In June 1988, EPA issued the MCPA Final Registration Standard and Tolerance Reassessment (FRSTR).

## Human Health Toxicity Assessment M

MCPA acid, MCPA sodium salt, MCPA DMAs, and MCPA-2-EHE forms are of low toxicity (category III or IV) for acute oral, dermal, inhalation, and primary dermal irritation. MCPA-2-EHE is of low toxicity for eye irritation, but the other three forms are classified as strong eye irritants. MCPA-2-EHE is a dermal sensitizer, whereas the other three forms are not.

#### Dietary Exposure (Food and Water)

People may be exposed to residue of MCPA through the diet. EPA assesses dietary risk by estimating exposure to MCPA residues from consumption of food and drinking water. The chronic and acute food risks are measured by the Population Adjusted Doses (PAD). Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD is not of concern. The acute dietary risk from MCPA residues on food is below the Agency's level of concern; that is, less than 100% of the acute PAD is utilized. For the most exposed subgroup, children (1-2 years of age), the percent acute PAD values is 36 at the 95<sup>th</sup> percentile of exposure. The chronic dietary risk from food alone is not of concern to the Agency. For the most exposed subgroup, children (1-2 years of age), the percent dietary risk is below the Agency's level of concern, and the chronic dietary risk from food alone is not of concern, to the Agency.

Drinking water exposure to pesticides can occur through ground water and surface water contamination. The PRZM/EXAMS and the SCI-GROW models were used on surface and ground water, respectively. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC). Risks from drinking water are assessed by comparing the DWLOC to the estimated environmental concentration (EECs) in surface water and ground water. Generally, the Agency has no risk concerns when the EECs are below the DWLOC. For acute dietary risk, the DWLOC is 1455 ug/l for the

general U.S. population and 322 ug/l for the population of interest, children 1-2 years of age. The EECs for surface water for both population subgroups are 47.3 ug/l, and 2.13 ug/l for both ground water subgroups. All values are below the DWLOC and below Agency's level of concern. For chronic dietary risk, the DWLOC is 111 ug/l for the general U.S. population and 5.88 ug/l for children 1-6 years of age. The EEC for surface water is 1.9 ug/l for both population subgroups and the EEC for ground water is 2.13 ug/l for both subgroups- all below the Agency's level of concern.

#### **Database Uncertainty Factor**

The Agency has concluded that a developmental neurotoxicity (DNT) study on MCPA 2-EHE is necessary to further characterize the potential for pre-natal neurotoxicity due to the presence of clinical signs indicative of neurotoxicity in acute and subchronic studies. The MCPA toxicology database does not include a DNT study and therefore a Database Uncertainty Factor is necessary to be protective of children. EPA determines the appropriate size of the Uncertainty Factor based on a comparison between the assumed DNT NOAEL and the endpoints used in the risk assessments. The approximate size of the Database Uncertainty Factor is derived by dividing the point of departure used for each exposure pathway by the assumed DNT NOAEL of 2.5 mg/kg/day.

Applying this dose analysis procedure for MCPA, a 10X Database Uncertainty Factor is required for acute dietary scenarios (including acute incidental oral exposure), based on a comparison between the developmental NOAEL of 40 mg/kg/day and the assumed DNT study NOAEL of 2.5 mg/kg/day. A 10X Database Uncertainty Factor is also required for acute residential dermal scenarios, based on a comparison between the oral equivalent NOAEL of 40-50 mg/kg/day and the assumed DNT study NOAEL of 2.5 mg/kg/day. A 3X Database Uncertainty Factor is required for residential short-term and intermediate dermal exposure scenarios, based on a comparison between an oral equivalent NOAEL of 7 mg/kg/day and the assumed DNT study NOAEL of 2.5 mg/kg/day. The Agency has determined that a 1X Database Uncertainty Factor is appropriate for chronic dietary exposure, incidental oral exposure, long term dermal exposure, short- and intermediate-term occupational dermal exposures, and all durations of inhalation exposure because the endpoints used for these assessments, a NOAEL of 4.4 mg/kg/day, is of the same order of magnitude of the assumed DNT study NOAEL (2.5 mg/kg/day) and in a similar dose range.

#### **Occupational Risk**

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of MCPA include workers in agricultural environments, turf farms, golf courses, and

lawn care professionals. Short- and intermediate-term occupational risks have been assessed. Risk for these potentially exposed populations are measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). For MCPA, occupational exposure MOEs greater than 100 do not exceed the Agency's level of concern. All of the occupational handler MOEs exceed target MOEs with baseline Personal Protective Equipment for all scenarios except for the mixing and loading of liquids for aerial, groundboom, and right-of-way sprayer applications, and the mixing and loading of wettable powder to groundboom application to golf courses. With the addition of chemical resistant gloves, all scenarios except for mixing/loading liquids for application to rangeland/pastureland do not exceed the Agency's level of concern. The MOE for mixing/loading liquids for rangeland/pastureland application does not exceed the Agency's level of concern when assessed with single layer PPE and a filtering face piece respirator with a protection factor of five.

Post-application exposures to MCPA can occur in the agricultural environment when workers enter fields recently treated with MCPA to conduct tasks such as scouting and irrigation. Only dermal exposures were evaluated in the post-application worker assessment. Post-application exposures to MCPA are anticipated to be primarily short-term and intermediate-term as MCPA is typically applied once per season with a short application time. The highest post-application exposure risks are for small grains; however, risks do not exceed the Agency's level of concern. The Worker Protection Standard (WPS) Restricted Entry Interval (REI) for MCPA is 12 hours for the ester form and 48 hours for the amine and sodium salt forms; there is no REI for the acid form because it is only contained in products used on non-agricultural sites such as lawns and golf courses.

#### **Residential Risk**

MCPA is registered for use by homeowners in the residential environment to kill weeds on lawns. Residents may be exposed to MCPA through mixing, loading, or applying the pesticide, or by entering a treated site after a residential or commercial applicator has applied MCPA. The duration of exposure is expected to be short-term for broadcast treatments because the label allows only two broadcast treatments per year. Exposures are also expected to be short-term in duration for spot treatments because the label recommends repeat applications in two to three weeks for hard-to-kill weeds.

Residential handler risks from application of MCPA products are below the Agency's level concern (i.e., MOEs for inhalation exposures exceed 1000, and MOEs for dermal exposures exceed 300). Risks are also below the Agency's level of concern for all residential post-application scenarios except for combined toddler acute exposures (from dermal, hand-to-mouth, object-to-mouth, and soil ingestion),

which slightly exceeded EPA's level of concern (combined MOE=940; target MOE =1,000)

Because the combined MOE for combined toddler acute exposures may be of concern to the Agency, the MCPA Task Force has committed to undertake a study to determine the dermal transfer efficiency of MCPA residues from turf to dry and wetted palms. This hand-press study is intended to confirm that the transfer coefficient used in the toddler exposure assessment is conservative and overestimates risk from mouthing behaviors, and that the chemical-specific data will verify that the residue dislodgeable from wet hands is, to some degree, less than the 5% default used in the assessment. This study must be submitted within the 9-month time period allotted to submit revised labels for MCPA.

#### Tolerances

The tolerances for MCPA have been established under 40 CFR §180.339 (a) for residues of MCPA (2-methyl-4-chlorophenoxyacetic acid) *per se* in/on various plant commodities, and tolerances are established under 40 CFR §180.339 (b) for the combined residues of MCPA and its metabolite 2-methyl-4-chlorophenol in livestock commodities. No Codex MRLs have been established for MCPA; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

The MCPA Task Force Three has agreed to voluntarily cancel use of MCPA on rice and grain sorghum. Therefore, the Agency will commence proceedings to propose the revocation of the corresponding tolerances.

The MCPA Task force Three has also agreed to significant reductions to the maximum label rates for MCPA. As a condition of reregistration, end-use products for these uses will be amended to reflect the new application rates.

#### **FQPA** Considerations

MCPA is a food-use chemical. Drinking Water Levels of Comparison (DWLOCs) have been calculated, and there are residential (non-occupational) uses of MCPA. Therefore, the considerations for aggregate exposure to MCPA are those from food, drinking water and residential exposure. For MCPA, an aggregate risk assessment was conducted for short-term risk (one to thirty days). Comparison of the short-term DWLOCs with the environmental concentrations of MCPA estimated using the PRZM-EXAMS and SCI-GROW modeling indicate that shortterm aggregate risks are not of concern. Acute aggregate risks were not assessed because it is extremely unlikely that acute turf exposures would occur concurrently with the acute dietary exposures. Intermediate and chronic aggregate risks were not assessed because there are no expected intermediate and chronic residential exposures. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to MCPA and any other substances, and MCPA does not appear to produce a toxic metabolite produced by other substances. For the purpose of this reregistration decision, therefore, EPA has not assumed that MCPA has a common mechanism of toxicity with other substances.

#### Environmental Environmental Fate Assessment In general, MC

In general, MCPA acid is practically insoluble in water, non-volatile, somewhat lipophilic (log  $K_{ow}$  2.8), and exists naturally as a solid. MCPA acid does not hydrolyze. MCPA photodegraded very slowly when applied to soil surfaces and irradiated with natural sunlight (half-life 67 days). In an aerobic soil metabolism study MCPA acid degraded with a half-life of 24 days. Under aerobic aquatic conditions, MCPA acid degraded with a total system half-life of >30 days in a water-sandy clay loam sediment systems. In laboratory batch equilibrium studies, MCPA acid was shown to be extremely mobile.

#### **Ecological Effects**

EPA has identified ecological risks of concern from MCPA use, particularly to terrestrial plants, terrestrial mammals, and avian species. These concerns were partially mitigated by adjusting the use pattern and lowering application rates. However, MCPA is a phenoxy herbicide that is highly toxic to plants. Therefore, some MCPA uses leave terrestrial plants at particular risk.

## **Risk Mitigation**

To mitigate human health and ecological risks of concern posed by MCPA, EPA is requiring the following risk mitigation measures:

#### **Use Cancellations**

The MCPA Task Force Three has requested the voluntary cancellation of rice and grain sorghum.

#### **Application Rate Reductions**

The MCPA Task Force Three has agreed to across the board reductions to the maximum label rates for MCPA. As a condition of reregistration, end-use products labeled for these uses will be amended to reflect the new application rates.

## **Toxicology Data**

- OPPTS GLN 870.110 Developmental neurotoxicity study in rats with the MPCA EHE formulation.
- OPPTS GLN 870.3465 Twenty eight (28) day inhalation study in rats (abbreviated 90-day protocol).

#### **Environmental Fate:**

- OPPTS GLN 835.6200 An Aquatic field dissipation study.
- OPPTS GLN 835.1410 Laboratory volatility study.
- OPPTS GLN 835.4100 & 835.1240 Laboratory fate data for aerobic soil metabolism, and a batch equilibrium study.

## **Ecological Effects:**

- OPPTS GLN 850.4100 & 850.4150 Seed Germination/Seedling Emergence, and Vegetative Vigor for three formulations of MCPA.
- OPPTS GLN 850.4400 Aquatic Plant Growth using three formulations of MCPA: (1) either the acid or sodium salt, (2) DMAS, and (3) EHE, all using a TEP.
- OPPTS GLN 850.2200 Avian Dietary LC<sub>50</sub> Guideline for one species (preferably bobwhite quail) using the MCPA EHE formulation.

## **Residue Chemistry:**

- OPPTS GLN 860.1500 A metabolism studies on peas.
- OPPTS GLN 860.1380 Storage stability data for wheat grain stored under ambient conditions for 28 days.
- OPPTS GLN 860.1300 A ruminant feed study.
- OPPTS GLN 860.1500 Four field trials are required reflecting a 0-day PHI for pasture forage.
- OPPTS GLN 860.1900 A study detailing confined accumulation in rotational crops planted following treatment at 1.5 lb ae/A (1x the maximum seasonal rate for annual crops).

## **Occupational Exposure:**

• OPPTS GLN 875.1100 - A hand press study.

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

## Product Labeling Changes Required

All MCPA end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the MCPA RED document.

## **Regulatory Conclusion**

The use of currently registered products containing MCPA in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. With the addition of label restrictions and amendments detailed in this document and the registrant's agreement to cancel use on grain sorghum and rice, MCPA products are eligible for reregistration. MCPA products will be reregistrered once the required product-specific data, and revised labeling are received and accepted by EPA.

## For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for MCPA during a 60-day time period, as announced in a Notice of Availability published in the <u>Federal Register</u>. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805. Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/pesticides/reregistration/status.htm

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the MCPA RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the MCPA RED, or reregistration of individual products containing MCPA, please contact the Special Review and Reregistration Division (7508C), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

For 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 1-800-858-7378, 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. Their internet address is http://npic.orst.edu.