

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Inorganic Chlorates Facts

EPA 738-F-08-001

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Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA based on scientific studies showing they do not pose unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticide products 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 reregisters pesticide products meeting current human health and safety standards that can be used without posing unreasonable risks to human health and the environment.

When a pesticide active ingredient 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 the pesticide inorganic chlorates (case no. 4049). The Agency has determined that sodium chlorate-containing products are eligible for reregistration provided that the risk mitigation measures outlined in the RED are adopted, label amendments are made to reflect these measures, and a safety finding can be made for sodium chlorite.

Use Profile and Regulatory History

Sodium chlorate (073301), calcium chlorate (073302), potassium chlorate (073303), and magnesium chlorate (530200) are the four inorganic chlorates listed as active ingredients. However, only one, sodium chlorate, is used as an active ingredient in currently registered products. For that reason, sodium chlorate is the primary focus of the RED. Sodium chlorate, calcium chlorate, and potassium chlorate are present as inert ingredients in other currently registered products.

Sodium chlorate is an inorganic salt herbicide that was first registered in 1966. It is a defoliant and a desiccant primarily used on cotton, but it also has other agricultural and non-agricultural uses. Other agricultural uses include rice, corn, soybeans, dry beans,

potatoes, sunflowers, flax, safflower, chili peppers, grain sorghum, and wheat. As a non-selective herbicide, it is used to kill grasses and weeds in industrial and non-agricultural sites such as driveways, tennis courts, and recreational areas. Products formulated as soluble concentrates can be applied using aerial, ground boom, or handheld equipment. Products formulated as granules or pellets can be applied using belly grinders, push-type spreaders, tractor-drawn spreaders, or by hand. There are 56 active product registrations containing sodium chlorate as an active ingredient.

In agriculture, application rates range from 6 to 12.5 pounds active ingredient per acre (lb ai/A). Industrial and other non-crop site rates range from 132 to 1032 lb ai/A, based on current labels. Sodium chlorate can be applied multiple times per year, and according to Agency data, approximately 2.8 million pounds are applied annually to agricultural, residential, and commercial use sites.

Human Health Exposure and Risk

No acute dietary (food and drinking water) endpoint was selected for sodium chlorate because effects attributable to a single dose were not seen in the available data. Therefore, acute dietary (food and drinking water) risk is not of concern to the Agency, and no mitigation measures are required. However, sodium chlorate is a thyroid toxicant producing thyroid gland follicular cell hypertrophy in rats and mice following chronic exposures. Sodium chlorate is classified, in accordance with EPA policy, as not likely to be carcinogenic to humans at doses that do not alter thyroid hormone homeostasis.

The chronic dietary risk assessment for food only is below the Agency's level of concern (LOC) for the general US population and all population subgroups. The most highly exposed subgroup, children 1 to 2 years of age, was at 28% of the chronic Population Adjusted Dose (cPAD). Since this is less than 100% of the cPAD, no mitigation is needed.

The chronic dietary risk assessment for chlorate in drinking water, calculated using the highest annual average concentration derived from the Information Collection Rule (ICR) Database (estimated at 0.69 mg/L), is below 100% of the cPAD and, therefore, below the Agency's LOC for the general US population and all population subgroups except for infants. Exposure to infants, the highest exposed subgroup, was 159% of the cPAD based on the highest annual average concentration of chlorate. However, using the 90th percentile annual average concentration (estimated at 0.24 mg/L) the chronic dietary (water only) risk for infants was 55% of the cPAD. Also for infants, using the median annual average concentration (estimated at 0.11 mg/L) the risk was 25% of the cPAD. The ICR Database was considered the most appropriate source for estimating exposure averages from individual water treatment plants because it was the most robust set of data.

All residential (non-occupational) handler and post-application risk estimates for inorganic chlorates, as active or inert ingredients in conventional pesticide products used in residential environments, are below the Agency's LOC (*i.e.*, margins of exposure or MOEs are greater than the LOC of 100). The handler inhalation MOEs ranged from 370

to 710,000. The post-application combined MOE (for inert ingredients) was 23,000 for all potential routes of exposure to children. Therefore, no residential mitigation is necessary.

Aggregate assessments combine food, drinking water, and any residential or other non-occupational exposures. Short term aggregate risks, assessed for adults only using the highest exposure scenario, are all below the LOC. Chronic aggregate risks, however, are above the LOC for both infants and children ages 1 to 2, when calculated using the estimated highest annual average drinking water concentration (0.69 mg/L). When the 90th percentile and median annual average water concentrations are used (0.24 or 0.11 mg/L, respectively), all population subgroups are below the LOC. The Agency believes that sodium chlorate does not constitute a risk of concern to the general population or any population subgroups, since the LOC exceedances are associated with a small number of water treatment facilities and inappropriate treatment practices. Furthermore, the Agency anticipates that the community water system outreach strategy discussed in the RED will greatly reduce potential drinking water byproduct exposure.

Most risk scenarios for occupational handlers of sodium chlorate did not exceed the Agency's LOC, but several did. However, by enacting the mitigation measures outlined in the RED, to include engineering controls and application restrictions, all scenarios are below the LOC (i.e. MOEs are greater than the LOC of 100). Post-application occupational exposure was not assessed because dermal and inhalation exposures are negligible due to the chemical's physical and chemical characteristics as an inorganic salt.

Environmental Exposure and Risk

Sodium chlorate is not a naturally occurring chemical. Physical properties indicate that it is not expected to volatilize from soil or water and has low potential to bioaccumulate. Sodium chlorate is highly soluble and is expected to be very mobile and partition predominately into water. In the environment, extensive redox reactions are expected to reduce the concentration of chlorate in the water column. Key findings from the ecological risk assessment are summarized below.

There appears to be no acute risk to fish at the Agency's LOCs. However, some data suggest that brown trout could be substantially more sensitive than other fish species tested to chlorate's toxicity. No toxicity studies are available to quantify the chronic risk to fish. For freshwater and saltwater invertebrates acute risks for both agricultural and non-agricultural uses of sodium chlorate are below the LOC of 0.5. Chronic risk to invertebrates was not assessed since treatment-related effects were not observed at any concentration in available studies. For non-endangered aquatic plants, the Agency's LOC of 1.0 was not exceeded for either the agricultural or non-agricultural uses of sodium chlorate (highest risk quotient or RQ was 0.91).

No mortality occurred in the submitted avian subacute toxicity studies at the highest concentration tested, representative of chlorate's agricultural use pattern. However, acute risk to birds cannot be precluded for chlorate's non-agricultural uses

because estimated environmental concentrations (EECs) from these higher application rates are significantly greater than those estimated for agricultural use patterns. However, mitigation measures enacted in the RED will limit avian exposure to sodium chlorate and reduce these risks. For chronic risks to birds, LOCs were exceeded for agricultural uses, and the highest calculated RQ was 11 (LOC is an RQ above 1.0). Chronic RQs were not calculated for sodium chlorate's non-agricultural uses, but based on the higher application rates and resulting EECs, RQs would exceed those calculated from agricultural uses. Risks to birds will be reduced through mitigation measures, including limiting applications to spot treatments and decreasing application rates.

For mammals, acute toxicity was not calculated because of inability to classify the dose response curve. Instead, high-end acute risk ratios were calculated and indicate that sodium chlorate's agricultural uses will not exceed the LOC of 1.0 except in one scenario (small mammals eating short grass). However, acute risks to mammals from sodium chlorate's non-agricultural uses are likely above the LOC due to higher application rates and resulting EECs. Considering these ratios are over-estimates and that mitigation measures will impose application restrictions, the likelihood of a risk of concern will be reduced. A conservative estimate of chronic toxicity to mammals for agricultural sites was calculated, and RQs exceeded the LOC of 1.0 (highest RQ was 2.6). Chronic toxicity was not calculated for non-agricultural use sites, but risk estimates would likely be considerably higher than those calculated for agricultural uses for the reasons stated previously. Mitigation measures outlined in the RED and the possibility that risk ratios are overstated reduce the likelihood of a risk of concern.

Adequate data are not available to allow for derivation of RQs for terrestrial plants. However, risk to plants is presumably higher than the Agency's concern level based on chlorate's non-selective mode of action as an herbicide.

The preliminary risk assessment for endangered species indicates that RQs exceed endangered species LOCs for chronic risks to birds (RQs up to 11 for agricultural uses and greater for non-agricultural uses); acute risks to mammals (RQs up to 33); chronic risks to mammals (RQs up to 1.2 for agricultural uses and greater for non-agricultural uses); and risks to aquatic plants (RQs up to 13). Risks could not be calculated for terrestrial plants and for chronic risks to fish. Potential indirect effects to any endangered species dependent upon a species that experiences effects from use of sodium chlorate can not be precluded based on the screening level ecological risk assessment. These findings are based solely on EPA's screening-level assessment and do not constitute "may affect" findings under the Endangered Species Act.

Risk Mitigation

The following mitigation measures are necessary to address identified risks for products containing sodium chlorate to be eligible for reregistration.

Agricultural use mitigation:

- Engineering controls (enclosed cockpits) for aerial applications on agricultural crops.

- For cotton, the maximum application rate will be reduced from 7.5 lbs ai/A to 6 lbs ai/A, and applications will be limited to a single application in all states except California, where a second application will be allowed.

Non-agricultural use mitigation:

- All non-agricultural uses will be limited to spot treatments only (with the exception of the granular formulation for use under asphalt, although this use will be limited to an 8000 ft² treatment area). The uses limited to spot treatments include, but are not limited to: building perimeters, driveways, parking lots, fence rows, military installations, pipelines, railroads, lumberyards, industrial sites, tennis court perimeters, picnic areas, bleachers, cemeteries, fuel tanks, airport runways, helicopter pads, wood decks, guard rails, highway medians, sidewalks/walkways, vacant lots, fire hydrants, recreational areas, and other similar areas.
- Use on rights-of-way and ditch banks will be cancelled.
- The label will specify a maximum application rate of 0.9 lb ai/100 ft².

Data Requirements

The generic database supporting the reregistration of sodium chlorate has been reviewed and determined to be substantially complete. However, some data gaps remain, and the data requirements listed below must be submitted to EPA. The OPPTS Guideline Numbers are noted in parenthesis. Note that the list below varies slightly from what is shown in the RED due to post-RED consultations and determinations within the Agency.

- UV/Visible Light Absorption (830.7050)
- Avian reproduction test (1-generation mallard duck) (850.2300)
- Honey bee acute contact toxicity (850.3020)
- Seedling emergence, Tier II (850.4100)
- Vegetative vigor, Tier II (850.4150)
- Submittal of analytical reference standards (860.1650)

Product Labeling Changes

All sodium chlorate products must comply with EPA's current pesticide product labeling requirements and with the labeling changes set forth in Section V of the Inorganic Chlorates RED document. All labels must be amended to incorporate the risk mitigation measures outlined in the RED. The Agency may require changes to the language of the sodium chlorate label in the future if deemed necessary under the Endangered Species Protection Program.

For More Information

Electronic copies of the Inorganic Chlorates RED and this fact sheet are available at <http://www.epa.gov/pesticides/reregistration/status.htm>. All supporting documents are available through the public docket EPA-HQ-OPP-2005-0507 located on-line through the

website above or in the Federal Docket Management System at <http://www.regulations.gov>.

For more information about EPA's pesticide reregistration program, the Inorganic Chlorates RED, or reregistration of individual products containing inorganic chlorates, please contact the Special Review and Reregistration Division (Mailcode 7508P), Office of Pesticide Programs, U.S. EPA, Washington D.C. 20460, telephone (703) 308-8000.

For information about the health affects 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. The NPIC internet address is <http://npic.orst.edu>.