

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Propamocarb Hydrochloride

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. The Agency develops mitigation measures or any regulatory controls needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that 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 3124, propamocarb hydrochloride.

Use Profile

Propamocarb hydrochloride is a fungicide used to control *Pythium* spp. and *Phytophthora* spp. on turf, outdoor woody and herbaceous ornamentals. The fungicide is formulated as a soluble concentrate/liquid. Propamocarb hydrochloride is applied as a bare-root dip, drench and foliar application. Propamocarb hydrochloride cannot be applied through any type of irrigation system. For terrestrial uses, it cannot be applied directly to water or to areas where water is present or to intertidal areas below the mean high water mark. Propamocarb hydrochloride treated clippings cannot be fed to animals or animals allowed to graze in treated areas. Finally, propamocarb hydrochloride cannot be used in California or on sod farms in Arizona.

Almost all usage of propamocarb hydrochloride in the United States is concentrated on golf courses with approximately 100,000 to 200,000 pounds of active ingredient applied per year.

Regulatory History

Propamocarb hydrochloride was first registered as a pesticide in the U.S. in 1984. Currently, one product, Banol (EPA Reg. No. 45639-88), is registered. Three Data Call-In notices (DCIs) have been issued for propamocarb hydrochloride. The first DCI was issued on September 30, 1991, under Phase IV of the reregistration program. It required submission of acute avian, invertebrate toxicity, hydrolysis, photodegradation, and neurotoxicity data due to associated use patterns and the fungicide being a carbamate. On March 10, 1995, a second DCI was issued for propamocarb hydrochloride and other pesticide active ingredients registered for applications on residential turf. Under this DCI, submission of foliar residue dissipation, post-application dermal passive exposure and post-application inhalation dosimetry exposure data were required. The post-application dermal passive exposure and post-application inhalation dosimetry exposure studies may be waived pending completion of the database on agricultural and residential post-application/reentry exposure currently being developed by the Agricultural Reentry Task Force and Outdoor Exposure Task Force, provided the registrant is a member of both Task Forces. A third DCI was issued on October 11, 1995, requiring avian reproduction, fish life cycle, aquatic plant growth, and seedling germination/seedling emergence studies due to use patterns associated with the fungicide. In addition, foliar residue dissipation, dermal passive dosimetry exposure, inhalation passive dosimetry exposure, honey bee acute contact, estimation of dermal exposure and estimation of inhalation exposure data were required for uses that were not addressed in the March 10, 1995, DCI.

Human Health Assessment

Toxicity

In studies using mammalian laboratory animals, propamocarb hydrochloride generally has been shown to be practically non-toxic to slightly toxic in terms of acute toxicity. Propamocarb hydrochloride was classified as slightly toxic for oral, dermal and eye irritation in terms of acute toxicity and practically non-toxic in terms of acute inhalation and dermal irritation. The fungicide was also observed not to be a dermal sensitizer. In terms of systemic effects, a NOEL of 150 mg/kg/day was established.

Maternal and developmental toxicity studies were conducted. However, due to the high dose at which fetal toxicity was observed, no definite conclusion can be made regarding developmental toxicity.

No evidence of mutagenicity or neurotoxicity was associated with the fungicide. Propamocarb hydrochloride is classified a Group D carcinogen, not classifiable as to human carcinogenicity. This classification is used for

materials with inadequate human and animal evidence of carcinogenicity due to a lack adequate data, as in the case of propamocarb hydrochloride.

The reference dose (RfD) for propamocarb hydrochloride was calculated to be 0.11 mg/kg/day. The RfD is an estimate of the acceptable daily intake of a pesticide taking into account uncertainty factors of the estimation. This RfD was based on a LOEL of 1000 ppm (33.3 mg/kg/day) of a 2-year feeding study in beagle dogs.

Dietary Exposure

As uses of propamocarb hydrochloride are currently limited to applications to ornamentals and turf, no dietary exposure is expected.

Occupational and Residential Exposure

There is potential exposure to occupational handlers during mixing/loading/application of propamocarb hydrochloride products using groundboom sprayers, high volume/low-pressure sprayers, low pressure handwand sprayers, high pressure handwand sprayers, backpack sprayers, hose-end sprayers, hand-held sprinkler cans, and transplant dip by hand. There is also potential exposure to persons entering treated sites after application is complete.

Human Risk Assessment

The Agency is concerned that the risks from post-application exposures to treated turf grown for sod and to ornamentals (greenhouse and nursery) grown for sale may be unacceptable based on the risk endpoints identified above for entry immediately following applications. However, no estimate can be made for the high volume/low pressure sprayer (commercial turfgrass sprayer) use and the hand-dip use due to the absence of sufficient exposure data at this time.

Environmental Assessment

Environmental Fate

Propamocarb hydrochloride is relatively non-persistent, is stable to photodegradation in water, is photodegradable on soil with a half-life of 35 days, degrades fairly rapidly by microbial-mediated metabolism, is persistent to anaerobic metabolism, dissipates rapidly under field conditions, has limited hydrolytic potential and bioconcentration in fish, and has

variable mobility from mobile to relatively immobile. Volatilization is not considered a probable route of dissipation. Abiotic hydrolysis is not a significant dissipation process. However, base-catalyzed hydrolysis may occur at extremely slow rates.

Ecological Effects

Propamocarb hydrochloride was observed to be practically nontoxic in terms of avian acute oral toxicity, avian subacute dietary toxicity, freshwater fish acute toxicity, freshwater invertebrate acute toxicity, and slightly to practically non-toxic in terms of mammalian acute oral toxicity. Estuarine/marine acute toxicity ranged from practically non-toxic for mysid shrimp and sheepshead minnow to slightly toxic for eastern oyster. No estimate can be provided in terms of terrestrial plant or chronic avian toxicity due to the absence of sufficient data at this time.

Environmental Risk Assessment

The LOCs for acute and chronic toxicity for freshwater fish are not exceeded for any current use nor for freshwater invertebrates. The use of propamocarb hydrochloride on field-grown ornamentals exceeds the Level of Concern (LOC) for birds, mammals and estuarine and marine mammals. In addition, the lack of data on chronic freshwater fish and honey-bee exposure does not allow the Agency to conduct the corresponding risk assessments. However, the registrant has proposed to amend their label to eliminate the field-grown ornamental use. Thus, the Agency believes this action will mitigate the LOC exceedance for birds, mammals and estuarine and marine mammals plus requirements for a chronic freshwater fish and honey-bee exposure studies.

As mentioned above, the Agency has required avian reproduction to evaluate chronic risks to birds. Additional data are also being required concerning terrestrial and semi-aquatic and aquatic plant toxicity to perform the corresponding plant risk assessments.

Risk Mitigation

To lessen the risks of human exposure posed by propamocarb hydrochloride, EPA is requiring the following risk mitigation measures:

- For uses within the scope of the WPS, the Agency is requiring persons entering treated areas before a 24-hour restricted-entry interval has expired to wear early-entry personal protective equipment consisting of coveralls over short-sleeve shirt and short pants, chemical-resistant footwear plus

socks, chemical resistant headgear for overhead exposures, and chemical-resistant gloves.

- For occupational uses outside the scope of the WPS, EPA is restricting entry into treated areas until sprays have dried.

Additional Data Required

EPA has required the following additional generic studies for propamocarb hydrochloride to confirm its regulatory assessments and conclusions:

- confirmatory data for post-application exposures for uses on turfgrass at residential sites and at sod-farm sites and for uses on ornamentals in greenhouses.
- exposure data for handler activities associated with high volume/low pressure spray and hand-dipping applications.
- chronic avian and aquatic invertebrate data and additional terrestrial plant phytotoxicity data.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All propamocarb hydrochloride end-use products must comply with EPA's current pesticide product labeling requirements and with the following.

To remain in compliance with FIFRA, manufacturing use-product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions For Use:

"Only for formulation into a fungicide for the following use(s): ornamental sod farms (turf), ornamental lawns and turf, and cutting beds and seedling areas for ornamental herbaceous plants, ornamental woody shrubs and vines."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under "Directions for Use" to permit the

reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S.EPA submission requirements regarding the support of such use(s)."
- (b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s)."

Personal Protective Equipment (PPE) Requirements for Pesticide Handlers

Sole active ingredient end-use products that contain propamocarb hydrochloride must be revised to adopt the handler PPE requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

Multiple active ingredient end-use products that contain propamocarb hydrochloride must compare the handler personal protective equipment requirements set forth in this section to the PPE requirements on the current labeling and retain the more protective. For guidance on which PPE is considered more protective, refer to PR Notice 93-7.

Products Intended for Occupational Use

Minimum PPE requirements (WPS and nonWPS uses): The minimum PPE for all WPS and nonWPS uses for which groundboom applications can be employed is:

"For groundboom applications, mixers and loaders must wear long-sleeved shirt and long pants, chemical-resistant gloves, and shoes plus socks".

PPE requirements for all other WPS and nonWPS uses: The PPE for all other WPS and nonWPS uses will be based on the acute toxicity of the end-use product. This PPE must be

compared to the minimum (baseline) (PPE). The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in labeling: The PPE must be placed on the end-use product labeling in the location specified in PR Notice 93-7 and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Reentry Requirements

Reentry Interval (REI for WPS uses): A 24-hour REI is required for uses within the scope of the WPS (see PR Notice 93-7) on all end-use products (see tests in PR Notices 93-7 and 93-11). This REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7.

Early reentry PPE requirements: The PPE label language required for early entry into WPS treated sites is:

"For early entry, wear coveralls over short-sleeve shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, and chemical-resistant headgear for overhead exposures."

WPS Notification Statement (WPS uses): The following statement must be added to all end-use product labeling that contain directions for one or more WPS uses:

"Notify workers of the application by warning them orally and by posting warning signs at entrances to treated areas."

Placement in labeling: The REI must be inserted into the standardized REI statement required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early entry PPE statement required by Supplement Three of PR Notice 93-7. The double notification statement must be inserted into the Agricultural Use Requirements box in the location required by Supplement Three of PR Notice 93-7.

Entry restrictions for NonWPS uses: The Agency is establishing the following entry restrictions for all nonWPS occupational uses of propamocarb hydrochloride end-use products:

"Do not enter or allow others to enter the treated area until sprays have dried."

Placement in labeling:

If WPS uses are also on label, then follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box and place the appropriate nonWPS entry restriction in that box. If no WPS uses are on label, then add the appropriate nonWPS entry restriction to the labels of all end-use products, except products primarily intended for homeowner use, in a section in the Directions For Use with the heading:

"Entry Restrictions:"

Engineering controls

The following engineering control statement is required on product labeling:

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

Application restrictions

These additional use restrictions are required for propamocarb hydrochloride labels:

"Do not apply this product in a way that will contact workers, other people or pets, either directly or from drift. Keep people and pets out of the area during application. Only protected handlers may be in the area during application"

"Do not apply more than a total of 12 fl. oz. (equivalent to 0.57 lb/ai) of propamocarb hydrochloride per 1000 sq. ft. (25 lbs ai/acre/year) of turfgrass per year."

"Do not use for field-grown ornamentals."

User safety requirements

Add the following user safety requirement to the end-use product labeling ONLY if PPE (other than long-sleeve shirt, long pants, shoes, and socks) are required on the label due to the acute toxicity of the end-use product:

"Follow manufacturer's instructions for cleaning/maintaining protective clothing and equipment. If there are no such instructions for washables, use detergent and hot water. Keep and wash protective clothing and equipment separate from other laundry."

User safety recommendations

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

Add the following user safety recommendation to the end-use product labeling ONLY if PPE (other than long-sleeve shirt, long pants, shoes, and socks) are required on the label due to the acute toxicity of the end-use product:

"Users should remove protective clothing and equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

Regulatory Conclusion

The Agency has determined that all uses of propamocarb hydrochloride, with the exception of the use on field-grown ornamental plants plus the high volume/low pressure and hand dipping application scenarios, are eligible for reregistration. A decision on the field-grown

ornamentals use plus the high volume/low pressure and hand dipping application scenarios cannot be made at this time because insufficient data are available to conduct a risk assessment for chronic effects to the environment or to characterize the risk to handlers of propamocarb hydrochloride via high volume/low pressure and hand-dip uses. The registrant has proposed voluntarily deleting the use for field-grown ornamentals from the product registration and is amending their label to reduce the maximum application rate for turf.

These products will be reregistered once the required confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to propamocarb hydrochloride will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for propamocarb hydrochloride during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the [name] RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the propamocarb hydrochloride RED, or reregistration of the individual product containing propamocarb hydrochloride, please contact the Special Review and Reregistration Division (7508W), 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 Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.