



# R.E.D. FACTS

## 4-Chlorophenoxy- acetic Acid (4-CPA)

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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 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 years ago 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 imposes any regulatory controls that are 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 announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 2115, 4-chlorophenoxyacetic acid, hereafter referred to as "4-CPA".

### **Use Profile**

4-CPA is used in the food industry as a plant growth regulator to restrict root growth during seed germination of mung beans. 4-CPA is applied to the water bath to soak the beans. Once the beans have soaked for several hours, they are washed to remove the surface residues, and are then germinated indoors for several days. After sprouting, the hulls and roots are discarded, and the remaining portion is packaged and sold for human consumption.

4-CPA is formulated in end-use products as a soluble concentrate, liquid, and crystals. It is applied by direct pour or by closed delivery systems. Use practice limitations prohibit the feeding of bean parts or hulls treated with 4-CPA to livestock. Contamination of water, food, or feed by the storage or disposal of 4-CPA also is prohibited.

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## **Regulatory History**

4-CPA was first registered as a pesticide in the U.S. in 1969 for use as a plant growth regulator for mung beans, and later as a fruiting bloom set for tomatoes.

EPA issued a Data Call-In for 4-CPA in 1984 requiring chronic toxicology data. A second Data Call-In was issued in 1987 to investigate possible dioxin/furan formation during the manufacturing process.

Under the reregistration program, in 1991, EPA issued a third Data-Call-In for data to characterize the chemistry, human toxicity, and environmental fate of 4-CPA. Another Data Call-In was issued in 1994 for the tomato use, which the registrant was no longer supporting for reregistration. As a result, the products labeled for use on tomatoes were voluntarily canceled, leaving two products labeled for use on mung beans.

## **Human Health Toxicity Assessment**

In acute toxicity studies using laboratory animals, 4-CPA is a severe eye irritant and is classified as Toxicity Category I for eye irritation in mammalian species. This classification represents the most severe level of acute toxicity. 4-CPA is slightly toxic through the oral and dermal routes (Toxicity Category III). It is only mildly toxic through the inhalation route (Toxicity Category IV) and is classified as non-irritating for primary dermal irritation. 4-CPA is not a skin sensitizer.

With the exception of ocular irritation, 4-CPA generally is of low subchronic mammalian toxicity. 4-CPA was shown to be a developmental toxin causing decreases in fetal body weight and inducing skeletal variations in rats. 4-CPA did not exhibit mutagenic potential.

Due to 4-CPA's lack of overt toxicity in subchronic dietary studies, the lack of acute dietary exposure concern, and the low volume/minor use status, EPA waived the requirements for chronic toxicity, carcinogenicity, and reproductive effects, which are normally required for food-use chemicals.

### **Dietary Exposure**

People may be exposed to residues of 4-CPA through the diet. Tolerances or maximum residue limits have been established for mung bean sprouts at 2.0 ppm and in/on tomatoes at 0.05 ppm (please see 40 CFR 180.202). However, in response to a petition by the registrant, the Agency will amend the existing tolerance for mung bean sprouts, lowering it to 0.2 ppm. In addition, the established tolerance on tomatoes will be revoked due to the lack of support for this use.

Mung bean sprouts are considered a raw agricultural commodity; thus, food additive tolerances have not been required or established for this use.

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EPA has assessed the dietary risk posed by 4-CPA. An acute dietary risk assessment was not required since no acute dietary toxicity end-point of concern was identified. In the chronic exposure analysis, for the overall U.S. population and 22 subgroups, exposure from the current 4-CPA tolerances represents 1.43% of the Reference Dose (RfD), an amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The exposure levels of the two most highly exposed subgroups, children 1-6 and 7-12 years old, represent 2.62% and 2.24% of the RfD, respectively. Therefore, chronic dietary risk is not of concern for this chemical.

### **Occupational and Residential Exposure**

The Agency believes that the potential for exposure to 4-CPA during pesticide handling operations exists, but is low. Neither a worker exposure assessment nor a risk assessment were required because 4-CPA generally is of low toxicity, and the potential for worker exposure associated with growing mung beans is very low.

Products containing 4-CPA are intended primarily for occupational use and are not likely to be used at residential sites. At this time, the use of 4-CPA is outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS), due to the industrial setting for applying this pesticide.

### **Human Risk Assessment**

4-CPA generally is of low acute and subchronic toxicity, but is a severe eye irritant. It also has been shown to be a developmental toxin in rats. Although people may be exposed to very low levels of 4-CPA in their diets, this exposure does not pose risks of concern. Since both the pesticide's toxicity and handlers' exposure levels are low, 4-CPA also poses only minimal risks to workers engaged in growing mung beans.

## **Environmental Assessment**

EPA waived most ecotoxicity data requirements for reregistration of the mung bean use of 4-CPA because this use is entirely indoors, resulting in practically no exposure to non-target organisms.

### **Environmental Fate**

The results of a hydrolysis study, which was the only data required to support the indoor mung bean use of 4-CPA, indicated that it is expected to be mobile in soil and aquatic environments. Any disposal of water treated with 4-CPA after use on mung beans must be in compliance with a National Pollutant Discharge Elimination System (NPDES) permit.

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## **Ecological Effects**

Since 4-CPA is registered for use entirely indoors, practically no exposure to non-target organisms results. The available data indicate that 4-CPA is practically non-toxic to small mammals on an acute oral basis, and practically non-toxic to warm water fish.

## **Ecological Effects Risk Assessment**

4-CPA as typically used indoors in growing mung beans is not likely to be released to the environment in significant amounts in effluent. Any exposure to fish, wildlife, or endangered species would be regulated under the NPDES permit program. Therefore, risk to fish, wildlife, and endangered species is minimal.

## **Additional Data Required**

EPA is requiring additional generic preliminary analysis data on one of the 4-CPA products, and additional product chemistry data on the second product, to confirm its regulatory assessments and conclusions.

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 4-CPA end-use products must comply with EPA's current pesticide product labeling requirements, and with the following:

### **Environmental Hazard Statement**

The following label statement is required on all end use products for the mung bean use (PR Notice 93-10):

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specially identified and addressed in a NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage plant authority. For guidance, contact your State Water Board or Regional Office of EPA."

### **Personal Protective Equipment (PPE) for Handlers**

Due to the potential for eye irritation (Toxicity Category I), EPA is requiring that handlers of the La Choy 100% product wear protective eyewear. The following language must be located on the label:

"Applicators and other handlers must wear goggles."

There are no other special toxicological concerns about 4-CPA that warrant the establishment of active-ingredient-based handler PPE requirements.

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Therefore, the PPE for handlers will be based on the acute toxicity of each end-use product.

### **Entry Restrictions for Occupational-Use Products**

All of the registered uses of 4-CPA are outside the scope of the Worker Protection Standard for Agricultural Pesticides (WPS). Therefore, there are no reentry restrictions. EPA is requiring the following labeling statements on all end-use products containing 4-CPA that are intended primarily for occupational use:

***Application Restrictions:***

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

***User Safety Requirements:***

"Follow manufacturer's instructions for cleaning/ maintaining PPE. If no such instructions exist for washables, use detergent and hot water. Keep and wash PPE separately 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."

"Users should remove PPE 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 use of currently registered products containing 4-CPA in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

4-CPA products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, 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 4-CPA 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.

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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 4-CPA 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 4-CPA RED, or reregistration of individual products containing 4-CPA, 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 8:00 am and 8:00 pm Eastern Standard Time, Monday through Friday.