United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-96-002 August 1996

R.E.D. FACTS

AMITROLE

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 any mitigation measures or regulatory controls needed to effectively reduce 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 0095, Amitrole.

Use Profile

Amitrole is a terrestrial non-food herbicide used primarily in industrial areas (outdoors), non-agricultural rights-of-way, fencerows, hedgerows, non-agricultural uncultivated areas, soils, ornamental and/or shade trees, and ornamental shrubs and vines. There are no tolerances for any food crop or water which will be used for irritation, drinking or other domestic purposes. Amitrole's mechanism of action inhibits carotenoid synthesis, chlorophyll formation, and limited regrowth of buds. Amitrole formulations include a solid/dust (technical) product, a wettable powder (in water soluble bags), and an emulsifiable concentrate (the registrant has requested voluntarily cancellation of this product). Amitrole is solely applied by fixed boom sprayers attached to tractors, trucks or railway (ground equipment).

Regulatory History

Amitrole was first registered as a pesticide in the U.S. in 1948. The EPA issued a Registration Standard March 30, 1984 (PB87-104766). The Registration Standard besides requiring submission of studies informed registrants that even though amitrole was not used on food crops and there was no dietary exposure to the chemical the Agency had major concerns for dermal exposure, with inhalation furnishing only a minor contribution to the

total body burden. Human exposure, in some circumstances, occurred at doses which resulted in antithyroid effects in laboratory animals. Amitrole's use patterns and application techniques met the oncogenicity risk criterion for Special Review. The Agency determined that it would not reregister any current product and it would not register any new product containing amitrole until all pivotal data was reviewed.

On May 15, 1984, the Agency issued a Notice of Special Review (Position Document-1) of pesticide products containing amitrole. The Agency's Special Review was initiated to address the use of amitrole on non-crop sites (highway rights-of-way, primarily) and by homeowners, and to examine the carcinogenic risk to mixers, loaders and applicators. The data indicated that amitrole induced thyroid, pituitary and liver tumors in laboratory animals. The registrant voluntarily acted on a number of measures that reduced worker exposure to amitrole. Among these were the deletion of the high exposure application methods such as knapsack sprayers, the adoption of a "no-glug" container design for the liquid formulation to reduce splashing while pouring, the addition of protective clothing requirements to labels, and packaging of the wettable powder formulation in water soluble packets. Lastly, the registrant voluntarily canceled all homeowner products.

During the Special Review phase, two Data Call-Ins (DCIs) were issued by the Agency. A DCI was issued on February 22, 1990 requesting efficacy, usage and worker exposure monitoring data for both liquid and powder formulations of amitrole. A second DCI was issued on August 16, 1991 requesting product chemistry, ecological and environmental fate studies and toxicology studies.

Based on a risk and benefit assessment, the Agency concluded that the benefits provided from the use of amitrole (taking into consideration the measures previously discussed) outweigh the risks. Thus, the Agency on October 8, 1992 issued a Notice of Final Determination (57 FR 46448) of the Amitrole Special Review. The Agency continued to require: restricted use (RU) classification, a cancer warning statement on the label, application methods remain limited to boom sprayers, and protective clothing requirements remain on the label. The Notice was published in the Federal Register and comments were invited for 30 days. No comments were received.

After reviewing all the submitted data and comparing other pesticidal chemicals also classified as "restricted use," the Agency has determined that the restricted use classification is no longer appropriate. Amitrole is classified as a B_2-probable human carcinogen. Two thirds of the Agency's calculated cancer risk of 10^{-5} to mixers/loaders (assuming handlers wear long sleeve shirts, long pants, shoes and socks) is from inhalation exposure. The Agency believes that the likelihood of inhalation exposure is almost non-existent since the amitrole is packaged in water soluble bags. Focusing

only on cancer risk from dermal exposure, the estimated cancer risk approaches 10^{-6}. Thus, with the low dermal absorption factor (0.5%) (since the registrant has requested voluntary cancellation of the amitrole use for ornamental plant nurseries), continued packaging in water soluble bags, additional protection (although minimal because of the low dermal absorption) afforded by chemical resistant gloves and chemical resistant apron, the Agency concluded that the Restricted Use classification could be rescinded if the registrant agreed to the following conditions: voluntarily cancel their liquid formulation product; retain the cancer warning label; retain the boom sprayer as the only application mode; retain the same use profile as a non-food use pesticide; and provide the Agency with handler exposure studies for mixers/loaders of water soluble packages to confirm the Agency's risk assessment and conclusions. In addition, the registrant understands that any proposed future expansion of their market will require that a separate risk assessment be performed for any new use/application method. Furthermore, amitrole labels must carry a ground water advisory and the registrant must submit additional ecological studies to complete the Agency's risk assessment.

Human Health Assessment

Toxicity

In studies using laboratory animals, amitrole technical has been shown to be in toxicity category IV and III (practically non-toxic and slightly toxic, respectively) for acute oral and acute dermal exposure. The requirement for an acute inhalation study was waived because a 2-year rat inhalation study is available. Even though this study was not useful for regulatory purposes it did show that the LC_{50} is probably at least greater than 0.5 mg/l (the highest target concentration tested). Therefore, it is likely that the acute inhalation is at least toxicity category III. Amitrole is also in toxicity category III for primary eye irritation and toxicity category IV for primary dermal irritiitation (both with rabbits). Amitrole is not a skin sensitizer in guinea pigs.

NOTE: For acute oral, dietary, mammalian/avian/aquatic toxicity:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic

Two human studies indicated minimal oral and dermal effects with amitrole. A dermal absorption study with amitrole (96.4% pure) and ^{14}-C-amitrole (4.03mCi/nmol) indicated that little or no ^{14}-C amitrole was absorbed over a period of up to 10 hours at dose levels up to 10.0 mg/rat.

Dietary Exposure

Amitrole is a non-food use pesticide. There are no food use patterns, and since chronic or lifetime exposure is an unlikely scenario, an RfD is not

required to be established nor did the Agency conduct a dietary risk assessment.

Carcinogen classification

Amitrole has been classified as a Group B_2-probable human carcinogen by the Office of Pesticide Programs Carcinogenicity Peer Review Committee (document dated August 30, 1991). This classification is based on the thyroid tumors seen in the rat (both sexes, multiple strains) and mouse (both sexes, two strains) and on liver tumors seen in the mouse (both sexes, multiple strains) as described in studies. The Agency calculated a Q1* of 0.68 from the thyroid tumor effects as seen in the first long term toxicological study.

Occupational and Residential Exposure

All products containing amitrole are for occupational use only. There are no homeowner use products containing amitrole. And although the Agency has identified inhalation as an appropriate route of exposure on which to conduct short term and intermediate term risk assessment, the Agency also believes that in reality there is little likelihood of actual inhalation exposure from mixing/loading/applying of amitrole. The inhalation exposure estimates are very conservative because:

(1) amitrole is not volatile, (2) amitrole is only packaged in water soluble bags (which greatly reduces the chance for incidental inhalation exposure), (3) the inhalation exposure values presented in Table 3 reflect data from the Agency's Pesticide Handlers Exposure Database (PHED V1.1), which for the water soluble packaging data set includes some instances where detections were not found but a value of half the limit of detection was assumed, and (4) the Agency assumed 100% adsorption of inhalation exposure from both the oral developmental toxicity study and the reproduction study. The assumption of half the limit of detection is a common Agency practice in establishing exposure/residue values.

As previously discussed, the registrant voluntarily restricted the use patterns of amitrole to reduce the exposure of amitrole to handlers. The wettable powder and liquid concentrate formulations were voluntarily packaged by the registrant to water soluble packets and "no-glug" containers, respectively. The only current application method is for fixed-boom sprayers attached to ground equipment such as tractors, trucks or railroad wagons.

The registrant has recently requested the voluntary cancellation of the liquid formulation (in no-glug container) and has also requested the use deletion of the only use currently within the scope of the Worker Protection Standard, ornamental plant nurseries.

The three exposure scenarios identified for amitrole are:

(1) Mixing/loading the liquid concentrate formulation (packaged in no-glug containers) to support ground application. As noted

previously, the registrant has requested voluntary cancellation of this product. The Agency has included the mixer/loader, exposure/risk estimates for this formulation since the voluntary cancellation is still in process.

(2) Mixing/loading the wettable powder formulation (packaged in water soluble bags) to support ground application, and

(3) Applying as a spray with fixed-boom ground equipment. (Exposure data for groundboom equipment is used as a surrogate for the fixed-boom ground equipment).

The Agency conducted an assessment of the inhalation risks associated with amitrole following short-term and intermediate-term exposures to occupational handlers. The Agency has determined that a risk assessment is not required for short-term and intermediate-term dermal exposures. Margins of exposure (MOE) for occupational inhalation exposures were calculated for handlers using the NOELs of 4 mg/kg/day for short-term and 0.9 mg/kg/day for intermediate-term exposure. Amitrole is not marketed to homeowners (only application methods is fixed-boom sprayer), therefore the sole exposure concern is for occupational handlers. The calculations indicate that with the exception of one scenario, all of the MOEs for short- and intermediate-term inhalation exposures at baseline protection (i.e., no respirator) exceed 100 indicating acceptable risk. The exception is the intermediate-term inhalation exposure of Scenario 1 (mixing/loading the liquid concentrate, which has an MOE of 82). However, the registrant is voluntarily cancelling this formulation.

Carcinogenic Risks

The Agency conducted an assessment of the carcinogenic risks associated with amitrole following exposures to occupational handlers including all currently registered uses, which includes the liquid concentrate formulation (packaged in a no-glug container) for which the registrant has recently requested a voluntary cancellation.

The calculations indicate that the risks at baseline protection (i.e., long-sleeve shirt, long pants, shoes, and socks) are in the 10^{-5} range for mixing/loading wettable powders (contained in water-soluble packaging) and application using open-cab groundboom sprayers, the surrogate for fixed-boom ground sprayers. The calculations indicate that the risks at baseline protection are greater than 10^{-4} for mixing/loading liquid formulations. These calculations do not reflect the exposure reduction expected to be realized from the mandatory use of "no-glug" containers for liquid formulations. The registrant has, however, recently requested voluntary cancellation for this formulation.

The risk assessment indicates that the risks at baseline protection are approximately 10^{-5} for mixing/loading the wettable powder formulation packaged in water soluble bags. Since the risk assessment was conducted using this assumption, the Agency is requiring that the wettable powder

formulation continue to be marketed only in water-soluble packaging. In addition, since the Agency has low confidence in the data used to assess exposure to mixers and loaders using water-soluble packaging and amitrole is a relatively potent carcinogen, additional risk reduction measures for mixers and loaders is being required. The following risk mitigation measures for mixers and loaders handling the wettable powder amitrole formulations, should adequately mitigate risk to these workers:

- mandatory use of water-soluble packaging for wettable powder amitrole formulations, and
- requiring mixers and loaders to wear a chemical-resistant apron, long-sleeve shirt, long pants, shoes, socks and chemical-resistant gloves.

There are no amitrole-specific post-application exposure data available. For many amitrole use scenarios, the Agency believes that the risks from post-application exposures will not pose an unacceptable risk to persons entering treated areas because, in general, amitrole is used in areas, such as rights-of-way, industrial areas, permanent landscape plantings, and other non-crop areas, where frequent or routine prolonged contact with treated surfaces is unlikely. Therefore, the Agency has determined that post-application exposures do not appear to pose an unreasonable risk to persons entering treated areas, as long as entry is not permitted until sprays have dried.

Environmental Assessment

Environmental Fate

Acceptable and supplemental information from environmental fate studies with respect to the persistence and mobility of amitrole under laboratory and field conditions has been reviewed. Persistence classes discussed in the following sections were based on the groupings (ranging from non-persistent to persistent) published in Goring et al., (1975) and McEwen and Stephenson (1979). The environmental fate data base for amitrole with terrestrial non-food crop use is essentially complete.

The following information is derived from acceptable environmental fate studies reviewed by the Agency. The studies determining laboratory persistence (degradation and metabolism processes) indicate amitrole is slightly to moderately persistent [aerobic soil half-life ($t_{1/2}$) ≈22-26 days; aerobic aquatic half-life of ≈57 days] with degradation primarily through biotic processes such as microbial-mediated metabolism. Abiotic hydrolysis is not a significant degradation process. Amitrole was reportedly stable to photodegradation in water and was shown to photodegrade slowly on soil with a $t_{1/2}$ of >30 days. Results of the anaerobic aquatic metabolism study demonstrate that amitrole is persistent with a $t_{1/2}$ of >1 year. In an aerobic aquatic metabolism study, amitrole was moderately persistent with an experimentally-determined $t_{1/2}$ of ≈57 days for a flooded sandy loam sediment. Results of terrestrial field dissipation studies in Washington and

Oregon show amitrole dissipating fairly rapidly under field conditions with DT_{50}s ranging from ≈17-21 days.

The mobility of amitrole was evaluated with batch equilibrium studies and amitrole was determined to be mobile in silty clay, sandy loam, sand, and silt soils (K_ds ranged from 0.152-0.922 ml/g). The reported vapor pressure of amitrole is 4.4×10^{-7} mm Hg (5.9×10^{-5} Pa) and the estimated Henry's Law Constant of 1.6×10^{-15} atm-m^3/mol are low; therefore, volatilization and subsequent photodegradation in air are not considered probable routes of dissipation.

The bioaccumulation in fish study was not submitted; however, the high solubility (280 g/l) and low octanol/water partition coefficient ($\log K_{ow} = -0.15$) indicate limited potential for bioaccumulation in fish.

Amitrole is mobile, somewhat persistent and may have the potential to contaminate ground water. This assessment is based on the acceptable environmental fate studies which indicate amitrole has a significant number of characteristics in common with pesticides that are known to leach to ground water. Amitrole is stable to hydrolysis, and aerobic soil and anaerobic aquatic metabolism and field dissipation data indicate that it is somewhat persistent. Amitrole is classified as mobile because the low K_d and K_{oc} values indicate it will not strongly adsorb to soil. Pesticides with similar properties have been found in ground water.

Amitrole may contaminate surface water from runoff or spray drift associated with ground spray application. Amitrole is stable to degradation from abiotic hydrolysis and aqueous photolysis, and is slightly to moderately persistent (aerobic soil metabolism $t_{1/2}$ ≈22-26 days; aerobic aquatic metabolism $t_{1/2}$ ≈57 days) in aerobic environments. Amitrole does not adsorb significantly to soil particles and may be transported in the dissolved phase by runoff to surface water bodies. Amitrole's primary route of dissipation is microbial-mediated metabolism; however, amitrole is stable in anaerobic environments.

Ecological Effects

The acute risk to nontarget animals (birds, insects, mammals, fish and aquatic invertebrates) is predicted to be low. Chronic risk to mammals was identified; however, the chronic risk to other nontarget animals (birds, fish and aquatic invertebrates) was not determined because chronic ecological effect data were not available.

Studies indicate that amitrole is practically non-toxic to avian species on an acute oral and subacute basis. For birds, it is important to note that the LC_{50} values used to calculate the RQs were greater that the highest dose tested (5,000 ppm). The Agency considers amitrole to represent low acute risk to birds. At this time chronic risk to birds cannot be assessed, because avian reproduction data are not available.

Amitrole is practically non-toxic to small mammals on an acute oral basis. The RQs for small herbivores and insectivores (0.13 to 0.29) exceeded by small margins the LOCs for endangered species (0.1) and restricted use (0.2). Amitrole however, may be hazardous to mammalian reproduction in localized areas. Using the acceptable two-generation rat reproduction study, the risk assessment indicates use of amitrole has the potential for chronic risk to mammalian species and may also chronically affect endangered mammalian species. The mammalian exposure asssessments use residue levels which represent the maximum estimated values, and the residues are expected to be lower on most food items. Amitrole residues are predicted to decline by microbial-mediated metabolism, physical removal by washoff and other dissipation pathways. The amitrole residue levels on food items in treated areas are not known because the treated areas are limited to nonagricultural use sites (rights-of way, fencerows, hedgerows, etc.) and the extent of exposure may be limited.

There is sufficient information to characterize amitrole as relatively non-toxic to bees.

The toxicity of amitrole to most aquatic organisms tested to date range from practically non-toxic (freshwater finfish) to moderately toxic (marine invertebrates). Chronic risk to freshwater fish can not be assessed because the fish life-cycle data are not available at this time.

There is sufficient information to characterize amitrole as slightly toxic to aquatic invertebrates. However, the chronic risk to freshwater invertebrates will be assessed once the invertebrate life cycle study is reviewed.

The acute risk from applications of amitrole is expected to be low to freshwater and marine/estuarine organisms. The risk quotients determined from application rates ranging from 3.6-8.0 lbs ai/A are less than the levels of concern for the tested aquatic animals at all use rates, except for marine/estuarine invertebrates. The RQ for mysid shrimp was 0.137 (8 lbs ai/acre) which exceeded the LOCs for endangered species (0.05) and restricted use (0.1) by a small margin. In this assessment, the screening model GENEEC was used to model runoff from non-agricultural use sites for amitrole. The GENEEC model was based on an agricultural use scenario and is a conservative estimate of exposure from surface runoff because agricultural land uses are intensive and may cover large areas.

The conclusion of low acute risk to estuarine crustaceans is based not only on the fact that the LOCs were exceeded by a small margin, but also because amitrole is used on non-agricultural use sites. In addition to marginal LOC exceedances and non-agricultural uses, the amount of amitrole applied annually in the United States is relatively small. Usage information for amitrole in the U.S. is between 40,000 and 60,000 pounds of the active ingredient on an annual basis. Furthermore, endangered

estuarine invertebrates are not currently listed by the United States Fish Wildlife Service (USFWS).

The available information indicates that amitrole affects the vegetative vigor of both monocots and dicots at very low levels (<0.01 lbs ai/A). The risks to non-target plants from sheet and channelized runoff was not determined with certainty because plant toxicity data were limited (seedling emergence data are not available). Qualitatively, amitrole's broad spectrum plant control due to its mode of action (i.e., inhibition of carotenoid synthesis) suggests exposure of amitrole may impact non-target plants. Based on the 3.6 to 8.0 lbs. ai/A use rates of amitrole, risk quotients exceed the levels of concern for terrestrial and semi-aquatic plants (1.0). Risk quotients are based on EC_{25}s from the dry weight parameter for wheat (monocot) and pepper (dicot) from the vegetative vigor study. The wheat and pepper plant EC_{25}s were the most sensitive plants tested and the lowest levels for the available plant toxicity data.

Because the risk assessment is incomplete for non-target terrestrial and aquatic plants, terrestrial (seedling emergence) and aquatic plant (all five species) testing is being required to confirm and complete the Agency's risk assessment and conclusions.

Additional Data Required

The generic data base supporting the reregistration of amitrole for the elegible uses has been reviewed and determined to be substantially complete for all uses. Nevertheless, the following studies are required to be conducted on the generic active ingredient: Guidelines 17-4(a) and (b), Avian reproduction studies and, Guideline 72-4(b), Aquatic Invertebrate Life Cycle with Daphnia Magna. Furthermore, the following confirmatory studies are required in order to complete the Agency's risk assessment and conclusions: Guideline 123-1(a), Terrestial Plant Testing: Seedling Emergence only. Guideline 123-2 Aquatic Plant Testing: All five species, and Guideline 231 and 232 Handler exposure study to provide dermal and inhalation data on mixers and loaders during the use of water-soluble packages.

The Agency is also 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 amitrole 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 amitrole RED document.

Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current Agency (EPA) regulations, PR Notices and applicable policies. 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 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 support of such use(s)."

End-Use Products

Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix D, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

Labeling Requirements for End-Use Products

Engineering Control Requirements for Pesticide Handlers

For sole-active-ingredient end-use products that contain amitrole, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain amitrole, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

Products Intended Primarily for Occupational Use

(WPS and nonWPS)

Minimum (Baseline) PPE/Engineering Control Requirements

The Agency is establishing minimum (baseline) engineering controls for occupational uses of amitrole end-use products.

For the wettable powder packaged in water soluble packages (non WPS), the Agency is requiring that mixers/loaders and persons cleaning

equipment wear: long sleeve shirt and long pants, chemical resistant gloves, chemical resistant apron, and shoes plus socks.

For the wettable powder packaged in water soluble packages (non WPS), the Agency is requiring that applicators wear: long sleeve shirt and long pants, and shoes plus socks.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. 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 personal protective equipment requirements 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.

Entry Restrictions

For sole-active-ingredient end-use products that contain amitrole the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For multiple-active-ingredient end-use products that contain amitrole the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

Products Intended Primarily for Occupational Use - WPS uses

Since the registrant's voluntary cancellation of in-scope (nursery-stock, the only WPS use) use has been received by the Agency, an REI is not being presented.

NonWPS use - Entry restrictions

The Agency is establishing the following entry restrictions for nonWPS occupational uses of amitrole end-use products:

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

Placement in labeling:

Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading: "Entry Restrictions."

Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing amitrole 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

a. {Registrant: place this on the labeling if coveralls are required for pesticide handlers on the end-use product label:}

Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

b. {Registrant: place this on the labeling always:}

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions 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."

Environmental Hazard Statment

The following labeling statement must be added to the "Environmental Hazards" section on all amitrole end-use products:

Ground water label advisory

"This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

add list of end use product labeling requirements here, summarizing every labeling change included in chapter V. of the RED

Regulatory Conclusion

The use of currently registered products containing amitrole in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products (not including the uses permitted with the liquid formulation in no-glug container and the ornamental plant nursery use) are eligible for reregistration.

Amitrole products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for amitrole 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 Amitrole 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 amitrole RED, or reregistration of individual products containing amitrole, 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.