



R.E.D. FACTS

Pesticide Reregistration

Linuron

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 0047, 3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea, commonly known as linuron.

Use Profile

Linuron is a herbicide used to control germinating and newly emerging grasses and broad-leaved weeds. It is applied to agricultural crops, ornamental bulbs, and poplar trees for use in shelterbelts in the mid-west. Most of the linuron applied in the U.S. is to soybean crops. Formulations include water dispersable granules, wettable powders, flowable concentrates, and emulsifiable concentrates/liquid suspensions.

Linuron usually is applied after a crop has been planted but before weeds emerge, using ground or aerial equipment. In some crops, such as carrots and celery, linuron is applied to newly emerging plants as an over-top spray. In asparagus, linuron is applied between cuttings of newly emerging spears for weed control during harvest.

Use practice limitations include prohibitions against applying linuron directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark; applying linuron aerially (DuPont only; Griffin allows aerial application to potatoes and soybeans before crop emerges); and applying linuron through any type of irrigation system.

Regulatory History

Linuron was first registered as a pesticide in the U.S. in 1966. EPA issued a Registration Standard for Linuron in June 1984 (NTIS #PB85-149011). From 1984 through 1988, linuron was the subject of a Special Review because it exceeded oncogenicity risk criteria. However, the weight of evidence suggested that its cancer-causing potential in humans is weak. EPA concluded that no regulatory action was warranted, and reduced linuron's cancer classification from a quantifiable to an unquantifiable Group C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence).

EPA issued Data Call-In notices (DCIs) in May 1986, September 1990 and November 1993, requiring additional studies on product chemistry, chronic toxicity, processing and cooking, ecological effects, phytotoxicity, and residue chemistry, as well as cropfield trials replacement data for studies generated by Craven Laboratories. Currently, 23 linuron end-use products and 5 technical products are registered.

Human Health Assessment

Toxicity

Linuron is of relatively low acute toxicity. It is slightly toxic by the oral, dermal and inhalation routes, and has been placed in Toxicity Category III (the second-to-lowest of four categories) for these effects. It causes slight eye irritation in rabbits (Toxicity Category III), and is not a skin irritant (Toxicity Category IV) or sensitizer.

A subchronic toxicity study using rats resulted in changes in blood cell counts, and retarded growth at the high dose level.

In a chronic toxicity and carcinogenicity study using beagle dogs, linuron caused changes in blood, including red blood cell destruction, and in liver weight. A study using rats resulted in testicular tumors and blood cell destruction. Another rat study showed growth retardation and destruction of red blood cells. A third rat study showed significant changes in blood pigments. An oncogenicity study using mice caused a statistically significant increase in liver tumors, as well as decreased body weight and body weight gain, increased liver weights, and other liver effects. As a result of the Agency's Special Review, linuron remains classified as an unquantifiable Group C carcinogen (that is, a possible human carcinogen for which there is limited animal evidence).

In a developmental toxicity study using rats, the highest dose level caused maternal toxic effects including decreased body weight gain and food consumption, as well as increases in postimplantation loss and fetal resorptions. In a study using rabbits, linuron caused decreases in maternal body weight, food consumption and liver weight, as well as more abortions, fewer fetuses per litter, decreased fetal body weight, and an increased incidence of fetuses with skeletal skull variations.

In a 2-generation reproductive toxicity study using rats, linuron caused effects on the parents including decreased body weight gain and abnormalities in the eyes and testes. Linuron was shown to interfere with the transmission of male hormones. Rats exposed to linuron could develop cell tumors in testicular tissue. A 3-generation study using rats showed reduced body weights and fertility, decreased pup survival, and decreased weanling body, liver and kidney weights, as well as liver atrophy. Linuron does not appear to be mutagenic.

Dietary Exposure

People may be exposed to residues of linuron through the diet. Tolerances or maximum residue limits have been established for linuron in many vegetables, grain crops, meat, milk, and other agricultural commodities (please see 40 CFR 180.184(a) and (b)). EPA has reassessed these tolerances and found that sufficient data are available to support the established tolerances for carrots; field corn grain; field corn forage and fodder; celery; cottonseed; parsnips; potatoes; sorghum grain; wheat grain and straw; meat and milk. Additional residue data are required for asparagus; sweet corn; sweet corn forage; sorghum forage and fodder; soybean forage and hay; wheat forage; and field corn grain dust. Several existing tolerances for barley, oats, and rye, forage, grain, hay, and straw; and corn, popcorn, forage and fodder will be revoked since there are no registered uses of linuron on these commodities. New tolerances have been proposed for lettuce, ginger and taro; several tolerance revisions have been proposed; and a tolerance for corn fodder needs to be raised.

Food and feed additive tolerance proposals are required for potato granules, chips, and processing waste. Under the Delaney clause of the Federal Food, Drug, and Cosmetic Act (FFDCA), however, food and feed additive tolerances may not be established for pesticides that induce cancer in man or animals. Although its cancer-causing potential in humans is weak, EPA still considers linuron to be a chemical that "induces cancer" within the meaning of the Delaney clause. Therefore, under current policy, EPA would not issue these food and feed additive tolerances, and would not continue in effect the tolerance for the associated raw agricultural commodity, potatoes.

EPA currently is evaluating legal challenges to its policies regarding pesticide tolerances, registrations and the Delaney clause. Because of these issues, the Agency is unable to make a reregistration eligibility decision at this time regarding the use of linuron on potatoes.

Although the basic manufacturer of linuron deleted the cotton use in 1991, cotton still exists on linuron end-use product labels. Registrants of these end-use products must now either submit a required cottonseed processing study or delete the cotton use from their labels.

EPA has assessed the dietary risk posed by linuron. For the overall U.S. population, chronic exposure from all existing linuron tolerances represents 2% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The two most highly exposed subgroups are non-nursing infants (less than 1 year old), whose exposure represents 6% of the RfD, and children age 1 to 6 years old, with exposures representing 4% of the RfD. Therefore, chronic dietary risk appears to be minimal.

Acute exposure to the subgroup of greatest concern, women of childbearing age, results in a Margin of Exposure (MOE) of 1,667 for developmental toxicity. This is likely to be an overestimate due to the conservative assumptions used. Thus, acute dietary risk also appears to be minimal.

Occupational and Residential Exposure

Based on current use patterns, workers may be exposed to linuron during and after applications to agricultural crops, ornamental bulbs and poplar trees. The Agency is not aware of any linuron products intended for home use.

Margins of Exposure (MOEs) were estimated for applicators and mixer/loaders of linuron. While most MOEs are greater than 100 (the margin generally considered acceptable), exposure of mixer/loaders during aerial applications is of concern, as is exposure of handlers using open mixing/loading methods.

Post-application/reentry worker exposure to linuron is unlikely, except during asparagus harvesting where linuron is applied between cuttings. However, a supplemental worker exposure study indicates that all the MOEs for asparagus harvesters are over 100. A 24-hour reentry interval required for this use was converted to a 24-hour restricted entry interval (REI) by the Worker Protection Standard (WPS). EPA is requiring a 24-hour REI for all linuron uses within the scope of the WPS, based on the asparagus reentry data.

Personal protective equipment (PPE) requirements for workers should be based on the acute toxicity of end-use products. However, due to concerns about worker risks, EPA is establishing minimum handler PPE requirements for any end-use product containing linuron. Such products may have more stringent PPE, but in no case may have less stringent PPE than: coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, chemical-resistant footwear, and chemical-resistant apron.

Human Risk Assessment

Linuron is of relatively low acute toxicity, but is classified as an unquantifiable Group C carcinogen (that is, a possible human carcinogen for

which there is limited animal evidence), and shows some evidence of developmental and reproductive toxicity.

Although people may be exposed to residues of linuron in a number of food commodities, acute and chronic dietary risks appear to be minimal. Handler and post-application worker risks are of concern, but are being mitigated by requiring a 24-hour REI and minimum PPE for all agricultural uses of linuron.

Environmental Assessment

Environmental Fate

Although the environmental fate data base for parent linuron is essentially complete, two environmental fate data requirements (leaching/adsorption/desorption and terrestrial field dissipation studies) are not fulfilled. The environmental fate assessment for linuron is incomplete and tentative because information on the persistence, mobility and dissipation pathways of several degradates of linuron is not available.

Parent linuron appears to be moderately persistent and relatively immobile. Increased mobility may occur under specific environmental conditions such as in coarse textured soils and soils with low levels of organic matter. Linuron dissipates principally by biotic processes such as microbial degradation. In surface soils with adequate organic matter, the combined processes of adsorption and microbial degradation would limit linuron's potential to migrate to ground water. Linuron could runoff to surface water bodies. In that case, it would degrade fairly rapidly to three primary metabolites. However, information on the persistence and mobility of these degradates is not currently available.

Linuron exhibits some of the properties and characteristics of chemicals that have been detected in ground water, and linuron itself has been detected in ground water in four states (Georgia, Missouri, Virginia and Wisconsin). Linuron is moderately persistent with an aerobic soil metabolism half-life ranging from 57 to 100 days. Because linuron is sufficiently persistent and may be mobile under certain environmental conditions, it has the potential to impact ground water quality.

Linuron can be applied by ground spray and therefore could contaminate surface waters through spray drift. It has the potential to be somewhat persistent in surface waters, particularly those with low microbiological activity and long hydrological residence times. It may be less persistent in water and sediment under anaerobic conditions than under aerobic conditions. Its bioconcentration potential is relatively low.

Linuron is not currently regulated under the Safe Drinking Water Act, and water supply systems are not required to sample and analyze for it. No Maximum Contaminant Level (MCL) or drinking water health advisories have been established for linuron. The primary treatment processes employed by most water systems may not always be completely effective in

removing linuron. As a result, the Agency does have some moderate concerns regarding potential risks of linuron to surface water source supply systems.

Ecological Effects

Linuron is practically nontoxic to mammals on an acute basis, and practically nontoxic to honey bees. Linuron is slightly toxic to birds on an acute basis. Though studies are not available, US Fish and Wildlife Service extrapolation suggests that linuron would be slightly toxic to practically nontoxic to birds on a subacute dietary basis. However, linuron causes reproductive effects in birds.

In acute oral toxicity studies, linuron is moderately toxic to both cold and warm water fish. Acute testing using a formulated product indicates that linuron is slightly toxic to moderately toxic to fish. In a fish early life stage chronic study, linuron caused effects on fish length even at the lowest dose level, so additional testing is required.

Linuron is highly toxic to aquatic invertebrates, while the formulated product is moderately toxic to freshwater aquatic invertebrates. A life cycle chronic test produced inconsistent results so additional testing is required. In estuarine/marine acute toxicity studies, linuron is highly toxic to the sheepshead minnow and moderately toxic to the eastern oyster and mysid shrimp.

A number of additional studies are required.

Ecological Effects Risk Assessment

Linuron poses minimal risk to honeybees. However, chronic risk to birds is posed at all use sites. Restricted use levels of concern are exceeded for birds on short grass, and endangered species levels of concern are exceeded for all uses evaluated.

Regarding mammals, the smaller the animal, the greater the level of concern for acute effects from exposure to linuron. For example, levels of concern are exceeded for the least shrew but not for the rat. Chronic effects in wild mammals are likely.

Regarding aquatic risks, restricted use and endangered species levels of concern are exceeded for fish from exposure to linuron in rights of way (ROW), and for aquatic invertebrates at all use sites evaluated. Chronic effects cannot be fully assessed without further testing.

Although further data on the toxicity of linuron to nontarget plants is needed, a preliminary aquatic plant risk assessment indicates that high risk and endangered plant levels of concern are exceeded for aquatic plants. The risk to terrestrial plants cannot be assessed without further data.

Endangered species levels of concern are exceeded in some circumstances for acute and chronic effects to birds, wild mammals and aquatic organisms, and for acute effects to nontarget plants. When the

Endangered Species Protection Program goes into effect, limitations on the use of linuron will be required to protect endangered and threatened species.

Risk Mitigation

Since the current uses of linuron exceed ecological effects levels of concern in many circumstances, EPA is requiring the following risk mitigation measures proposed by the technical registrant, DuPont:

- Reduce application rates for use of linuron on soybeans, field corn, potatoes and asparagus.
- Limit the maximum number of applications to 1 per year (pre-emergent use only) for soybeans, field corn, and potatoes, and to 3 per year for asparagus.
- Prohibit aerial applications.
- Prohibit use on sand or loamy sand, and on soils of less than 1% organic matter.
- Voluntarily cancel the high application rate uses including hybrid poplar and non-cropland (rights-of-way) uses.
- Add a ground water advisory to all product labels.
- Add a surface water advisory to all product labels.

Since it meets the proposed triggers, EPA will consider linuron as a candidate for classification as a restricted use pesticide due to ground water concerns, once the ground water restricted use rule is finalized. Also, the potential for spray drift exists when linuron is applied by ground spray.

Once pertinent data are submitted and reviewed, EPA will decide whether spray drift labeling statements are required for linuron.

Additional Data Required

EPA is requiring the following generic studies for linuron to confirm its regulatory assessments and conclusions:

Starting Materials and Manufacturing Process;
Foliar Dislodgeable Residues (Carrots/Celery);
Soil Dislodgeable Residues (Carrots/Celery);
Dermal Exposure (Carrots/Celery);
Inhalation Exposure (Carrots/Celery);
Cropfield Trials - Asparagus, Corn Aspirated Fractions (Grain Dust), Sorghum Forage and Fodder and Wheat;
Cropfield Trials - Soybean Forage and Hay;
Acute Avian Dietary Toxicity with TGAI - Quail and Duck;
Acute Aquatic Invertebrate Toxicity;
Fish Early Life Stage - Both Rainbow Trout and Sheepshead Minnow;
Aquatic Invertebrate Life Cycle - Mysid Shrimp;
Leaching/Adsorption/Desorption;

Terrestrial Field Dissipation;
Cottonseed Processing Study - To support use on cotton;
Cropfield Trials - Sweet corn - To support use on sweet corn;
Acute Marine/Estuarine (TEP) - Sheepshead Minnow using DF
formulation for rights-of-way.

The following studies also are required, though they are not part of the target data base:

Seed Germination/Seedling Emergence - 10 Species;
Vegetative Vigor - 10 Species;
Aquatic Plant Growth - 4 Additional Species.

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

Worker Protection Standard

Entry Restrictions

WPS Uses - A 24-hour restricted entry interval (REI) is required for all uses within the scope of the Worker Protection Standard (WPS). The personal protective equipment (PPE) required for early entry must be the PPE required for handlers of linuron (see below). Labels of multiple active ingredient products that contain linuron must bear the more protective of either these entry restrictions or those on current labeling.

Non-WPS Uses - Labels of products with uses outside the scope of the WPS must bear the following statement:

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

Personal Protective Equipment Requirements

Products containing linuron may contain more stringent PPE, but in no case may require less stringent PPE than the following requirements. Producers must compare the PPE requirements in this section with those on current labeling and retain the more protective.

Handler PPE for Occupational Use Products - For all uses of linuron, both within and outside the scope of the WPS, the minimum or baseline PPE requirements for pesticide handlers (mixers and loaders) are:

- coveralls over long-sleeved shirt and long pants,
- chemical-resistant footwear,
- chemical-resistant gloves, and
- chemical-resistant apron.

Early Entry PPE - Since linuron is in Toxicity Category III for eye and skin irritation potential and acute dermal toxicity, the PPE required for early entry is coveralls, chemical-resistant gloves, shoes and socks.

Other Labeling Requirements

Environmental Hazard Section - The labels of all linuron end-use products must be revised to bear the following statements under this section:

Ground Water Advisory

"This chemical is known to leach through soil into ground water under certain conditions as a result of agricultural use. Use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground-water contamination."

Surface Water Advisory

"Linuron may contaminate surface water through spray drift or, under certain conditions, from surface runoff into adjacent surface water bodies (ponds, lakes, streams, etc.). For several weeks post-application, linuron has a high potential to runoff when applied to fields with any of the following conditions: sloping land draining into nearby surface waters; very poorly to somewhat poorly drained soils; areas with extremely shallow ground water; frequently flooded areas; fields with surface water canals or ditches; and highly erodible land cultivated with poor management practices."

For Terrestrial Uses Except Rights-of-Way

"This pesticide is toxic to fish and aquatic invertebrates. Do not apply to water or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Do not contaminate water when disposing of equipment wash water or rinsate."

For Rights-of-Way - If a registrant chooses to support the rights-of-way use, he must submit the data required in this RED document and his labels must bear the following statement:

"This pesticide is toxic to fish and aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters or rinsate."

If a registrant does not support the rights-of-way use, he must amend his labels to delete this use.

Directions for Use Section - The labels of all linuron end-use products must be revised to bear the following statements under this section:

Application Restrictions:

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

"Aerial application is prohibited."

"Use on sand or loamy sand is prohibited."

"Use on soils of <1% organic matter is prohibited."

Crop Uses Section - The labels of all linuron end-use products must be revised to bear the following application rates for the respective crops, under this section:

Application Rates:

For use on soybeans: A maximum application rate of 1.0 lb ai/A, with use limited to single application (pre-emergent use only) per year.

For use on corn, field: A maximum application rate of 0.75 lb ai/A, with use limited to single application (pre-emergent use only) per year.

For use on potatoes: A maximum application rate of 1.5 lbs ai/A, with use limited to single application (pre-emergent use only) per year.

For use on asparagus: A maximum application rate of 2.0 lbs ai/A per year, with use limited to 3 applications per year.

Do not exceed 2.0 lbs total per acre per year.

Regulatory Conclusion

Although levels of concern are exceeded for ecological effects and ground water quality, most uses of currently registered products containing linuron, amended to reflect the risk mitigation measures imposed in this RED, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, products containing linuron for all registered uses **except** use on cotton, non-cropland (rights-of-way), sweet corn, and potatoes are eligible for reregistration.

EPA is unable to make a reregistration eligibility decision for use of linuron on cotton, non-cropland (rights-of-way) and sweet corn because the Agency does not have key generic data to support these uses. The basic manufacturer, DuPont, has voluntarily cancelled or plans to cancel these uses, so end-use product registrants must either delete the uses from their labels or submit the required data.

EPA also is unable to make a reregistration eligibility decision regarding the use of linuron on potatoes because, under current policy, the food additive tolerances needed to support this use appear to be barred by the Delaney clause in the FFDCA.

Linuron products with eligible uses 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 linuron 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 linuron 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 linuron RED, or reregistration of individual products containing linuron, 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 6:00 pm Central Time, Monday through Friday.