

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

Chlorsulfuron

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. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet current human health and safety standards and can be used without posing unreasonable risks to human health and the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Document (RED) document. This fact sheet summarizes the information in the RED document for chlorsulfuron (Chemical Code 118601 and Case No. 0631).

Use Profile

Chlorsulfuron (2-chloro-N-[[[4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]benzenesulfonamide) is used as a pre- and post-emergent herbicide to control a variety of weeds on cereal grains, pasture and rangeland, industrial sites, and turf grass.

Based on available usage information for the years 1988 through 1999, the Agency estimates that chlorsulfuron usage averaged approximately 72,000 pounds of active ingredient per year to treat over 5.5 million acres. Its largest markets in terms of total pounds active ingredient are winter wheat (90%) and spring wheat (5%). The remaining usage is primarily on barley, oats, fallow fields and pasture/hay. Crops with a high percentage of the total U.S. planted acres treated include winter wheat (11%) and oats (2%), while registered sites with little or no usage include lawn and ornamental turf. Most chlorsulfuron usage is in California, Idaho, Kansas, Minnesota, North Dakota, Oklahoma, Oregon, South Dakota, Texas, and Washington. Data are not yet available for the new use on pastures and rangelands that EPA approved in 2002; however, chlorsulfuron is reportedly used

in these areas by the US Department of Interior (Bureau of Land Management) to control invasive weed species.

Regulatory History

Chlorsulfuron was first registered in the United States in 1982 by E.I. du Pont de Nemours and Company. It was formulated into products for use on food crops (wheat, barley, and forage grasses) and non-food crops (non-cropland grasses and tree plantings). Since 1988 additional products have been registered, mostly by DuPont. Nufarm Americas Inc. has one registered product containing chlorsulfuron (EPA Reg. # 228-375) and Lesco Inc has one registered product containing chlorsulfuron (EPA Reg. # 10404-59). In addition there are two products registered as Special Local Needs (SLN) registrations for use in Oklahoma and Texas to allow aerial application to wheat.

Chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This action established new tolerances for residues for chlorsulfuron in or on grass, forage and grass hay. This action also reassessed all other existing tolerances of chlorsulfuron as required by the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by FQPA. Therefore, this Reregistration Eligibility Decision document and supporting risk assessments address only the environmental and occupational risks from the use of chlorsulfuron. For information on dietary and residential risks, please refer to the earlier notice published in the *Federal Register*.

Human Health Assessment

Toxicity

As outlined in the 2002 *Federal Register* notice for chlorsulfuron, EPA has reviewed all toxicity studies submitted to the Agency and has determined that the toxicity database is sufficient to support this reregistration eligibility decision for all currently registered uses. For specific details on the toxicological endpoints to assess dietary and residential exposure, FQPA Safety Factor, dietary, residential and aggregate risk assessments and tolerance reassessments, please see the notice published in the *Federal Register* on August 14, 2002 (volume 67, number 157).

The occupational assessment for chlorsulfuron uses a NOAEL of 75 mg/kg/day from a rabbit developmental toxicity study as the endpoint for short-term dermal and inhalation exposure. Based on the use pattern and site information for chlorsulfuron, exposure on an intermediate- or long-term basis is not expected. Since no dermal or inhalation absorption data are available for chlorsulfuron, toxicity by the dermal and inhalation routes are considered to be equivalent to toxicity by the oral route of exposure (i.e., dermal absorption factor is assumed to be 100%).

Dietary and Residential Exposure and Risk

As mentioned earlier, chlorsulfuron dietary and residential aggregate risks were assessed in an Agency action published in the *Federal Register* on August 14, 2002 (volume 67, number 157). This assessment found that the risks from chlorsulfuron aggregate exposures (food + drinking water + residential) were not of concern. For all exposure scenarios, toddlers were the most highly exposed population subgroup. For both short-term and chronic exposure, aggregated risk from

food, water and residential exposures account for a small portion of the risk cup. The expected concentration of chlorsulfuron in drinking water was 41.3 ppb for surface water and 3.5 ppb for groundwater. The Agency would have become concerned only if the expected concentrations in drinking water were greater than 1,461 ppb for short-term exposure and 161 ppb for chronic exposure. Therefore, the risks from exposure to combined chlorsulfuron residues on food, in drinking water, and in a residential setting are not of concern. For more detailed information on dietary and residential risks, please refer to the earlier notice published in the *Federal Register*.

Occupational Exposure and Risk

Based on current use patterns, occupational handlers (mixers, loaders, and applicators) may be exposed to chlorsulfuron during and after normal use. The Agency identified 11 handler scenarios resulting from mixing/loading and applying chlorsulfuron for crop and non-crop uses. EPA is concerned about any MOE for chlorsulfuron that is less than 100, which incorporates uncertainty factors of 10x for interspecies extrapolation and 10x for intraspecies variation.

At the baseline level of protection (i.e., long-sleeved shirt and long pants, shoes, socks, no respiratory protection and no chemical-resistant gloves) all route-specific and combined MOEs are greater than the target MOE of 100 and therefore risks are not of concern (MOEs range between 1,000 and 56,000). Therefore, risks are below EPA's level of concern and no additional levels of protection were considered in the risk assessment.

FQPA Considerations

The Agency has concluded that the FQPA Safety Factor for chlorsulfuron can be reduced to 3X. The Agency believes that the additional 3X uncertainty factor (UF) is needed to address deficiencies in the toxicity database, including the lack of an adequate reproduction study. An UF of 3X (as opposed to a 10X) is adequate because the chronic RfD is based on the NOAEL of 5 mg/kg/day established in the Combined Chronic/Carcinogenicity Study in Rats. The 3X FQPA database uncertainty factor applies to all dietary and non-dietary residential exposure scenarios. No Special FQPA Safety Factor is required because the toxicology database for chlorsulfuron contains acceptable guideline developmental studies which show no quantitative or qualitative evidence of increased susceptibility following *in utero* exposure.

Tolerance Reassessment

The tolerances for chlorsulfuron meet the FQPA safety standards for the U.S. population and sensitive populations, including infants and children. EPA find that there is a reasonable certainty of no harm to the general population and any subgroup from the use of chlorsulfuron.

Environmental Assessment

Environmental Fate

Chlorsulfuron is likely to be persistent and highly mobile in the environment. It may be transported to nontarget areas by runoff and/or spray drift. Degradation by hydrolysis appears to be the most significant mechanism for degradation of chlorsulfuron, but is only significant in acidic environments (23 day half-life at pH = 5); it is stable to hydrolysis at neutral to high pH. Degradation half-lives in soil environments range from 14 to 320 days.

Ecological Toxicity

Chlorsulfuron is practically nontoxic to both freshwater and estuarine/marine fish on an acute exposure basis and is slightly toxic to estuarine/marine invertebrates. Aquatic plant toxicity ranged from practically nontoxic to very highly toxic. Chlorsulfuron is practically non-toxic to birds and mammals on an acute exposure basis and is also practically nontoxic to birds on a subacute dietary exposure basis. Following chronic exposure, bobwhite quail exhibited significant reductions in female body weight, 14-day old survivors/normal hatchlings, viable embryos/eggs set, and 14-day hatchling survival/eggs set. Chlorsulfuron is also practically nontoxic to honeybees on an acute contact basis.

Risks to Terrestrial and Aquatic Organisms

The Agency conducted a screening level ecological risk assessment to determine the potential impact of chlorsulfuron use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for chlorsulfuron.

Almost all ecological risk quotient (RQ) are below the LOC, with the exception of non-target plants. As mentioned earlier, screening-level risk quotients (RQs) for non-target and endangered/threatened aquatic plants range from 12 to 21 for non-target aquatic plants and from 18 to 31 for endangered aquatic plants. Likewise, RQs for terrestrial plants from the use on small grains range from 2 to 313 for non-target plants and from 16 to 1552 for endangered or threatened plants. Direct exposure scenarios were not calculated, but RQs for plants and endangered plants would be significantly higher than those estimated from exposure via spray drift and/or runoff. Because chlorsulfuron is an herbicide and may therefore harm non-target plants exposed via drift, the Agency requires that chlorsulfuron be applied in a manner that minimizes spray drift. Strict use restrictions to minimize spray drift will be placed on the labels for all chlorsulfuron products.

The Agency believes that specific drift language amendments proposed in this RED will substantially reduce, though may not completely eliminate, the risks to non-target plants. The Agency intends to conduct an additional assessment of chlorsulfuron, and may consider other similar herbicides, at a later date. Reviewing these pesticides as a possible group will allow the Agency to assess the risks from all of these pesticides simultaneously, rather than individually on a case-by-case basis. A cohesive, comprehensive decision to protect non-target plants (including endangered and threatened species) can then be implemented more consistently for

all pesticides in the group. The Agency intends to initiate this review after August 3, 2006.

Risk Mitigation

To lessen the risks posed by chlorsulfuron, EPA, the registrants and the user community have agreed on the following risk mitigation measures:

Ecological Risk

1. Measures to control spray drift are expected to reduce the risk of chlorsulfuron to non-target plants.
2. Allow only one application per growing season, except for industrial use sites, where total pounds applied per year may not exceed 0.125 lb ai/A
3. Restrict application to industrial use sites to ground application only, except for rights-of-way where application by helicopter is permitted
4. Limit application to fine turf and ornamentals to spot treatment only where the area being treated does not exceed 240 square yards per acre.

Additional Data Required

EPA is requiring several confirmatory data requirements for chlorsulfuron. For a complete listing of required studies with corresponding guideline number, see Section V of the chlorsulfuron RED document.

Ecological Data Requirements

The technical registrant has agreed to conduct a special study to evaluate the risk to non-target plants exposed to small droplets of chlorsulfuron. The Agency is concerned with the potential for adverse reproductive effects of chlorsulfuron on off-site non-target plant species. Such effects can have consequences to plant populations and community dynamics, as well as to higher trophic-level organisms. The Agency will work with the registrant to develop appropriate protocols with which this uncertainty can be minimized. EPA will evaluate risks to non-target plants, and any additional mitigation, after these studies are repeated and acceptable data have been submitted and reviewed.

Toxicity Data Requirements

The EPA is requiring that registrants submit toxicity data, including a 21-day dermal toxicity, 90-day inhalation toxicity study, and a two-generation reproduction study.

Product Labeling Changes Required

All chlorsulfuron end-use products must comply with EPA's current pesticide product labeling requirements and with the labeling changes set forth in Section V of the chlorsulfuron RED document.

Regulatory Conclusion

EPA has determined that all products containing chlorsulfuron as the active ingredient are eligible for reregistration, provided changes specified in the chlorsulfuron RED are incorporated into the label and additional data identified in Section V of the RED confirm this conclusion.

**For More
Information**

Electronic copies of the RED and this fact sheet are available on the Internet. See <http://www.epa.gov/pesticides/reregistration/status.htm> or <http://www.epa.gov/edockets>.

For more information about EPA's pesticide reregistration program, the chlorsulfuron RED, or reregistration of individual products containing chlorsulfuron, contact the Special Review and Reregistration Division (7508C), 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 Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 am Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is <http://npic.orst.edu>.