



Aliphatic Alcohols Facts

Pesticide Registration

All pesticides sold or distributed in the United States must be registered by the Environmental Protection Agency (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 pesticide products 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 the aliphatic alcohols of case 4004.

Regulatory History and Uses

Reregistration case number 4004 consists of straight chain aliphatic alcohols with 6 to 16 carbon atoms in the chain, which has been abbreviated in previous documents as aliphatic alcohols (Cx-Cxx) or (C6-C16). Currently, case 4004 consists of four active ingredients. Three of these active ingredients are used as plant growth regulators on tobacco. These are described as fatty alcohol blend (PC code 079029), 1-octanol (079037) and 1-decanol (079038). The fatty alcohol blend under PC code 079029 is predominantly a mixture of 1-octanol and 1-decanol, although some labels list 0.5% 1-hexanol (C6) and 1.5 % dodecanol (C12) among the active ingredients. The single product listed under PC code 079037, although listed as 1-octanol, is also in fact a mixture of 1-octanol and 1-decanol. The earliest registered label for use of aliphatic alcohols for tobacco sucker control included in the Agency's Pesticide Product Label System (PPLS) was issued to Uniroyal in 1964.

The fourth active ingredient in case 4004, 1-dodecanol (PC code 001509), was first registered for use as a Lepidopteran pheromone/sex attractant in 1993. The potential human health risks from 1-dodecanol were reassessed in 2002 by the Agency's Biopesticides and Pollution Prevention Division (BPPD), as described in the document, *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical Lepidopteran Pheromones. July 26, 2002*. The RED document describes the potential ecological effects of the use of 1-dodecanol.

Other aliphatic alcohols are not assessed in the RED. The fatty alcohol product included under PC code 079059 is not being supported, and will be voluntarily cancelled. In April 1995, the Agency completed a RED for case number 4003 (C1 - C5), which consists of aliphatic alcohols with only one to five carbons. The active ingredients addressed in that assessment included ethanol (PC code 001501) and isopropanol (PC code 047501).

Health Effects

The human health risk assessment incorporates potential exposure and risk from all sources, which for aliphatic alcohols are limited. The uses of the aliphatic alcohols of case 4004 do not involve use on food commodities.

The data base of submitted toxicity studies and published literature is sufficient to assess the uses of the aliphatic alcohols. Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, toxicity endpoints were not established, and a qualitative risk assessment was performed for the aliphatic alcohols.

The greatest potential for adverse effects from use of the aliphatic alcohols is the potential for severe and sometimes non-reversible eye irritation, which was observed in some eye-irritation studies. One of these primary eye irritation studies indicated that aliphatic alcohols are characterized as Toxicity Category I for eye irritation.

Risks and Risk Mitigation

Human Health

There are no human health risks of concern for aliphatic alcohols. However, the Agency is updating the Restricted Entry Interval (REI) and Personal Protective Equipment (PPE) requirements for aliphatic alcohols. 1-Decanol, which is a component of all the tobacco sucker control products in this case, is an acute Toxicity Category I eye irritant; therefore, pursuant to the Worker Protection Standard (WPS) and according to the OPPTS Label Review Manual 3rd Edition, products with agricultural uses must require a 48 hour REI and the following PPE for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear.

Ecological

The risk assessment identified no exposure scenarios with aliphatic alcohols that pose ecological risks of concern to the Agency. A number of guideline studies had not been submitted for the aliphatic alcohols, but sufficient information was available to allow the Agency to reach this conclusion. For instance, because environmental fate data are not available, physical and chemical properties for the aliphatic alcohols were estimated by Quantitative Structure-Activity Relationships (QSAR) using EPISuite v3.21 (Estimation Programs Interface for Windows (EPIWIN)). The main route of dissipation for the aliphatic alcohols was determined to be volatilization; half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. The volatility of the aliphatic alcohols was taken into consideration for estimates of potential ecological concentrations which were compared to endpoints from available ecotoxicity studies. Risk quotients calculated in this manner did not exceed the Agency's levels-of-concern for non-endangered or endangered and threatened (listed) species.

Some ecotoxicity data, such as chronic studies for estuarine fish and invertebrates, and chronic toxicity to birds, were neither submitted to the Agency nor available in the ECOTOX database. However, the volatility of the aliphatic alcohols makes it unlikely that they would be available for transport in runoff if a significant rain event did not occur within a few hours of application. The Agency does not expect a chronic risk to birds because 1) the aliphatic alcohols are not acutely toxic to birds at doses many times higher than expected exposure, 2) the volatility of the aliphatic alcohols makes chronic exposure unlikely, with estimated environmental concentrations dropping more than an order of magnitude within 30 minutes, 3) the aliphatic alcohols assessed are listed as food additives and are "Generally Recognized as Safe" (GRAS) by the U.S. Food and Drug Administration¹, and 4) a mammalian chronic toxicity study indicates the aliphatic alcohols are not chronically toxic to mammals. Based on these conclusions, the Agency will not require missing chronic toxicity data at this time.

However, because the toxicity data are not available, the Agency cannot completely preclude risk to listed birds and estuarine/marine animals at this time. Similarly, since a no-effect level was not determined for aquatic plants, the Agency cannot preclude direct effects on these organisms, although exposure is expected to be negligible.

Data Requirements

The generic data base supporting the reregistration of aliphatic alcohols has been reviewed and determined to be substantially complete. However, one data gap, the UV/VIS Absorption study (Guideline 830.7050), remains. This study will be included in the generic DCI for this RED, which the Agency intends to issue at a future date. In addition, updated Confidential Statements of Formula (CSFs) are required.

¹ <http://vm.cfsan.fda.gov/~dms/efus.html>

Regulatory Conclusion

The Agency has determined that products containing the aliphatic alcohols of case 4004 as active ingredients are eligible for reregistration provided that the risk mitigation measures are adopted and labels are amended to reflect these measures.

For More Information

Electronic copies of the Aliphatic Alcohols RED and all supporting documents are available in the public docket EPA-HQ-OPP-2007-0134 located on-line in the Federal Docket management System (FDMS) at <http://www.regulations.gov>.

For more information about EPA's pesticide reregistration program, the Aliphatic Alcohols RED, or reregistration of individual products containing aliphatic alcohols, please contact the Special Review and Reregistration Division (7508P), Office of Pesticide Programs, U.S. EPA, Washington, D.C. 20460, telephone 703-308-8000.

For information about the health affects 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 pm 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>.