United States Environmental Protection Agency | Office of Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-R-93-004 June 1993

R.E.D. FACTS

Biobor

Pesticide Reregistration

All pesticides sold or used 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 undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Document, or RED. This fact sheet summarizes the information in the RED for the active ingredients 2,2'-(1-methyltrimethylenedioxy)bis(4-methyl-1,3,2-dioxaborinane) and 2,2-oxybis(4,4,6-trimethyl-1,3,2-dioxaborinane), which comprise the reregistration case Biobor.

Use Profile

Biobor is a fungicide used in the fuel tanks and fuel lines of vehicles, farm equipment and industrial engines to prevent the growth of microbial organisms such as slime-forming bacteria and fungi, which could interfere with the unloading, use and quality of non-gasoline fuels. Biobor products are formulated as ready-to-use liquids.

Regulatory History

Biobor was initially registered as a pesticide in the United States in 1965. EPA required additional information regarding the health and environmental effects of Biobor during the Antimicrobial Data Call-In issued in 1987, and through a second data call-in 1992.

Currently, six end use products are registered which contain the active ingredients include in the Biobor reregistration case.

Human Health Assessment

Toxicity

Biobor is of relatively low acute toxicity by the oral, dermal and inhalation routes of exposure; it has been placed in Toxicity Categories III and IV (indicating the lowest degree of acute toxicity) for these effects. However, Biobor does produce severe irritation to the eyes, and is placed in Toxicity Category I (signaling a high degree of acute toxicity) for this effect.

Developmental toxicity studies using rats showed reduced fetal weights and reduced or incomplete ossification of parts of the skeleton. Studies in rabbits showed similar skeletal effects. However, Biobor showed no evidence of mutagenicity in a first-tier battery of studies.

Dietary Exposure

Boric acid esters, including Biobor, undergo rapid hydrolysis in the presence of water, forming boric acid or borate ion. These substances are essential to plant life, and small amounts are normally present in the human diet. Therefore, EPA does not anticipate that low levels of exposure to Biobor are associated with any significant degree of risk. Biobor is not registered for use on food, feed or processed commodities. Therefore, dietary exposure or risk is not expected.

Occupational and Residential Exposure

Minimal occupational exposure can be expected based on the currently registered uses of Biobor. A ready-to-use liquid which is added to fuel tanks, Biobor is available in one quart, five gallon, and 55 gallon sizes. Although there is the potential for minimal exposure while using the smaller sized containers of Biobor, use of a closed system metering pump is required by product labeling for delivery of the 55 gallon drum contents into large storage or fuel tanks.

Applicator Exposure

Biobor does not pose human dietary risks since no food-related uses are registered and dietary exposure is not anticipated.

A closed system must be used during application of large quantities of Biobor, and the chemicals generally are of low acute toxicity. Thus the risk to workers from exposure to Biobor is expected to be very low. Biobor can cause severe eye irritation. Therefore, to protect the eyes of mixers, loaders and applicators, product labeling will require the use of goggles and face shields. Animal studies using Biobor showed some developmental effects. However, there is little likelihood of a developmental toxicity risk to workers because Biobor's pattern of use results in minimal occupational exposure.

Environmental Assessment

Environmental Fate

Biobor is used inside fuel and oil storage tanks, and exposure to the environment should not result as long as Biobor products are used in accordance with approved label directions. EPA has required few environmental fate studies.

Ecological Effects

For the reasons discussed above, EPA is not requiring extensive ecotoxicity studies on Biobor products. The Agency is requiring acute toxicity studies on birds, fish and invertebrates, to characterize Biobor's acute toxicity to these species in case of accidents and to develop appropriate product labeling.

Ecological Effects Risk Assessment

EPA did not conduct a risk assessment for Biobor since it is registered only for use inside enclosed fuel containers. Exposure to the environment resulting from the use of this pesticide is expected to be negligible.

Additional Data Required

EPA is requiring product-specific data, including product chemistry and acute toxicity studies, as well as revised labelling for reregistration of pesticide products containing Biobor. Three confirmatory ecotoxicity studies also are required to develop appropriate environmental labeling precautions, for normal use situations and in case of accidents.

Product Labeling Changes Required

The labels of all registered pesticide products containing Biobor must comply with EPA's current pesticide labeling requirements. Additional labeling is also required to ensure the Federal Aviation Administration is consulted regarding the fuel additive use.

Technical Biobor is a severe eye irritant but because there are no EPA registered manufacturing-use products, changes to current labels do not apply. Changes to current product labeling may be made after the end-use product toxicology data have been submitted and reviewed.

Regulatory Conclusion

The use of currently registered pesticide products containing Biobor in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of products containing Biobor are eligible for reregistration.

These Biobor products will be reregistered once the required product-specific data and revised labeling are received and accepted by EPA. Products which contain other active ingredients in addition to Biobor will be eligible for reregistration only when all of their other active ingredients are also determined to be eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Document (RED) for Biobor 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 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), U.S. EPA, Washington, D.C. 20460, telephone (703) 305-5805.

Following the comment period, the Biobor RED 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 Biobor or about EPA's pesticide reregistration program, please contact the Special Review and Reregistration Division (7508W), OPP, U.S. EPA, Washington, D.C. 20460, telephone 703-308-8000. For information about reregistration of individual products containing Biobor, please contact Marshall Swindell, Product Manager, Registration Division (7505C), OPP, U.S. EPA, Washington, D.C. 20460, telephone (703) 308-6908.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide health 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.