

A developmental toxicity study in rats was conducted on ATONIK®. Administration was by gavage at dose levels of 0, 100, 300, and 600 mg/kg/day. Significantly decreased body weight gain and food consumption was observed at 600 mg/kg/day in the female rats. One death was noted and attributed to the test chemical. The maternal no observed effect level (NOEL) and LOEL were determined to be 300 and 600 mg/kg/day, respectively. No developmental toxicity was observed. The NOEL for developmental toxicity was determined to be 600 mg/kg/day.

The Ames Test, Mouse Micronucleus Assay and the Mouse Lymphoma Assay were each performed with each of the three active ingredients in ATONIK®. All results were negative.

The toxicity studies are sufficient to demonstrate that there are no foreseeable human or domestic animal health hazards possible from use of these active ingredients as plant regulators in the concentrations present in ATONIK®.

D. Aggregate Exposure

The end-use product, ATONIK®, contains the three active ingredients in very low concentrations. At the application rates employed, the level of active ingredient which may be present in any of the food or feed items would be far below the levels which demonstrated any effects in the subchronic oral feeding study, the developmental toxicity study or the mutagenicity studies. It can be shown that in order to reach a dose rate comparable to the LOEL of 1,600 mg/kg/day obtained in the subchronic oral feeding study, a person weighing 50 kg would have to consume all of the produce from 4 acres of crop every day.

Further, due to the rapid uptake and metabolism of the three active ingredients in the plants, it is most unlikely that any of the residue would be available for potential exposure.

Similarly, exposure of the residues to humans from consumption of water would be equally unlikely. There is no allowed use of the product containing the three active ingredients on lawns, rights-of-way, golf courses, or other areas where human exposure may result. Therefore, exposure from these areas would be non-existent.

E. Cumulative Exposure

Exposure through other pesticides and substances with the same mode of toxicity is not likely. What little toxicity that is observed is only observed at extremely high concentrations of these active ingredients.

F. Safety Determination

The three active ingredients in the end-use product, ATONIK®, are all biochemicals. The low toxicity of each of these alone and in combination, as discussed above, demonstrates that these chemicals, at the rates established, will not pose any known risk to human health, either as children or as adults. These three active ingredients are already exempted from the requirements of a tolerance for use on cotton, rice and soybeans.

G. Effects on the Immune and Endocrine Systems

The Agency has no information to suggest that ATONIK® will have an effect on the immune and endocrine systems. The Agency is not requiring information on the endocrine effects of this biological pesticide at this time. Congress has allowed 3 years after August 3, 1996, for the Agency to implement a screening program with respect to endocrine effects.

H. Existing Tolerances

Exemptions from the requirements of a tolerance have already been established for residues of the biochemical plant regulators Sodium o-Nitrophenolate, Sodium p-Nitrophenolate, and Sodium 5-Nitroguaiacolate in or on the raw agricultural commodities cottonseed, cotton gin by products, rice, rice straw, soybeans, and soybean forage and hay.

I. International Tolerances

No known international tolerances have been granted for this pesticide. Therefore, based on the completeness and reliability of the toxicity data from the published literature and conservative exposure assessment, Asahi Manufacturing Company, Ltd., concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues of the ATONIK® including all anticipated dietary exposure and all non-occupational exposures.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-50842; FRL-5798-4]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit to the following applicant. The permit is in accordance with, and subject to, the provisions of 40 CFR part 172, which defines EPA procedures with respect to the use of pesticides for experimental use purposes.

FOR FURTHER INFORMATION CONTACT: By mail: Sheila Moats, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 9th Floor, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 308-1259, e-mail: moats.sheila@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has issued the following experimental use permit:

70515-EUP-1. Issuance. J P BioRegulators, Inc., IR-4 Project Rutgers University, Cook College, P.O. Box 231, New Brunswick, NJ 08903-0231. This experimental use permit allows the use of 72 kilograms each year for the biochemical phospholipid: Lyso-PE (lysophosphatidylethanolamine) on 520 acres of apples, citrus, cranberries, grapes, peaches, pears, nectarines, strawberries, and tomatoes to evaluate pre-harvest and post-harvest ripening and storage shelf-life. The program is authorized only in the States of Arizona, California, Florida, Massachusetts, Michigan, Ohio, Washington, West Virginia, and Wisconsin. The program is effective from June 3, 1998 to June 1, 2001.

Persons wishing to review this experimental use permit are referred to the designated contact person. Inquires concerning this permit should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection,
Experimental use permits.

Dated: June 24, 1998.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

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