

3-[N-Butyl-N-acetyl]-aminopropionic acid, ethyl ester (113509) Technical Document

Issued: 2/99

1. Description of the Chemical(s)

Generic Name(s) of the active ingredient: IR3535

OPP Chemical Code: 113509

Year of Initial Registration: 1999

Trade name of end-use product: IR3535™ (Insect Repellent 3535)

Type of Pesticide: Repellent

Basic Producers:

EM Industries Inc.
Hawthorne, NY

Basic Producers:

U.S. Agent:
Anne Gochman (EM Industries/RONA Division)
7 Skyline Drive
Hawthorne, NY 10532

2. Use Sites, Target Pests, and Application Methods

- **Target Pests:** Mosquitoes, deer ticks, body lice and biting flies.
- **Registered Uses:** IR3535™ (Insect Repellent 3535) is a manufacturing use product designed for for production of end-use insect repellents against mosquitoes, deer ticks, body lice and biting flies.
- **Method and and Rates of Application:** The formulated product is to be applied on exposed skin.
- **Application Timing:** As needed.

3. Food Clearamces / Tolerances

A numeric tolerance or exemption from the requirement of a tolerance is not needed since there are no food uses associated with the registration. Nevertheless, safety factors from the Food Quality Protection Act of 1996 (FQPA) were considered.

4. Science Findings

A. Chemical Description

The active ingredient, IR3535 is a technical grade synthetic biochemical pesticide that is produced by an integrated process. It is a substituted B amino acid structurally similar to naturally occurring B-alanine. It is a liquid which contains 98% 3-[N-Butyl-N-acetyl]-aminopropionic acid, ethyl ester as active ingredient and 2.00% inert ingredients. The CAS number is 52304-36-6.

B. Biochemical Classification

In 1997, EPA-OPP's Biochemical Classification Committee classified IR3535 as a biochemical, based on facts that it is functionally identical to naturally occurring beta alanine in that both repel insects, the basic molecular structure is identical, the end groups are not likely to contribute to toxicity and it acts to control the target pest via a non-toxic mode of action.

C. Toxicology

Adequate mammalian toxicology data are available and support registration of the active ingredient 3-[N-Butyl-N-acetyl]-aminopropionic acid ethyl ester. The required acute mammalian toxicology studies have been submitted. The data indicate that the active ingredient has an acute oral LD₅₀ >5000 mg/kg in rats (Toxicity Category IV), an acute dermal LD₅₀ >3000 mg/kg in rats (Toxicity Category III), a dermal irritation study in rats (Toxicity Category IV), an acute inhalation LC50 > 5.1 mg/L, for a four hour exposure in rats (Toxicity Category IV}, and the primary eye irritation study in rabbits, (Toxicity Category II). It is not a sensitizer. The triggers for submitting additional toxicology studies were not met.

A 90-day feeding study was not required because the non-food uses do not require a tolerance or an exemption from the requirement of a tolerance and proposed uses are not likely to result in repeated human exposure by the oral route. The triggers for genotoxicity and immunotoxicity studies were not met and thus the studies are not required.

D. Food Quality Protection Act Requirements

Safety factors from FQPA were evaluated. Although the product is manufactured, it is the same as the naturally occurring substance. Given the low toxicity of IR3535 as indicated by toxicity data, a determination of reasonable certainty of no harm for the general population, as well as subgroups including infants and children, was made.

E. Human Health Effects

1. Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

There are no food uses associated with the proposed use of the active ingredient IR3535. Therefore, acute and chronic dietary risks should be minimal based on lack of exposure. Furthermore, lack of acute and subchronic mammalian toxicity add further weight to the lack of risk from exposure. FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and a completeness of the database, unless EPA determines that a different margin of exposure (safety) will be appropriate for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, the Agency believes there is reliable data to support the conclusion that IR3535 is practically non-toxic to mammals, including infants and children, and, thus, there are no threshold effects therefore, EPA has not used a margin of exposure (safety) approach to assess the safety of IR3535. As a result, the provision requiring an additional margin of safety does not apply.

2. Common Mode of Action

The mode of action is not toxic.

3. Risks Posed by Potential Residential, School or Day Care Exposure

The proposed use pattern is for end-use products formulated from this technical active ingredient is for application on exposed skin to repel mosquitoes, deer ticks, body lice and biting flies. Dermal exposure from residues could occur as a result of direct application on skin of children, but the health risk is expected to be minimal to nonexistent based on low toxicity, use of IR3535 in Europe for over 20 years as an insect repellent without significant adverse effects and appropriate label language.

4. Drinking Water Exposure and Risk Characterization

Exposure to IR3535 in drinking water is not expected.

5. Aggregate Exposure

Based on low toxicity, low application rate, and widespread use without report of adverse effects, the risks for aggregate exposure from multiple routes are considered negligible.

F. Occupational and Residential Exposure and Risk Characterization

Based on the application methods, the potential for dermal, eye, and inhalation exposure to IR3535 is minimal to nonexistent for applicators and handlers. Due to the of the lack of significant mammalian acute toxicity, data on worker exposure (i.e. occupational exposure data) to the active ingredient are not required at this time. However, due to the potential for eye irritation, risks from occupational exposure will be mitigated through appropriate label language.

G. Environmental Assessment

The environmental assessment data requirements were not triggered under current requirements 40 CFR Section 158.690(d)(2)(vii through xv).

H. Ecological Effects

The ecological effects data requirements were not triggered under current requirements because this is a repellent without direct application to the environment.

I. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered since the repellent is to be applied to exposed skin and thus poses no danger to the environment and ground water.

J. Ecological Risk Assessment

The non-target data requirements were not triggered since the mode of application precludes contact with non-target organisms.

K. Efficacy Data

IR3535 is registered as a manufacturing use product, therefore, efficacy data was not required. It will ultimately be used to formulate end use products. The products formulated from IR3535 for control of public health pests must be registered separately and will be subject to efficacy data requirements.

5. Summary of Required Data

All hypersensitivity incidents must be reported to the Agency when/if they occur.

6. Regulatory Actions

Unacceptable adverse effects from the use of IR3535 are not expected. Unconditional registration was issued.

7. Additional Contact Information

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