



PESTICIDE FACT SHEET

Name of Chemical:
Reason for Issuance:
Date issued:

Novaluron
Conditional Registration
September 24, 2001

DESCRIPTION OF CHEMICAL

Chemical Name: 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxy-ethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea

Trade Name: Rimon[®]

EPA Chemical Code: 124002

Chemical Class: Benzoylphenyl urea

CAS Number: 116714-46-6

Year of Initial
Registration: 2001

Pesticide Type: Insecticide

Pests Controlled: Whiteflies, thrips and leafminers

U.S. and Foreign
Producers: Makhteshim Agan of North America, Inc.
551 Fifth Avenue, Suite 1100
New York, NY 10176.

ACTIVE INGREDIENT AND FORMULATIONS

Novaluron is a new pesticide chemical belonging to the class of insecticides called insect growth regulators (IGR). IGRs slowly kill the insects over a period of few days by disrupting the normal growth and development of immature insects. Novaluron acts as an insecticide mainly by ingestion, but has some contact activity. IGR insecticides are comparatively safer to beneficial insects and environment and is compatible for use in an integrated pest management system.

Makhteshim-Agan of North America, Inc. is registering two Novaluron formulations: Rimon[®] Technical, a manufacturing use product (MP) and Rimon[®] 10 EC, an end-use product (EP) containing 98.5% and 10.0% active ingredient, respectively.

USE PATTERN

Rimon[®] Technical is sold for formulating other end-use-product formulations. Rimon[®] 10 EC is an emulsifiable concentrate recommended for the control of whiteflies, thrips, leafminers and armyworms on containerized ornamentals grown in greenhouses. The Rimon[®] 10 EC is mixed with water and applied as a foliage spray using conventional spray equipment. Depending upon the pest population pressure, 3 to 12 ozs. of product is mixed with 100 gallons of water and applied as a full coverage spray at the rate of 1 gallon per 200 sq. ft. of bench area, which is equivalent to 200 gal/acre. Two applications at the highest rate at 30 day intervals are allowed, which amounts to a maximum seasonal rate of 52 fl. ozs. of Rimon[®] 10 EC or 0.34 lb ai/acre/season. To prevent buildup of resistance, rotation with other insecticides having dissimilar mode of action is recommended between successive applications.

PHYSICAL/CHEMICAL PROPERTIES

Adequate product specific chemistry data have been submitted for the registration of Novaluron insecticide. The manufacturing process indicate that no toxicologically significant impurities, such as chlorinated dioxins, nitrosamines and hexachlorobenzenes are formed.

HUMAN HEALTH ASSESSMENT

Summary of Toxicology Findings

Novaluron has low to moderate acute toxicity (Toxicity Category IV for oral and inhalation and III for dermal route). It is not an eye and dermal irritant and is not a skin sensitizer.

In a subchronic rat oral study, mortality, clinical signs, body weights, food consumption and efficiency, ophthalmoscopic examinations, clinical chemistry, urinalysis and gross pathology were unaffected by the test substance. At 2000 ppm, cumulative body weight gains were observed and some histopathological changes in the spleens were noted; however, these effects were not statistically significant. Based on these histopathological parameters in the spleen, the no observed adverse effect level (NOAEL) was estimated to be 8.3 mg/kg/day while the lowest observed adverse effect level (LOAEL) was 818.5 mg/kg/day. For intermediate-term incidental exposure assessment, the end points of the subchronic oral toxicity study was used.

A 28-day rat dermal toxicity study was conducted to evaluate dermal exposure, the route most directly applicable to the indoor use on ornamentals grown in containers. No systemic effects were noted up to a dose limit of 1000 mg/kg/day and no maternal or developmental toxicity was noted.

Mutagenicity of Novaluron was tested for gene mutation, chromosomal aberration and DNA damage by *in-vitro* assays. Novaluron was not cytotoxic with or without S9 activation in *Salmonella typhimurium* and did not induce a genotoxic response in any strain. In a mammalian cell chromosome aberration assay, Novaluron produced no evidence of clastogenic activity in the lymphocytes, in the presence or absence of S9 activation. In an unscheduled DNA synthesis (UDS) assay, Novaluron produced sporadic increase in gross and net nuclear grain counts; but, was considered non-mutagenic as the sporadic increases in grain counts were not reproducible. In a differential killing assay using *Bacillus subtilis* strains M45 and H17, Novaluron was equivocal for bacterial DNA damage in the absence of S9 activation; but, was negative in the presence of S9 activation. Based on the available

studies, there is no concern for mutagenicity. Two additional studies are needed to confirm the negative findings observed in the five mutagenicity studies already evaluated by the Agency.

Novaluron has no anticipated dietary or residential exposures at this time; therefore, an aggregate risk assessment is not warranted. The requirement for a carcinogenicity study also is not applicable for the proposed use of Novaluron.

Occupational Exposure

The use directions are to apply Rimon[®] 10 EC mixed with water, as a foliage spray to containerized ornamentals grown in greenhouses using conventional high pressure hand sprayers. The application rate is to mix 12 ozs. of product in 100 gal of water and spray @ 200 gal/Acre, which is equivalent to 0.17 lb ai/Acre. The number of applications per season are 2 at a spray interval of 30 days. At this application rate, the maximum use rate is 0.34 lb ai/Acre/season. The registrant is proposing a re-entry interval (REI) of 12 hours, which is acceptable to the Agency at this time. No dermal toxicological end points were identified and no chemical specific data are available to assess potential post-application and re-entry exposures to pesticide handlers. Therefore, the occupational exposure for pesticide handlers was estimated based on short/intermediate term inhalation end points with a NOAEL of 8.3 mg/kg/day from a subchronic rat oral study. Using historical data from Pesticide Handler's Exposure Database, margins of exposure (MOEs) for occupational exposure were estimated to be >100, which do not exceed the Agency's level of concern.

Food Quality Protection Act (FQPA) considerations were not addressed this time since the current registration is for indoor non-food use only. The registered use pattern does not involve residential uses and establishing food tolerances.

ENVIRONMENTAL EXPOSURE

The current registration for Novaluron is for use on container grown ornamentals in greenhouses only. Therefore, Novaluron's mobility and persistence in soil and water and its eco-toxicity to terrestrial and aquatic life were not evaluated. Also Novaluron's properties to contaminate ground and surface waters are not applicable due to its indoor uses.

OUTSTANDING DATA REQUIREMENTS

The following additional data are needed to fully characterize the potential risks of long term use of Rimon[®] insecticide.

1. *90-Day Inhalation*: A rat inhalation toxicity study is required for characterization of risks due to the potential for inhalation exposure of Rimon[®] 10 EC when the label is expanded to include outdoor uses on ornamental plants and shade trees.
2. *Mutagenicity*: An *in-vitro* mammalian cell gene mutation and an *in-vivo* cytogenetics assay (i.e., micro nucleus assay) are the two additional studies needed to satisfy the current guideline requirements for mutagenicity.

PUBLIC INTEREST FINDING

Novaluron belong to a new class of pesticide chemicals called benzoylphenyl ureas. Some compounds of this group are broad spectrum insecticides with insect homonal mimicking mode of action. These IGRs affect chitin

synthesis of immature insects disrupting their normal growth and development. The Rimon[®]10 EC is being registered for the control of whiteflies, thrips, leafminers, and other foliar feeding insect pest of ornamental plants grown in greenhouses. Novaluron is expected to reduce the reliance on organophosphates, such as acephate, diazinon, chlorpyrifos, and dimethoate, carbamates, such as (carbaryl and bendiocarb and pyrethroids, such as bifenthrin and cyfluthrin. Novaluron has low mammalian acute toxicity and has low risk to environment and non-target organisms; thus becomes an important component in any integrated pest management system. Additional uses of Novaluron for the control of insect pests on food crops is being prepared for filing by the registrant.

GOVERNMENT PERFORMANCE AND RESULTS ACT (GPRA)

Registering Novaluron will meet the objectives of GPRA (Title 3.1.1) by assuring pesticides of newer chemistry that are safer to humans and environment.

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