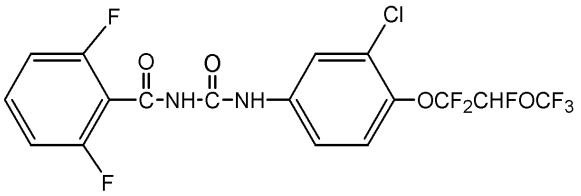
NOTICE

Novaluron

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has before it an application for approval of the new Technical Grade Active Constituent, novaluron. The active constituent is a new insecticide that is active against the orders *Coleoptera*, *Heteroptera* and *Lepidoptera*.

In accordance with section 12 of the Agvet Codes, the NRA invites any person to submit a relevant written submission as to whether the application for TGAC approval should be granted. Submissions should state the grounds on which they are based. Such grounds should relate only to the matters that the NRA is required to take into account in deciding whether to grant approval. Comments must be received by the NRA within 28 days of the date of this Gazette.

Particulars of the Active Constituent

Common name:	Novaluron (BSI, pa E-ISO approved)
IUPAC name:	(±)-1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxy-ethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea
CA name:	(±)-*N*-[[[3-chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)-ethoxy]phenyl]amino]-carbonyl]-2,6-difluorobenzamide
Synonyms and code number:	Rimon; MCW-275; GR 572 (FCF/T46)
CAS Number:	116714-46-6
Molecular formula:	$C_{17}H_9ClF_8N_2O_4$
Molecular weight:	492.77
Chemical structure:	
Chemical Family:	Benzoyl urea insect growth regulator
Mode of Action:	Inhibition of chitin synthesis, causing abnormal endocuticular deposition and abortive moulting.

Summary of the NRA's Evaluation of Novaluron TGAC

The Chemistry and Residues Evaluation Section of the NRA has evaluated the chemistry aspects of novaluron TGAC (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable.

On the basis of the data provided, it is proposed that the following Minimum Compositional Standard be established for novaluron TGAC:

Active constituent	**Minimum content**
Novaluron	Not less than 985 g/kg

Other compounds of toxicological significance are not expected to occur in novaluron TGAC as a result of the raw materials and the synthetic route used.

The Chemicals and Non-Prescription Medicines Branch of the Therapeutic Goods Administration has considered the toxicological aspects of novaluron TGAC, and advised that there are no toxicological objections to the approval of this chemical.

An ADI of 0.01 mg/kg is recommended based on a NOEL of 1.1 mg/kg bw/day in a 2-year rat study using a 100-fold safety factor.

An ARfD is not necessary for novaluron since the compound exhibits low toxicity in acute and short-term studies in animals.

The National Drugs and Poisons Schedule Committee (NDPSC) has recommended that novaluron be exempt from scheduling.

The NRA accepts the findings and recommendations of its advisers on these criteria.

The NRA is satisfied that the proposed importation and use of novaluron TGAC would not be an undue toxicological hazard to the safety of people exposed to it during its handling and use.

Written submissions on the NRA's proposal to grant approval for novaluron TGAC should be addressed in writing to:

Dr Paul Sethi
Chemistry and Residues Evaluation Section
National Registration Authority for Agricultural and Veterinary Chemicals
P.O. Box E240
KINGSTON ACT 2604

Phone: (02) 6272 3987
Fax: (02) 6272 3551