

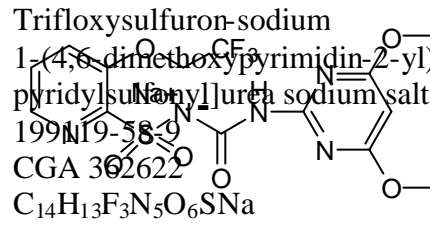
NOTICE

Trifloxysulfuron-Sodium

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has before it an application for approval of the new active constituent, trifloxysulfuron-sodium. The active constituent is a new sulfonylurea herbicide for the control of broadleaf weeds and nutgrass in cotton.

In accordance with section 12 of the Agvet Code, the NRA invites any person to submit a relevant written submission as to whether the application for trifloxysulfuron-sodium 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 the approval. Comments must be received by the NRA within 28 days of the date of this Gazette.

Particulars of Active Constituent

Common Name:	Trifloxysulfuron-sodium
IUPAC Name:	1-(4,6-dimethoxy-2-pyridylsulfonyl)urea sodium salt
CAS No:	19919-58-9
Manufacturers Code:	CGA 362622
Molecular formula:	$C_{14}H_{13}F_3N_5O_6SNa$
Molecular Wt.:	459.3
Chemical Structure:	

Chemical Family:	Sulfonylurea
Mode of Action:	Inhibition of acetolactate synthase, inhibiting the biosynthesis of the essential branched chain amino acids, valine and isoleucine, and stopping cell division and plant growth.

Summary of the NRA's evaluation of Trifloxysulfuron-sodium active constituent

The Chemistry and Residues Evaluation Section of the NRA has evaluated the chemistry aspects of trifloxysulfuron-sodium active constituent (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 trifloxysulfuron-sodium:

Active constituent	Minimum content
Trifloxysulfuron-sodium	Not less than 890 g/kg

Other compounds of toxicological significance are not expected to occur in trifloxysulfuron-sodium 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 trifloxysulfuron-sodium, and advised that there are no toxicological objections to the approval of this chemical.

An acceptable daily intake (ADI) of 0.2 mg/kg bw/day is recommended based on a no observable effect level (NOEL) of 15 mg/kg bw/day in a 12 month dog study using a 100-fold safety factor.

An acute reference dose of 6 mg/kg bw is recommended based on a NOEL of 600 mg/kg bw in an acute oral neurotoxicity study in rats, and using a 100 fold safety factor.

The National Drugs and Poisons Schedule Committee (NDPSC) has recommended that trifloxysulfuron-sodium be exempt from scheduling in the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

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

The NRA is satisfied that the proposed importation and use of trifloxysulfuron-sodium 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 trifloxysulfuron-sodium should be addressed in writing to:

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

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