

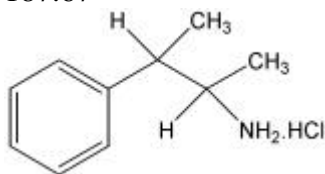
## NOTICE

### Phenylpropanolamine Hydrochloride

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) has before it an application for the approval of a new active constituent, phenylpropanolamine hydrochloride. Phenylpropanolamine hydrochloride is an indirect-acting sympathomimetic and a direct constrictor of sphincter smooth muscles.

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 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:	Phenylpropanolamine hydrochloride
IUPAC Name:	(1 <i>RS</i> ,2 <i>SR</i> )-2-amino-1-phenylpropanol hydrochloride
CAS Number:	154-41-6
Manufacturer's Code:	None
Minimum Purity:	980 g/kg
Molecular Formula:	C <sub>9</sub> H <sub>14</sub> ClNO
Molecular Weight:	187.67
Structure:	

Application:	Treatment of urinary incontinence associated with urethral sphincter incompetence in bitches
Mode of Action:	Indirect-acting sympathomimetic with an action similar to that of ephedrine but less active as a CNS stimulant. It has a direct action on sphincter smooth muscles

#### Summary of the NRA's Evaluation of Phenylpropanolamine Hydrochloride Active Constituent

The Chemistry and Residues Evaluation Section of the NRA has evaluated the chemistry aspects of phenylpropanolamine hydrochloride (manufacturing process, quality control procedures, batch analysis results and analytical methods) and found them to be acceptable. Phenylpropanolamine hydrochloride is a new active constituent and there are compendial specifications available (Ph. Eur.). On the basis of the data provided, it is proposed that the following Minimum Compositional Standard be established for Phenylpropanolamine hydrochloride:

<b>Active constituent</b>	<b>Minimum Requirement</b>
Phenylpropanolamine hydrochloride	Must comply with the Ph. Eur. monograph specifications for phenylpropanolamine hydrochloride

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

The Chemicals and Non-prescription Medicines Branch of the Therapeutics Goods Administration has considered the toxicological aspects of phenylpropanolamine hydrochloride, and advised that there are no toxicological objections to the approval of this chemical.

The National Drugs and Poisons Schedule Committee (NDPSC) has included phenylpropanolamine hydrochloride in Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) except in preparations containing 25 mg or less per recommended dose when labelled for relief of coughs and colds which are in Schedule 3.

As the chemical will not be used in food producing animals, an acceptable daily intake and acute reference dose are not required.

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

The NRA is satisfied that the proposed importation and use of phenylpropanolamine hydrochloride 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 phenylpropanolamine hydrochloride should be addressed in writing to:

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