

125601

SHAUGHNESSEY NO.

1

REVIEW

EEB BRANCH REVIEW

DATE: IN 11-10-82 OUT 2/15/83

FILE OR REG. NO. 10182-TT

PETITION OR EXP. PERMIT NO.

DATE OF SUBMISSION 10-28-82

DATE RECEIVED BY HED 11-5-82

WARD REQUESTED COMPLETION DATE 2-25-83

EEB ESTIMATED COMPLETION DATE 2-18-83

WARD ACTION CODE/TYPE OF REVIEW 115/New Chemical

TYPE PRODUCT(S): I, D, H, F, N, R, S Plant Growth Regulator

DATA ACCESSION NO(S). 248689

PRODUCT MANAGER NO. Taylor 25

PRODUCT NAME(S) PP 333 WP

COMPANY NAME ICI Americas Inc.

SUBMISSION PURPOSE Proposed Full Registration of Ornamentals Use

SHAUGHNESSEY NO.

CHEMICAL, & FORMULATION

%A.I.

125601

Paclobutrazol

55.2%

PP 333 (Paclobutrazol)

100 Pesticide Label Information

100.1 Pesticide Use

PP 333 is a plant growth regulator. The active ingredient is "paclobutrazol". This compound is intended for use on ornamental trees by injection.

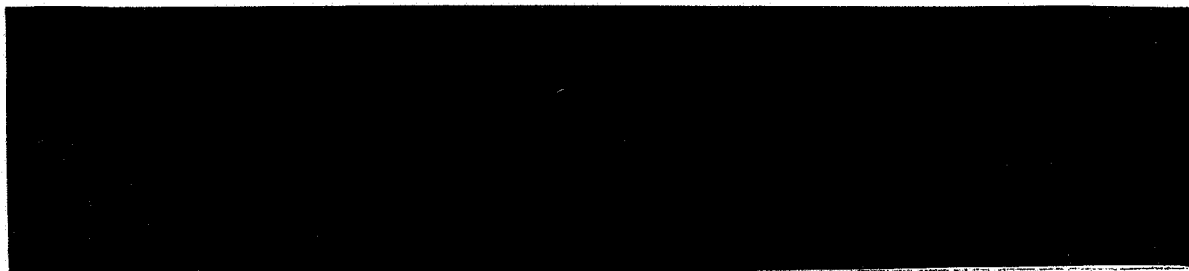
100.2 Formulation Information

(from "Confidential Statement of Formula" EPA form 8570-4)

Active Ingredient

Paclobutrazol technical (PP 333):
 (2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-
 2-1,2,4-triazol-1-yl) pentan-3-ol.....55.2%

Inert Ingredients



N.B.- % a.i. on proposed label is 50%. This does not agree with amount stated on the Confidential Statement of Formula, EPA form 8570-4.

100.3 Application Methods, Directions, Rates Timing

"PP 333 can be injected into trimmed or untrimmed trees at any time of the year. Best results are obtained when trees are trimmed prior to injection. Tree trimming after injection can reduce the effectiveness of the compound".

Application Rates

All injectable deciduous	6 oz* to 7.5 gallons
	of water or
or	
Broadleaf evergreen trees	4 level tablespoons
	per gallon

* 1 oz of PP 333 = 5 level tablespoons

Techniques

6 - 16" DBH** trees - require 3 injection holes equally spaced around trunk 24-36" above ground.

> 16" DBH - require 6 injection holes
(** DBH = diameter of tree at breast height)

Volume

Total injection volume (TIV) depends on DBH.
Calculate by the following formulae:

Tree DBH	# holes	Total Injection Volume (TIV)	Volume per hole
6-16" DBH	3	$TIV = (DBH)^2 \times 1.59$	$TIV/3$

> 16" DBH	6	$TIV = DBH \times 25.45$	$TIV/6$
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Equipment

Label recommends pressurized injection system developed by:
 U.S.D.A., Nursery Crop Research Laboratory, Delaware, Ohio
 (G.K. Brown, J. Arboculture 4:7-13).

Precaution

"Do not inject PP 333 into trees that do not appear healthy,
 into bearing fruit or nut trees or sugar maple trees tapped
 for sugar."

100.4 Target Organisms

All non-fruit-bearing and non-sugar-producing deciduous and broadleaf
 evergreen tree species (ornamentals).

100.5 Precautionary LabelingEnvironmental Hazards:

"Do not contaminate water by cleaning of equipment or
 disposal of wastes."

In case of significant spill, call CHEMTREC
 800-424-9300."

In addition the directions instruct:

"Precautions

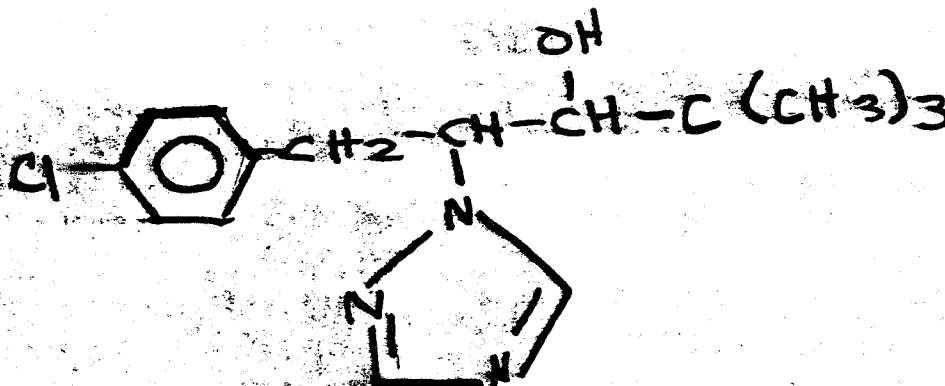
"Do not inject PP 333 into trees that do not appear healthy,
 into bearing fruit or nut trees or sugar maple trees tapped
 for sugar."

101 Physical and Chemical Properties101.1 Chemical Name

(+) = (R*, R*)- -[(4-chlorophenyl)methyl]- α -
 (1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol

(also as noted in Sec. 100.2 -

(2RS, 3RS)-1-(4-chlorophenyl)-4,4-dimethyl-
 (2-1,2,4-triazol-1-yl)-pentan-3-ol

101.2 Structural Formula101.3 Common Name

Paclobutrazol

101.4 Trade Name

PP 333

101.5 Molecular Weight

Not available for this review.

101.6 Physical State

off-white solid

101.7 Solubility

in water - 35 mg/l (unknown Temp.)

acetone - ? both used as solvents in

DMSO - ? acute tox. tests.

102 Behavior In the Environment

No data was supplied with this submission

103 Toxicological Properties103.1 References from Toxicology Branch

None were available for this review

103.2 Minimum Requirements

103.2.1 Avian Acute Oral LD50

<u>Species</u>	<u>LD50</u>	<u>Validation Category</u>	<u>Date Reviewed</u>
Mallard	>7913 mg/kg	Supplemental	1-14-83

103.2.2 Avian Dietary LC50

<u>Species</u>	<u>LC50</u>	<u>Validation Category</u>	<u>Date Reviewed</u>
Bobwhite quail	25,000 ppm	Core	1-18-83
Mallard	220,000 ppm	Core	1-17-83

103.2.3 Fish Acute LC50

<u>Species</u>	<u>LC50</u> (95% c.i.)	<u>Validation Category</u>	<u>Date Reviewed</u>
Bluegill	23.6 mg/l (20.4-26.0)	Core	1-20-83
Rainbow Trout	27.8 mg/l (26.1-30.0)	Core	1-19-83

103.2.4 Aquatic Invertebrates LC50

<u>Species</u>	<u>LC50</u>	<u>Validation Category</u>	<u>Date Reviewed</u>
<u>Daphnia magna</u>	33.2 mg/l (25.8-53.0)	Core	1-20-83

103.3 Additional Terrestrial Laboratory Tests

none submitted

103.4 Additional Aquatic Laboratory Tests103.4.6 Other

The submission on testing Daphnia magna with technical PP 333 also tested a 50% formulation, i.e., GFU-029. The 48-hr. EC₅₀ = 94 (65-135) mg/l, however only 16 mg ai/l was in solution during this test. These results were judged "core" for formulation testing, (see DER for details), but do not support registration of technical PP 333.

103.5 Field Studies

none submitted.

104 Hazard Assessment

104.1 Discussion

This is a "new" chemical, i.e., not previously registered for a pesticide. A "full" risk assessment is requested.

This use pattern is ornamental trees. The solutions of PP 333 will be injected directly into the trunks of trees and presumably be delivered to distal portions.

Paclobutrazol is "practically non-toxic" to birds in acute and subacute toxicology studies submitted with this request. It is considered "slightly toxic" to aquatic invertebrates and freshwater fish, again as evidenced by data submitted with this request for registration. (DER's appended to this review).

The maximum use rates are calculated approximately 133 ml per hole, as directed by proposed label. In a 6-16" DBH tree, this amounts to $3 \times 133 = 399$ ml; in a >16" DBH tree, this amounts to $6 \times 133 = 798$ ml per tree. Since this is a 55.2% A.I. product, the maximum amount of paclobutrazol (PP 333) is:

6-16" DBH = 220.24 ml/tree
>16" DBH = 440.49 ml/tree

Due to the injection technique as directed on the proposed label, no environmental residues, are expected for the surfaces of vegetation (foliar), soil or water. Small amounts of residues could be expected for leaves and berries of ornamental fruit trees. These are expected to be <5000 ppm, a level which should provide an adequate safety margin for birds, according to the acute toxicology data reviewed.

104.2 Likelihood of Exposure to non-target organisms

Due to the injection technique little or no exposure is expected for either aquatics or terrestrial species. Exposure for birds and mammals eating berries is expected at <5000 ppm. Therefore no unreasonable adverse effects are anticipated, however we have not been able to review mammalian toxicology and environmental fate data because these were not submitted. We would therefore not be able to comment on chronic hazards, e.g. those resulting from exposure to PP 333 via decomposed trees, nor for potential reproductive hazards.

104.3 Endangered Species Considerations

For the reasons given in the above sections, no acute hazard is expected for endangered vertebrates, if label directions are followed.

104.4 Adequacy of Toxicity Data

The fish and wildlife safety data submitted under Acc. No. 248689 are adequate to support registration of the technical chemical and of PP 333 (55.2% formulation) except:

— the mallard duck acute oral LD₅₀ (Ross, et al 1979) is inadequate to support registration because the age of birds was not reported (except as "young adults"). These birds received "chick" diet. We require a precise reporting of the bird's age, and an explanation of why "chick" diet was fed to "young adults".

104.5 Additional Data Required

For the acute mallard LD₅₀ study (Ross, et al, 1979 - under Acc. No. 248689), supply the precise age of the birds tested, and provide a explanation for the use of "chick" diet for "young adults".

105 Classification

106 RPAR Criteria

none performed

107 Conclusions

107.1 Environmental Fate and Toxicology Acknowledgement

This review was performed without the knowledge of Environmental Fate nor Toxicology Branch opinion (no reviews were available from these Branchs.

107.2 Classification Labeling

no judgement is made

107.3 Environmental Hazard Labeling

The proposed label statements are deemed adequate.

107.4 Data Adequacy Conclusions

The proposed registrations of technical PP 333 and the 55.2% formulated product are supported adequately by fish and wildlife submissions except for the mallard acute LD₅₀ (Ross, et al, 1979) which is inadequate to support a full registration at this time.

107.5 Data Requests

With regard to the mallard acute LD₅₀ study - Acc. No. 248689 (Ross, et al, 1979) - the Registrant should report the precise age of the birds tested and explain use of "chick" diet on "young adult" birds.

107.7 Recommendations

EEB has completed a full risk assessment (3(c)(5) finding) of the proposed registration of paclobutrazol for use on ornamental trees. Based upon the available data and use information EEB concludes that the proposed use provides for minimal hazards to nontarget organisms.

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