



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

JUL 29 1992

MEMORANDUM

SUBJECT: Phase IV Review of Proxel

FROM: Doug Urban, Acting Chief
Ecological Effects Branch
Environmental Fate and Effects Division *Doug Urban 7/29/92*

TO: Tom Myers
Product Manager, PM-52
Special Review and Reregistration Division (H7508W)

EEB has reviewed the Phase IV data requirements for Proxel. The chemical name is 1,2-Benzisothiazolin-3-One. PC Code No.098901.

This action is under DP Barcode D178125 and D176405.

EEB is currently reviewing the following submissions:

71-2(a) Acute Avian Diet, Quail (MRID No. 41732001)
72-1(c) Acute Toxicity Fish - Trout (MRID No. 41687101)

The following submissions have been reviewed and the results are as follows:

•Thompson, R.S. and D.V. Smyth. 1977. Determination of the Acute Toxicity of Proxel Press Paste (Active Ingredient 1,2-Benzisothiazolin-3-one) to *Daphnia magna*. Report No. BL/B/1779. Prepared by Imperial Chemical Industries Limited, Brixham Laboratory, Brixham, Devon, UK. Submitted by ICI Americas Inc., Wilmington, DE. EPA MRID No. 00133867.



Recycled/Recyclable
Printed on paper that contains
at least 75% recycled fiber

This test is not scientifically sound. There were several significant differences in its design compared to the design recommended by the SEP, and the results are not comparable to tests meeting present-day standards. The test was performed in total darkness when there should be 16-hr photoperiod, the test vessels were glass test tubes containing 10 ml of test solution and 5 daphnids. The loading was therefore 1 daphnid/2 ml. The recommended test containers are 250-ml glass beakers containing 200 ml of solution and 10 daphnids giving a loading of 1 daphnid/20 ml, and there was no control formulated product control with carrier and/or inert ingredients.

•Roberts, N.L, C.N.K. Phillips, C.B. Howlett, A. Anderson, and I.S. Dawe. 1988. The Acute Oral Toxicity of Proxel Press Paste to the Bobwhite Quail. Study performed by Huntingdon Research Centre Ltd., Cambridgeshire, England. Laboratory Study No. ISN 164/88278. Submitted by ICI Americas, Wilmington, Delaware. MRID No. 409913-01.

This study is scientifically sound and fulfills the requirements for an avian oral LD₅₀ test for a formulated product containing 73.4% active ingredient. The acute oral LD₅₀ of Proxel was estimated to be 617 mg/kg (based on nominal concentrations) with 95% confidence limits of 464 and 816 mg/kg. The no-observed effect level was not determined, due to toxic effects at all dosage levels. With an LD₅₀ of 617 mg/kg, the test material is considered slightly toxic to bobwhite quail.

Based on use patterns (Luis Report) of aquatic non-food industrial (pulp paper mills) and indoor non-food (metalworking fluids, industrial adhesives and coatings, emulsions, oil recovery drilling muds/packer fluids, paints), **additional data** are required from EEB.

Provided that the studies that are in review are acceptable, the only data that are required and outstanding are:

- 72-2 Toxicity to Aquatic Invertebrates
- 72-3 Acute Toxicity to Shrimp
- 72-3 Acute Toxicity to Mollusks
- 72-3 Acute Toxicity to Estuarine fish

Phase IV Data Requirements for EEB are attached. If you have any questions, please do not hesitate to contact Mike Davy at 305-7081.

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Date: 7/20/92
Case No: 3026
Chemical No: 098901

Data Requirements	Composition ¹	Use Pattern ²	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail/Duck	(TGAII)	F,M	Yes	40991301	No
71-1(b) Acute Avian Oral, Quail/Duck	(TEP)	F,M	No		No
71-2(a) Acute Avian Diet, Quail	(TEP)	F,M	No	41732001 (in review)	No
71-2(b) Acute Avian Diet, Duck	(TEP)	F,M	No		No ³
71-3 Wild Mammal Toxicity		F,M	No		No
71-4(a) Avian Reproduction Quail		F,M	No		No ⁴
71-4(b) Avian Reproduction Duck		F,M	No		No ⁴
71-5(a) Simulated Terrestrial Field Study		F,M	No		No
71-5(b) Actual Terrestrial Field Study		F,M	No		No
72-1(a) Acute Fish Toxicity Bluegill	(TGAII)	F,M	No		No ⁵
72-1(b) Acute Fish Toxicity Bluegill	(TEP)	F,M	No		No
72-1(c) Acute Fish Toxicity Rainbow Trout	(TGAII)	F,M	No	41687101 (in review)	No ⁵
72-1(d) Acute Fish Toxicity Rainbow Trout	(TEP)	F,M	No		No
72-2(a) Acute Aquatic Invertebrate Toxicity	(TGAII)	F,M	No		Yes ⁶
72-2(b) Acute Aquatic Invertebrate Toxicity	(TEP)	F,M	No		No
72-3(a) Acute Estu./Mari Tox Fish	(TGAII)	F,M	No		Yes ⁷
72-3(b) Acute Estu./Mari Tox Mollusk	(TGAII)	F,M	No		Yes ⁷
72-3(c) Acute Estu./Mari Tox Shrimp	(TGAII)	F,M	No		Yes ⁷

* In Bibliographic Citation column, "Yes" indicates study may be upgradeable

Date: 7/20/92
Case No: 3026
Chemical No: 098901

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition ¹	Use Pattern ²	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA 3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	(TEP)	F,M	No		No
72-3(e) Acute Estu/Mari Tox Mollusk	(TEP)	F,M	No		No
72-3(f) Acute Estu/Mari Tox Shrimp	(TEP)	F,M	No		No
72-4(a) Early Life-Stage Fish		F,M	No		No
72-4(b) Live-Cycle Aquatic Invertebrate	(TEP)	F,M	No		No
72-5 Life-Cycle Fish	(TEP)	F,M	No		No
72-6 Aquatic Org. Accumulation		F,M	No		No
72-7(a) Simulated Aquatic Field Study		F,M	No		No
72-7(b) Actual Aquatic Field Study		F,M	No		No
122-1(a) Seed Germ./Seedling Emerg.		F,M	No		No
122-1(b) Vegetative Vigor		F,M	No		No
122-2 Aquatic Plant Growth		F,M	No		No
123-1(a) Seed Germ./Seedling Emerg.		F,M	No		No
123-1(b) Vegetative Vigor		F,M	No		No
123-2 Aquatic Plant Growth		F,M	No		No
124-1 Terrestrial Field Study		F,M	No		No
124-2 Aquatic Field Study		F,M	No		No ⁸
141-1 Honey Bee Acute Contact		F,M	No		No
141-2 Honey Bee Residue on Foliage		F,M	No		No
141-5 Field Test for Pollinators		F,M	No		No

* In Bibliographic Citation column indicates study may be upgradeable

1. Composition:

TGA = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product

2. Use Patterns:

A = Terrestrial Food Crop; B = Terrestrial Feed Crop; C = Terrestrial Non-Food Crop; D = Aquatic Food Crop; E = Aquatic Non-Food Outdoor; F = Aquatic Non-Food Industrial; G = Aquatic Non-Food Residential; H = Greenhouse Food Crop; I = Greenhouse Non-Food Crop; J = Forestry; K = Outdoor Residential; L = Indoor Food; M = Indoor Non-Food; N = Indoor Medical; O = Indoor Residential; Z = Use Group for Site 00000

3. Recent EEB policy requires only one avian dietary study with Bobwhite Quail (preferred) or Mallard Duck for indoor food/non-food or aquatic nonfood industrial uses.
4. Based on use pattern, chronic exposure to birds is not anticipated.
5. Recent EEB policy requires only one fish acute toxicity study with Rainbow Trout (preferred) or Bluegill Sunfish for indoor non-food or aquatic nonfood industrial uses.
6. TRID No. 4588-010-23 (MRID No. 00133867) was reviewed and found to be invalid. Another study must be done.
7. Study is required due to chemical use of oil drilling muds/packer fluids. ACC. No. 245840 for estuarine fish and shrimp is invalid due to aeration.
8. Bees are not expected to be exposed to this chemical.