

US EPA ARCHIVE DOCUMENT



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

November 30, 1999

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 2693-RII  
DP Barcode: D258582  
Case No: 062406

To: Marshall Swindell, PM 33 / Karen Leavy-Munk  
Regulatory Management Branch  
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510C)

*Ian Blackwell*

Through: Karen Hicks, Team Leader  
Chemistry and Toxicology Team  
Product Science Branch  
Antimicrobials Division (7510C)

*Karen P. Hicks*  
*12/2/99*

Michele E. Wingfield, Chief  
Product Science Branch  
Antimicrobials Division (7510C)

Applicant: Courtalds Coatings, Inc.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Cuprous Oxide	42.69
Zinc 2-Pyridinethiol 1-Oxide	3.18
<u>Other Ingredient(s):</u>	<u>54.13</u>
Total:	100.00%



(The acute toxicity reviewers of) OPP/EPA have not yet agreed to accept the Low-Volume Eye Test. The use of this study may be approved in the near future. However, at this point in time, this study is not acceptable. It is not known when EPA/OPP will decide upon the acceptance of the LVET method.

However, the registrant lists the toxicity category of the primary eye irritation study as I on page 16 of the report, MRID Number 488771-01. This implies that the registrant is willing to accept toxicity category I for the primary eye irritation study for this product. As such, EET/PSB will waive the requirement for the primary eye irritation study based on the toxicity category I of the primary skin irritation study. If the registrant wants to have the primary eye irritation study placed into another category, they will have to submit sufficient data to support that contention.

The acute toxicity profile for File Symbol 2693-R11 is currently:

acute oral toxicity	III	cited
acute dermal toxicity	III	cited
acute inhalation toxicity	IV	cited
primary eye irritation	I	waived
primary skin irritation	I	cited
dermal sensitization	Nonsensitizer	cited

LABELING:

ID #: 002693-00188 Intersmooth 365 Ecoloflex SPC Antifouling BEA 363

**RESTRICTED USE CLASSIFICATION RECOMMENDED:**

Due to eye irritation, dermal irritation toxicity categories.

The PM Team should decide if restricted use classification is necessary or if alternative labeling will allay the requirement for restricted use classification.

**SIGNAL WORD: DANGER**

**PRECAUTIONARY STATEMENTS:**

Corrosive. Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles or face shield. Wear protective clothing and rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN:

Note to PM/CRM/Registrant: The proposed label should contain a "Note to Physician." The following statements are suggested types of information that may be included, if applicable:

- technical information on symptomatology;
- use of supportive treatments to maintain life functions;
- medicine that will counteract the specific physiological effects of the pesticide;
- company telephone number to specific medical personnel who can provide specialized medical advice.

The following "Note to Physician" statement is required for the subject product:

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

**DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)**

**Product Manager:** 33  
**MRID No.:** 448771-02

**Reviewer:** Ian Blackwell  
**Study Completion Date:** 7/16/98  
**Report No.:** MB 98-6636.04

**Testing Laboratory:** MB Research Laboratories, Inc.  
**Author(s):** Daniel R. Cerven, M.S. (Study Director)

**Quality Assurance (40 CFR §160.12):** Included

**Test Material:** Intersmooth 460 Ecoflex, Lot #G580; "brown liquid"

**Dosage:** 10 microliters (0.010 mL)

**Species:** New Zealand White rabbit

**Sex:** 4 males + 2 females

**Weight:** 2.2-3.0 kg

**Age:** young adult

**Source:** Ace Animals, Inc.

**Summary:**

1. **Toxicity Category:**
2. **Classification:** supplementary

**Procedure (Deviations From §81-4):**

☞ The test material was dosed at 10 microliters directly onto the cornea.

**Results:**

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	1/6	3/6	3/6	3/6	---	1/6	0/6	0/6
Iritis	3/6	4/6	4/6	1/6	---	0/6	0/6	0/6
<b>Conjunctivae</b>								
Redness	4/6	4/6	4/6	3/6	---	1/6	0/6	0/6
Chemosis	4/6	4/6	4/6	3/6	---	0/6	0/6	0/6
Discharge	6/6	4/6	4/6	4/6	---	2/6	1/6	1/6

--- = no observations at this point

Red discharge noted in 6/6 one hour after dosing.

Pannus noted in 2/6 on day 7.

White discharge noted in 4/6.  
Circumorbital alopecia in 1/6 on day 14.  
This product is possibly corrosive.

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