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

DEC 1 1999

12/1/1999

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Review of the Leach Rate of Zinc *Omadine*[®] from *Ecoloflex*[®] Paint,
Reference Code BEA468/G580, in Synthetic Seawater (3.80 %)

TO: Marshall Swindell, Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

FROM: Chris Jiang, Chemist
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

CJ 11/19/99

THRU: Allen Vaughan, Team Leader, Team-3
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

Allen W. Vaughan

and

Norm Cook, Branch Chief
Risk Assessment and Science Support Branch
Antimicrobials Division (7510C)

Norm Cook
12-01-99

REGISTRANT: International Paint, Inc.

Chemical Name: Zinc 2-pyridinethiol-1-oxide (3.80 %)

DP Barcode: D258584

PC Code: 088002

Case 062406/Registration

Submission: S566622

EPA Reg. No.: 2693-R11

MRID #: 44877105

DATA EVALUATION RECORD

1. Chemical

a. Chemical name: Zinc 2-pyridinethiol-1-oxide

Commercial name: Intersmooth® 365 Ecoloflex SPC Antifouling Paint

DP Barcode: D258584

CAS #: 13463-41-7

Submission #: S566622

Case Type: Reg. 2693-RII

Chemical code: 088002

2. TEST MATERIAL: INTERSMOOTH® 365 ECOLOFLEX SPC ANTIFOULING PAINT
(3.80 %)

3. STUDY/ACTION TYPE:

Review leach Rate data submitted in support of registration

4. STUDY IDENTIFICATION:

James C. Ritter: "Leach Rate of Zinc *Omadine*® from *Ecoloflex*® BEA468/G580 Paint in Synthetic Seawater."

Performed by: Arch Chemicals, Inc.

Study completed: March 3, 1999

Study submitted: July 7, 1999

MRID #: 448771-05

5. CONCLUSIONS AND RECOMMENDATIONS:

The study author states that the study was conducted in compliance with GLP as set forth in CFR 40, part 160.

The study finds that the average leach rate for 3.80% Intersmooth® 365 Ecoloflex SPC Antifouling Paint (dark brown) is 8.4 µg/cm²/day for day 1, 6.5 µg/cm²/day for day 21, and 3.9 µg/cm²/day for day 49. The average release rate was found to be 5.4 µg/cm²/day from day 21 through day 49. The cumulative release rate for the same active between day 21 through day 49 was 65.3 µg/cm².

The leach rate data for Intersmooth® 365 Ecoloflex SPC are found to be unacceptable because the concentration of the active ingredient on the label (3.18 %) is inconsistent with the concentration of the test material used in the study (3.80 %). The study is scientifically sound; however, the registrant needs to resolve this inconsistency. A leaching study should be conducted on the formulation that has an active concentration of 3.18% of zinc omadine and submitted to the Agency for review. Because the test material in the study is an alternate formulation, the study can have fewer data points than the test material for the basic formulation.

6. BACKGROUND:

a. Basis of Study:

The release rate data for the antifouling paint containing zinc omadine reviewed in this submission was determined using a method that is based on the ASTM Standard Test Method for Organotin Release Rates for Antifouling Coating Systems in Sea Water (called ASTM Standard Test Method D 5108-90: Organotin Release Rates for Antifoulant Coating Systems in Sea Water).

The study was carried out in 25 liters of synthetic sea water which was prepared using ASTM D1141-90 (Standard Specifications for Substitute Ocean Water) and was stored in a rectangular glass aquarium at 23 ± 2 °C. The water was continually pumped through cartridges containing approximately 10 ounces (283.5 grams) of granular activated carbon and 500 grams of Bio-Rad Chelex 20 ion-exchange resin to make sure that the copper concentration in the holding tank never exceeded 200 ppb.

b. Materials and Methods:

Polycarbonated cylinders with a diameter of 2.5" (approximately 6.4 cm) were sanded with 400-grit wet/dry sandpaper before being coated on a 200 cm² area with the test substance in triplicate. Before the initiation of the study, the cylinders were aged for seven days.

c. Leaching Studies:

The test cylinders were suspended and situated in a holding tank in such a way that the painted surface was totally immersed in seawater where the pH by adjustment with dilute NaOH or HCl (7.9 to 8.1), salinity (30 to 35 parts per thousand), and temperature (23 ± 2 °C) were maintained. The water was circulated through the carbon and ion exchange cartridges at a rate of two to eight turnovers per hour. The test cylinders were removed from the holding tank for sampling on a semiweekly basis for a period of 49 days. The cylinders were rotated at 60 ± 5 rpm for an hour and exposed to 1.5 liters of synthetic seawater. After that time, aliquots of seawater were collected and analyzed by atomic absorption spectroscopy (AAS), using a Perkin-Elmer 5100PC AAS, to make sure that the concentration of zinc omadine was below the seawater solubility of 6 ppm and that of copper was below 200 ppb. These aliquots of seawater were also analyzed by HPLC using a Hewlett Packard 1050 and 1090 system.

d. Running conditions for the HPLC chromatograph:

Because zinc omadine dissociates slightly in solution, it cannot be analyzed in seawater directly by HPLC without prior derivatization. Therefore, the samples of seawater were treated with EDTA and 7-fluoro-4-nitrobenzo-2-oxa-1,3-diazole (NBD-F), which reacts with the thiol group on the omadine portion of the molecule, and analyzed under the following conditions:

Column: Partisil CCS/C8 (2 x 250 mm)

Mobile Phase: water/acetonitrile

Detection Wavelength: 234 nm (263 nm on day 1 and day 3)

Injection Volume: 200 μ L

Gradient:	Time (minutes)	Flow Rate (mL/min)	% Acetonitrile
	0	0.2	30
	10	0.2	30
	13	0.2	100
	18	0.2	100
	19	0.2	30
	19.1	0.3	30
	37	0.3	30
	37.1	0.2	30
	40	0.2	30

For the analysis of zinc omadine in the paint, the zinc omadine was extracted by DMSO/acetone. Then the extract was derivatized with 5 mL of 7-chloro-4-nitrobenzo-2-oxa-1,3-diazole (NBD-Cl) reagent (2% NBD-Cl in acetonitrile/water, 35/65) and 2 mL of disodium EDTA reagent (1.6% solution in water). NBD-Cl is a weaker reagent than NBD-F, as the complete derivatization of zinc omadine is not necessary for the paint. After a reaction time of 30 minutes, the derivatized samples were filtered through a 0.45- μ m Autovial[®] nylon filters (Whatman, Inc.) and analyzed under the following conditions:

Column: Partisil 5C8 (4.6 x 250 mm)

Guard Column: Brownlee C8 (4.6 x 30 mm OS-GU)

Detection Wavelength: 263 nm

Injection Volume: 20 μ L

Flow Rate: 1.0 mL/min

Mobile Phase A: Water

Mobile Phase B: Acetonitrile

Gradient Conditions: 10 min at 30% B, to 100% B at 13 min, hold 5 min

Confidential appendix

DER Summary

Leach rate data

Plots of leach rate data

Salinity, pH, and Temperature

Concentration of zinc omadine and copper

Calculations

Chromatograms

Summary of leaching data for alternate formulations

cc: Chemfile: (088002)

Reviewed by: Chris Jiang Team: Three, Date 11/2/99

Secondary Reviewer: Najm Shamim Team: Two, Date 11/12/99

Branch: RASSB Team Leader: Allen Vaughan

DATA EVALUATION RECORD

STUDY TYPE: Leaching

DP BARCODE: D258584

PC CODE: 088002

SUBMISSION CODE: S566622

CASE TYPE:/EPA File No: 2693-RII

TEST MATERIAL: Zinc 2-pyridinethiol-1-oxide (3.80 %)

SYNONYMS: Bis(2-pyridylthio-1-oxide)zinc, Zinc pyriithione,
Zinc pyridinethione, Zinc omadine

SPONSOR: (Lab.) Arch Chemicals, Inc. (Arch Chemicals, Inc.)

MRID#: 44877105

EPA Reg NO. 2693-188 DER# 44877105

Page _____ is not included in this copy.

Pages 7 through 19 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
 - A draft product label.
 - The product confidential statement of formula.
 - Information about a pending registration action.
 - FIFRA registration data.
 - The document is a duplicate of page(s) _____.
 - The document is not responsive to the request.
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Summary of leaching data for alternate formulations from day 21 to day 49

Color	Average leach rate	Cumulative release rate
Dark Brown	7.2 $\mu\text{g}/\text{cm}^2/\text{day}$	82.8 $\mu\text{g}/\text{cm}^2$
Dark Red	6.5 $\mu\text{g}/\text{cm}^2/\text{day}$	79.4 $\mu\text{g}/\text{cm}^2$
Dark Red	4.3 $\mu\text{g}/\text{cm}^2/\text{day}$	53.6 $\mu\text{g}/\text{cm}^2$

DP BARCODE: D258584

CASE: 062406
SUBMISSION: S566622

DATA PACKAGE RECORD
BEAN SHEET

DATE: 12/01/99
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 176 RESB NW PRO-OC-NW N-F/F
CHEMICALS: 025601 Copper(I) oxide 42.6900%

ID#: 002693-RII Intersmooth 365 Ecoloflex SPC Antifouling BEA 363
COMPANY: 002693 INTERNATIONAL PAINT, INC.
PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B
PM TEAM REVIEWER: KAREN LEAVY-MUNK 703-308-6237 ROOM: CS1 6W9
RECEIVED DATE: 07/07/99 DUE OUT DATE: 01/13/00

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 258584 EXPEDITE: N DATE SENT: 08/11/99 DATE RET.: 12/01/99
CHEMICAL: 025601 Copper(I) oxide
DP TYPE: 001

	CSF: Y		LABEL: Y		ADMIN DUE DATE: 12/09/99
ASSIGNED TO	DATE	IN	DATE	OUT	NEGOT DATE: / /
DIV : AD	08/12/99		12/01/99		PROJ DATE: / /
BRAN: RASSB	08/12/99		12/01/99		
SECT: RASSB3	09/07/99		11/29/99		
REVR : CJIANG	09/07/99		11/29/99		
CONTR:	/ /		/ /		

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the leach rate studies for acceptability.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
258582	PSB/EET	08/11/99	12/09/99	Y	Y	Y