

DATE: August 25, 1981

SUBJECT: Polyflo 2018 Antifouling Paint
EPA File Symbol 5204-AI

FROM: Sherell A. Sterling
FHB/TSS

SAW
9-4-81
E 9/9/81

TO: Richard Mountfort
Product Manager (23)

Applicant: M & T Chemicals, Inc.
P.O. Box 1104
Rahway, NJ 07065
Attention: A. E. Slesinger

Active Ingredients:

Cuprous oxide.....52.0%
Tributyltin methacrylate.....9.9%
Inert Ingredients.....38.1%

Background:

Acute Oral, Acute Dermal, Eye and Skin Irritation studies were submitted for "Bio Met 304 Cu/O Red Paint" to support the registration of this product. These studies were conducted by Bio/dynamics of East Millstone, New Jersey. The method of support is "cite-all."

Recommendations:

1. The test substance, Bio Met 304 Cu/O Red Paint, must be further identified. It is important that we know the composition of Bio Met 304 Cu/O Red Paint to compare it with Polyflo 2018.
2. The Acute Oral, Acute Dermal, Eye and Skin Irritation studies were adequate and acceptable for conditional registration of Bio Met 304 Cu/O.
3. An Acute Inhalation study must be submitted or particulate size and vapor pressure must be submitted. For further information, please refer to the enclosed copy of the Proposed Guidelines for Human Hazard evaluation.
4. No further recommendations can be made until the test substance is identified (see #1). Labeling recommendations are withheld until this requested information is submitted and reviewed.

Review:

1. Acute Oral Toxicity Study in Rats; Bio/dynamics #6636-81; June 30, 1981; Acc. No. 245596.

Procedure: Groups of Sprague-Dawley rats were given a single dosage of Bio Met 304 Cu/O Red Paint. Originally, range-finding tests demonstrated that a full test with 4 dosage levels must be performed. The dosages were 2.0, 2.5, 3.2, 4.0 g/kg. A control was also tested with 1.0% methyl-cellulose. Test ran for 14 days. All animals were subjected to necropsies.

Results: Mortalities in the test group were reported as follows: 0/5 M and 0/5 F at 2.0 g/kg; 0/5 M, 3/5 F at 2.5 g/kg; 2/5 M, 2/5 F at 3.2 and 4.0 g/kg; 4/5 M, 5/5 F at 5.0 g/kg. The LD50 for M was 3.9 g/kg with a 95% confidence range of 3.1-4.7 g/kg. The LD50 for F was 3.2 g/kg with a 95% confidence range of 2.6-3.8 g/kg. The combined M,F LD50 was 3.5 g/kg with a 95% confidence range of 3.1-3.9 g/kg. Observations included: decreased activity and respiration rates, soft stool and/or fecal staining, urinary staining; oral and ocular discharge; alopecia. Necropsy revealed: lungs - mottled, red foci; stomach - fluid filled, mottled walls, thickened or thinned walls; intestines - fluid filled, mottled walls; adrenals - large, red foci, pale; liver - mottled, hard.

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION

2. Acute Dermal Toxicity Study in Rabbits; Bio/dynamics #6637-81; June 17, 1981; Acc. No. 245596

Procedure: Groups of New Zealand white rabbits were dermally exposed to single doses of Bio Met 304 Cu/O Red Paint. A range-finding group was run which indicated that only one test group at 2 g/kg was necessary. The test group exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days. All animals were subjected to necropsies.

Results: All animals survived the 14-day study period. The LD50 was demonstrated to be greater than 2 g/kg. Observations during the study included: extensive necrosis, eschar, exfoliation. At necropsy, the following were observed: lungs - red, red foci, mottled; spleen - small, pitted, slightly roughened; adrenals - red; ovaries - multiple clear cysts (4/5 F).

Study Classification: Core Guideline Data.

Toxicity Category: III-CAUTION. An unusually high number of females were found to have multiple clear cysts.

3. Eye Irritation Study in Rabbits; Bio/dynamics #6638-81; June 9, 1981; Acc. No. 245596.

Procedure: Nine New Zealand white rabbits each received 0.1 ml of Bio Met 304 Cu/O Red Paint in one eye. Three treated eyes were washed with luke-warm water for one minute, 20 seconds after instillation of the test substance. Observations were made at 24, 48, 72 hours; 4, 7, 9, 11 and 14 days.

Results: At 24 hours in the unwashed eyes, corneal opacity was noted in 6/6=20; iris irritation in 5/6=5; redness in 6/6=2; chemosis in 4/6=2, 2/6=3; discharge in 1/6=2, 5/6=3; necrosis in 2/6. At 7 days, redness in 6/6=2; chemosis in 6/6=2; discharge in 3/6=1; necrosis and alopecia noted. By day 14, redness in 4/6=1; chemosis in 4/6=1; discharge in 2/6=1; alopecia noted.

In the washed group at 24 hours, corneal opacity in 3/3=20; iris irritation in 3/3=5; redness in 3/3=2; chemosis in 1/3=2, 2/3=3; discharge in 3/3=2; necrosis. By day 7, iris irritation in 1/3=5; redness in 3/3=2; chemosis in 3/3=2; necrosis. By day 14 in the washed eyes, chemosis noted in 3/3=1; alopecia.

Study Classification: Core Guideline Data.

Toxicity Category: II - Warning

4. Primary Dermal Irritation Study in Rabbits; Bio/dynamics #6639-81; June 8, 1981; Acc. No. 245596.

Procedure: Six New Zealand white rabbits each were exposed to 0.5 ml of Bio Met 304 Cu/O Red Paint at each of 4 sites, 2 abraded and 2 intact. Exposure was for 24 hours under occlusive wrap. Observations were made at 25 hours instead of 24 hours (due to difficulties in removing patches) and 72 hours. Readings continued for 14 days.

Results: At 25 hours, intact and abraded sites all showed severe erythema and edema, necrosis at all sites. Severe erythema and edema also noted at all sites. The Primary Irritation Index was 8.0. Observations at later dates included: necrosis, eschar, desquamation, exfoliation, moderate to severe erythema and edema.

Study Classification: Core Guideline Data.

Toxicity Category: I-DANGER

	(302-303) MUP's	304	304	Polyfl 2001 A TBTM TBTf	Polyfl 2018 TBTM C ₄ O
Acute Oral	III	III	III	III	III
Eye Irritation	II	II	I	I	II
Dermal Irritation	II	I	I	I	I
Acute Dermal	III	III	III	III	III

Do we send reviews & data about testes & ovaries to TB, HEID? Yes

The toxicity of the MUP's and paints are basically identical. Therefore MUP 302 & 303 can be registered with 304's precautionary statements. Nautical Paint's products are formulated with 302 & 303. Although not identical to M&T's paints they contain ingredients found in already registered TBTf paints, with a Cite-Ail GTP statement these products can be registered with Polyfl 2001 A precautionary statements