

PM-31 2-23-95
WALT FRANCIS
Room 248

MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 365-76
Gortan Broad Spectrum Bactericide

From: Lucy D. Markarian, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

ly 2/23/95

To: Walter Francis / Velma Noble, PM 31
Antimicrobial Branch
Registration Division (7505C)

Applicant: US Professional Laboratories
L & F Products
225 Summit Avenue
Montvale, NJ 07645-1575

FORMULATION FROM LABEL:

<u>Active Ingredient(s)::</u>	<u>% by wt.</u>
Hexahydro-1,3,5-tris(2-hydroxyethyl-s-triazine	78.5 %
<u>Inert Ingredient(s):</u> 21.5 %
.....	Total: 100.0 %

BACKGROUND

U S professional Laboratories of L & F products, has submitted n eye irritation study as 6(a)(2) data for the product Grotan under EPA 365-76. Based on the results of the test the registrant would like to change the signal word and precautionary label from CAUTION to Danger as expeditiously as possible.

RECOMMENDATION

The submitted eye study supports the change. The study shows that the subject product is corrosive to the eye. The study of the file did not yield any toxicological data to support the registration. In the light of the apparent corrosive nature, at least in the eyes, it is recommended that other required studies be also submitted.



The eye test is considered core minimum data, because the QA statement states that the inspected in life portion of the test was the dose preparation. This was an eye study that used the liquid test material as received. It is difficult to understand how the dose needed any preparation. The case has been referred to OECA.

LABEL

The signal word is DANGER.
Based on the eye study the precautionary statement must include:

Corrosive. Causes irreversible eye damage. do not get in eyes or on clothing. Wear goggles or face shield. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

The ststatement of practical treatment must include:

- If in eyes: Call physician. Keep eye lids open and flush with a gentle steady stream of water for 15 minutes.
- If swallowed: Drink promptly a large quantity of milk, egg white or gelatin mixture, or if these are not available a large quantity of water. Avoid alcohol.

Note to the physician: Probable mucosal damage may contraindicate gastric lavage.

The label may have to be revised upon the submission and acceptance of the outstanding data.

Note to the PM

Category I placement of the ocular hazard potential places this product in restricted use classification. The PM must decide if alternative labeling language is sufficient to offset the hazard and the need for restricted use classification. If it is not placed in restricted use classification, then CRP will be necessary.

DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: 31
MRID No.: 435173-01
Testing Laboratory: Springborn
Author(s): Deborah A. Douds
Species: Rabbit, New Zealand White
Sex: 3 male & 3 female
Weight: 2.832 - 3.363 K
Age: Adult
Source: Myrtle's Rabbitry, Thompson Station, TN
Dosage: 0.5 ml
Test Material: BD-024-3A, clear, light yellow viscous liquid
Quality Assurance (40 CFR §160.12): Included, questionable

Reviewer: L. Markarian
Report Date: 1/6/95
Report No.: 3157-167

Summary:

1. **Toxicity Category:** I
2. **Classification:** Core minimum

Procedure (Deviations From §81-4):

Test material was instilled in the conjunctival sacs of six pre examined eyes as received. Evaluations were at 1, 24, 48, and 72 hrs and days 7, 10, 14, and 21, according to Draize. Fluorescein was used to confirm corneal findings starting at 24 hrs.

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	7	10	14	21
Cornea Opacity	5/6	6/6	6/6	6/6	6/6	5/6	5/6	4/6
Iris	6/6	6/6	6/6	6/6	3/6	2/6	1/6	1/6
Conjunctivae								
Redness	6/6	6/6	6/6	6/6	6/6	5/6	4/6	1/6
Chemosis	6/6	6/6	6/6	6/6	3/6	2/6	3/6	1/6
Discharge	6/6	6/6	6/6	6/6	2/6	1/5	1/6	1/6

Comments: Additionally sloughing of the corneal epithelium, Vascularization of cornea, raised areas on the cornea, blanching of the conjunctivae, and hair loss around the eye were observed.

Tox Chem No: 083301

Current Date: 2/23/95

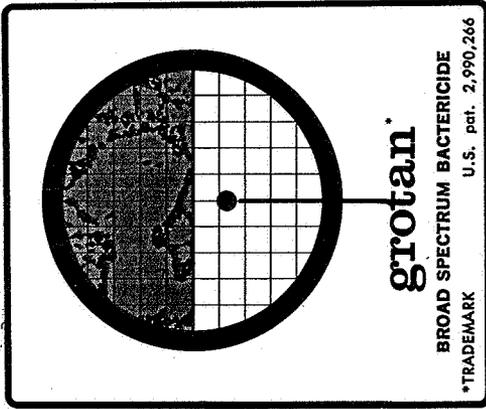
Hexahydro-1,2,3,5-tris(2hydroxyethyl)-
s-Triazine

Laboratory: Springborn Laboratories, Inc., 640 North Elizabeth street,
Spencerville, Ohio 45887

S T U D Y M A T E R I A L MRID NO R E S U L T S TOX CAT CORE GRADE

Eye Irritation BD-024-3A 435173-01 Corrosive I Minimum
in Rabbits
3157.167
1/6/95

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A LONG LASTING BROAD SPECTRUM BACTERICIDE, SLIMICIDE, AND FUNGICIDE FOR THE PRESERVATION OF METAL CUTTING FLUIDS AND COOLANTS

ACTIVE INGREDIENT:

Hexahydro — 1, 3, 5, — tris (2—hydroxethyl) — s — triazine 78.5%

INERT INGREDIENTS:

..... 21.5%

CAUTION: Keep out of reach of children.

GROTAN CONCENTRATE is harmful if swallowed. Avoid skin contact and splashing in eyes. Wash eyes with large amounts of water if exposed. If irritation persists, get medical attention.

U.S.D.A. Reg. No. 10,000-1

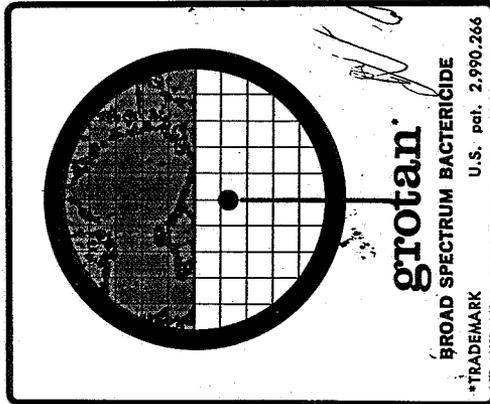
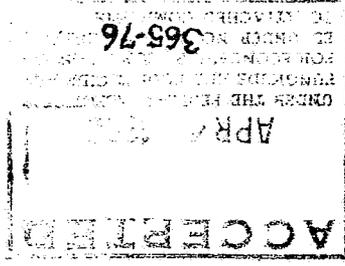
HALLEMITE
LEHN & FINK INDUSTRIAL PRODUCTS DIVISION
OF STERLING DRUG INC.

OFFICES — 225 SUMMIT AVE.
 MONTVALE, NEW JERSEY 07645

PLANT — 4934 LEWIS AVE.
 TOLEDO, OHIO 43612

DIRECTIONS:
SOLUBLE EMULSION AND SYNTHETIC CUTTING FLUIDS

1. For best results, drain and clean the system before adding fresh cutting fluid.
2. Add 0.15% of GRO-TAN to the use dilution. (1.2 pints per 100 gallons of diluted cutting fluid).
3. 0.15% of GROTAN should be added to the use dilution of the make-up fluid.



NET CONTENTS 10 LBS.