

Textile Products Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419-8300
Telephone 919 632 6000

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September 4, 1992

Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Attention: Section 8(e) Coordinator (CAP Agreement)

RE: 8E CAP - 0024

Dear Section 8(e) Coordinator:

Enclosed are triplicate copies of a study CIBA-GEIGY Corporation is submitting pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement number 8E CAP-0024. We are submitting the following information, as required by the CAP Agreement:

Company Name: CIBA-GEIGY Corporation
444 Saw Mill River Road
Ardsley, New York 10502-2699

Attention: Mr. Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances
Compliance
Telephone (914) 479-2776

Tested Chemical: C.I. Basic Blue 3; also identified as Maxilon Blue 5G

CAS No.: 55840-82-9

Report Title: Acute Toxicity Studies with Maxilon Blue 5G (IBT No. 8530-09921, dated 2/2/77)

Summary:

Doses of the test material ranging from 266.7 mg/kg to 15,380 mg/kg were administered to 16 rats/sex. Clinical signs noted included hypoactivity and salivation at the low doses and muscular weakness, labored breathing at higher doses. Males appeared to be less sensitive to the acute oral toxicity of the test material (LD50 = 1,103 mg/kg) than were females (LD50 = 490.0). The acute oral LD50 value of less than 500 mg/kg in female rats for this test material serves as the basis for reporting this study under TSCA section 8(e).



"THE POWER OF PARTNERSHIP"
Textile Products Division

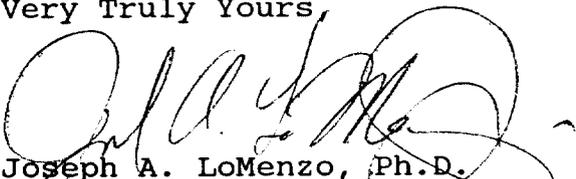
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Category: Unit II.B.2.b

Prior Reporting: Not Applicable

Please call the undersigned at telephone number (919) 632-2889 if you have any questions about this submittal.

Very Truly Yours,



Joseph A. LoMenzo, Ph.D.
 Product Stewardship Director
 Textile Products Division

Enclosures
 2 copies of this letter
 3 copies of the study

cc: A. Di Battista

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~~44~~-176501-100-0

Industrial **BIO-TEST** *Laboratories, Inc.*

1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

REPORT TO

CIBA-GEIGY CORPORATION

ACUTE TOXICITY STUDIES WITH
MAXILON BLUE 5G

FEBRUARY 2, 1977

IBT NO. 8530-09921

EC & S OFFICE REC'D FEB 10 1977

These study results apply only to acute exposure and should not be used to determine possible repeated or prolonged exposure effects.

Industrial **BIO-TEST** *Laboratories, Inc.*

1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

February 2, 1977

Dr. Edgar M. Flint
Associate Director
Industrial Medicine
CIBA-GEIGY Corporation
Ardsley, New York 10502

Dear Dr. Flint:

Re: IBT No. 8530-09921 - Acute Toxicity Studies with
Maxilon Blue 5G - Batch No. 28896

We are submitting herewith our laboratory report prepared in
connection with the above study.

Very truly yours,



J. C. Calandra
President

JCC:jd

*These study results apply only to
acute exposure and would not be
used to determine possible repeat-
ed or prolonged exposure effects.*

REPORT TO
CIBA-GEIGY CORPORATION
ACUTE TOXICITY STUDIES WITH
MAXILON BLUE 5G
FEBRUARY 2, 1977
IBT NO. 8530-09921

I. Introduction

At the request of the CIBA-GEIGY Corporation, the following studies were conducted with a gray powder identified as Maxilon Blue 5G, Batch No. 28896:

- Acute Oral Toxicity Study - Albino Rats
- Acute Dermal Toxicity Study - Albino Rabbits
- Eye Irritation Test - Albino Rabbits
- Primary Skin Irritation Test - Albino Rabbits

II. Summary

The results of the acute toxicity studies with Maxilon Blue 5G, Batch No. 28896, are summarized below:

<u>Test</u>	<u>Results</u>
Acute Oral Toxicity Study - Albino Rats	Males - Slightly Toxic Females - Moderately Toxic Combined - Slightly Toxic LD ₅₀ : Males = 1,103 mg/kg Females = 490.0 mg/kg Combined \approx 785 mg/kg Standard Deviation of LD ₅₀ : Males = + 320.3 mg/kg Females = + 142.3 mg/kg
Acute Dermal Toxicity Study - Albino Rabbits	Practically Nontoxic LD ₅₀ > 3,038 mg/kg
Eye Irritation Test - Albino Rabbits	Moderately Irritating (34.2/110.0)
Primary Skin Irritation Test - Albino Rabbits	Slightly Irritating (1.4/8.0)

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

Report prepared by:

Helfried Paa
Helfried Paa
Assistant Group Leader
Dermal Toxicity

Report approved by:

C. W. Mastri
C. W. Mastri, B.S.
Section Head, Acute Toxicity

Florence K. Kinoshita
Florence K. Kinoshita, Ph.D.
Technical Manager, Toxicology

M. L. Keplinger
M. L. Keplinger, Ph.D.
Manager, Toxicology

III. Results

A. Acute Oral Toxicity Study - Albino Rats

1. Mortality and Body Weights

The individual mortality and body weight data are presented in Table I.

2. Reactions and Pathology

The pharmacotoxic symptoms exhibited by the rats post-oral administration of Maxilon Blue 5G are presented in Table II.

Necropsy examination of the animals that died revealed test material stained tissues. The persistence of the stain prevented the observation of possible gross pathologic alterations. Examination of the survivors revealed necrotic tissue in the stomach lining in animals 8-F and 18-M. The gross lesions observed were considered to be associated with the oral administration of Maxilon Blue 5G.

TABLE I

Acute Oral Toxicity Study - Albino Rats

Mortality and Body Weight Data

IBT No.: 8530-09921

Test Material: Maxilon Blue 5G

Form Administered: As a 50.0 percent
(w/v) aqueous
solution

Classification:

Males - Slightly Toxic

Females - Moderately Toxic

Combined - Slightly Toxic

Acute Oral LD₅₀:

Males = 1,103 mg/kg

Females = 490.0 mg/kg

Combined \approx 785 mg/kgStandard Deviation of LD₅₀:Males = \pm 320.3 mg/kgFemales = \pm 142.3 mg/kg

Dose Level (mg/kg)	Animal Number and Sex	Individual Body Weights (grams)		Number Dead / Number Tested	Percent Dead
		Test Day Number: 0	Test Day Number: 14		
266.7	1-M	200	336	0/4	0
	2-M	202	328		
	3-F	176	186		
	4-F	150	216		
400	5-M	222	326	1/4	25
	6-M	230	322		
	7-F	168	(5 hours) 202		
	8-F	168	202		
600	9-M	194	318	1/4	25
	10-M	214	322		
	11-F	188	(1 hour) 210		
	12-F	168	210		
900	13-M	224	282	3/4	75
	14-M	208	(3 days) 202		
	15-F	150	(3 hours) 210		
	16-F	150	(6-22 hours) 210		

TABLE I continued

Acute Oral Toxicity Study - Albino Rats

Mortality and Body Weight Data

IBT No.: 8530-09921

Test Material: Maxilon Blue 5G

Dose Level (mg/kg)	Animal Number and Sex	Individual Body Weights (grams)		Number Dead / Number Tested	Percent Dead
		Test Day Number: 0	Test Day Number: 14		
1,350	17-M	214	(15 minutes)	3/4	75
	18-M	224	278		
	19-F	184	(6-22 hours)		
	20-F	176	(4-1/2 hours)		
2,025	21-M	234	(5 hours)	4/4	100
	22-M	216	(6-22 hours)		
	23-F	164	(6-22 hours)		
	24-F	166	(30 minutes)		
4,556	25-M	260	(2 hours)	4/4	100
	26-M	248	(3 hours)		
	27-F	168	(15 minutes)		
	28-F	180	(3 hours)		
15,380	29-M	234	(15 minutes)	4/4	100
	30-M	230	(15 minutes)		
	31-F	170	(15 minutes)		
	32-F	184	(15 minutes)		

Note: Figures in parentheses indicate time of death.

TABLE II
Acute Oral Toxicity Study - Albino Rats
Summary of Reactions

IBT No.: 8530-09921
Test Material: Maxilon Blue 5G
Form Administered: As a 50.0 percent (w/v) aqueous solution

Reactions	266.7			400.0			600.0			900.0			1,350			2,025			4,556			15,380		
	O	R		O	R		O	R		O	R		O	R		O	R		O	R		O	R	
Hypoactivity	5 M	2 D		5 M	2 D		5 M	2 D		5 M	3 D		5 M	4 D		5 M	N		5 M	N		5 M	N	
Salivation	5 M	6-22 H		5 M	N		5 M	N		5 M	N													
Muscular weakness	-	-		-	-		-	-		-	-		2 H	6-22 H		15 M	N		5 M	N		5 M	N	
Labored breathing	-	-		-	-		-	-		-	-		4 H	6-22 H		4 H	N		5 M	N		5 M	N	
Diarrhea	-	-		2 H	6-22 H		2 H	6-22 H		2 H	6-22 H		2 H	4 D		2 H	N		2 H	N		-	-	
Prostration	-	-		-	-		-	-		-	-		4 H	6-22 H		-	-		-	-		-	-	
Diuresis (males only)	-	-		2 H	6-22 H		2 H	6-22 H		2 H	6-22 H		-	-		-	-		-	-		-	-	
Alopecia	-	-		-	-		6 D	N		-	-		-	-		-	-		-	-		-	-	
Fur at caudal region stained green	6 D	N		-	-		6 D	N		6 D	N		-	-		-	-		-	-		-	-	

Note: All animals in each group were observed exhibiting the above symptoms at the designated time intervals except alopecia, which was noted only in animal 10-M at the 600 mg/kg dose level.

O = Onset
R = Recovery
D = Days
H = Hours
M = Minutes
N = No Recovery
- = No Reaction

B. Acute Dermal Toxicity Study - Albino Rabbits

1. Mortality and Body Weights

The individual mortality and body weight data are presented in Table III.

2. Reactions and Pathology

No pharmacotoxic symptoms were observed in the rabbits following dermal exposure to Maxilon Blue 5G. Diarrhea was noted in rabbits 1-M and 2-M on the 5th and 7th days of observation, respectively. Both animals recovered by day 10. In addition, a slight body weight loss was noted in the rabbits during the first week of observation. This body weight loss and the occurrence of diarrhea were attributed to the stress of the experimental procedure and/or naturally occurring disease.

The test material appeared to be slightly irritating to the skin of the albino rabbit. Possible erythema at 24 hours could not be evaluated due to the staining of the dye on the skin. Slight desquamation was present at the test skin sites at 7 and 14 days.

Necropsy examination did not reveal any gross pathologic alterations, except for the local skin changes as previously described.

TABLE III

Acute Dermal Toxicity Study - Albino Rabbits

Mortality and Body Weight Data

IBT No.: 8530-09921

Test Material: Maxilon Blue 5G

Form Administered: As an aqueous
slurryClassification: Practically Nontoxic
Acute Dermal LD₅₀ > 3,038 mg/kg

Dose Level (mg/kg)	Animal Number and Sex	Individual Body Weights (kg)			<u>Number Dead</u> Number Tested	Percent Dead
		Test Day Number:				
		0	7	14		
3,038	1-M*	2.56	2.36	2.62	0/4	0
	2-M	2.62	2.56	2.86		
	3-F*	2.88	2.72	3.00		
	4-F	2.96	2.86	3.18		

* The skin at the site of application was abraded.

C. Eye Irritation Test - Albino Rabbits

The results of the eye irritation test are presented in Table IV.

TABLE IV

Eye Irritation Test - Albino Rabbits

Results

BT No.: 8530-09921

Test Material: Maxilon Blue 5G

Form Administered: Instillation (100 mg, undiluted)

Special Instructions: Unwashed eyes

Classification: Moderately Irritating
Maximum Mean

Irritation Score: 34.2/110.0

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	7 Days	14 Days
Cornea (D-A) ris	1	20 (1-4)	10 (1-2)	5 (1-1)	0	0	0
		5	5	5	0	0	0
		16 (3-2-3),B	18 (3-3-3),B	12 (3-1-2),B	10 (3-1-1),B	6 (3-0-0),B	0
	Total	41	33	22	10	6	0
Cornea (D-A) ris	2	15 (1-3)	5 (1-1)	0	0	0	0
		5	5	0	0	0	0
		12 (2-2-2)	8 (2-1-1)	6 (2-1-0)	6 (2-1-0)	4 (2-0-0)	0
	Total	32	18	6	6	4	0
Cornea (D-A) ris	3	20 (1-4)	5 (1-1)	0	0	0	0
		5	5	0	0	0	0
		12 (2-2-2)	10 (2-1-2)	8 (2-1-1)	6 (2-1-0)	4 (2-0-0)	4 (2-0-0)
	Total	37	20	8	6	4	4
Cornea (D-A) ris	4	20 (1-4)	5 (1-1)	0	0	0	0
		5	5	0	0	0	0
		10 (2-1-2)	8 (2-1-1)	8 (2-1-1)	6 (2-1-0)	2 (1-0-0)	0
	Total	35	18	8	6	2	0

TABLE IV continued

Eye Irritation Test - Albino Rabbits

Results

3T No.: 8530-09921

Test Material: Maxilon Blue 5G

Tissue	Rabbit Number	1 Hour	24 Hours	48 Hours	72 Hours	7 Days	14 Days
Cornea (D-A)	5	20 (1-4)	5 (1-1)	5 (1-1)	0	0	0
		5	5	0	0	0	0
		10 (2-1-2)	8 (2-1-1)	8 (2-1-1)	6 (2-1-0)	2 (1-0-0)	0
Total		35	18	13	6	2	0
Cornea (D-A)	6	10 (1-2)	5 (1-1)	0	0	0	0
		5	5	0	0	0	0
		10 (2-1-2)	8 (2-1-1)	6 (2-1-0)	6 (2-1-0)	4 (2-0-0)	0
Total		25	18	6	6	4	0
Averages							
Cornea		17.5	5.8	1.7	0.0	0.0	0.0
Iris		5.0	5.0	0.8	0.0	0.0	0.0
Conjunctiva		11.7	10.0	8.0	6.7	3.7	0.7
Total		34.2	20.8	10.5	6.7	3.7	0.7

Cornea:
 Density = Value x 5
 Area = Value x 5
 Maximum Score = 80

Iris:
 Iris Score = Value x 5
 Maximum Score = 10

Conjunctiva:
 R = Redness
 S = Swelling
 D = Discharge
 Conjunctival Score = (R+S+D) x 2
 Maximum Score = 20

B = Chemical burn

D. Primary Skin Irritation Test - Albino Rabbits

The results of the primary skin irritation test are presented in Table V.

TABLE V

Primary Skin Irritation Test - Albino Rabbits

Results

IBT No.: 8530-09921

Test Material: Maxilon Blue 5G

Form Administered: 500 mg applied to
premoistened sitesSpecial Instructions: 24-hour exposure
period; occluded
sitesClassification: Slightly Irritating
Mean Primary

Irritation Score: 1.4/8.0

Animal Number	Irritation Scores for Abraded Skin Sites at:				Irritation Scores for Intact Skin Sites at:			
	24 Hours		72 Hours		24 Hours		72 Hours	
	Er.	Ed.	Er.	Ed.	Er.	Ed.	Er.	Ed.
1	*	1	0	0	*	0	0	0
2	*	0	0	0	*	0	0	0
3	*	1	0	0	*	0	0	0
4	3	1	0	0	*	0	0	0
5	2	0	1	0	2	0	1	0
6	2	1	0	0	*	0	0	0
Mean	2.3	0.7	0.2	0.0	2.0	0.0	0.2	0.0
Subtotal			3.2				2.2	

Primary Irritation Score = 1.4

* The test material stained the skin. A possible grade 2 erythema may have been present but not been detected. Therefore, the mean scores for erythema at 24 hours were based only on those animals where an evaluation was possible.

Key:

Er. = Erythema

Ed. = Edema

IV. Appendix

The detailed investigational procedures employed in these studies are presented in the following pages:

ACUTE ORAL TOXICITY STUDY - ALBINO RATS

Young albino rats derived from Sprague-Dawley stock were used as test animals. All animals were kept under observation for five days prior to experimental use, during which period they were checked for general health and suitability as test animals. The animals were housed in stock cages and were permitted a standard laboratory diet plus water ad libitum, except during the 16-hour period immediately prior to oral intubation when food was withheld.

Initial screening was conducted in order to determine the general level of toxicity of the test material. Selected groups of albino rats were administered the test material at several dose levels. All doses were administered directly into the stomachs of the rats using a hypodermic syringe equipped with a ball-tipped intubating needle.

After oral administration of the test material, the rats were housed individually in suspended, wire-mesh cages and observed for the following 14 days. Initial and final body weights, mortalities, and reactions were recorded. A necropsy examination was conducted on all animals.

At the end of the observation period, the acute oral median lethal dose (LD₅₀) of the test material was calculated, if possible, using the techniques of Weil*, Thompson**, and Thompson and Weil***. The test material was then assigned a classification in accordance with Harold C. Hodge****. The classification system is presented in the following Table.

* Weil, Carrol S.: Tables for Convenient Calculation of Median-Effective Dose (LD₅₀ or ED₅₀) and Instructions in Their Use. Biometrics, Sept. 1952.

** Thompson, William R.: Use of Moving Averages and Interpolation to Estimate Median-Effective Dose. Bact. Rev., Nov. 1947.

*** Thompson, William R. and Weil, Carrol S.: On the Construction of Tables for Moving Average Interpolation. Biometrics, March 1952.

**** Hodge, Harold C., "The LD₅₀ and its value", American Perfumer and Cosmetics 80, 57 (1965).

TABLE

Acute Oral Toxicity Study - Albino Rats

Classification of Test Materials
Based on Acute Oral LD₅₀

Acute Oral LD ₅₀ (Range of Values)	Classification	Probable lethal dose for a 70 kg man in commonly used measures
Less than 5 mg/kg	Extremely toxic	a taste (less than 7 drops)
5 - 50 mg/kg	Highly toxic	between 7 drops and 1 teaspoonful
50 - 500 mg/kg	Moderately toxic	between 1 teaspoonful and 1 ounce
500 - 5,000 mg/kg	Slightly toxic	between 1 ounce and 1 pint or 1 pound
5,000 - 15,000 mg/kg	Practically non-toxic	between 1 pint and 1 quart
Greater than 15,000 mg/kg	Relatively harmless	more than 1 quart

ACUTE DERMAL TOXICITY STUDY - ALBINO RABBITS

Young adult albino rabbits of the New Zealand strain were used as test animals. All rabbits had been maintained under observation in the laboratory for at least seven days prior to testing. During the pre-test period, the animals were examined with respect to their general health and suitability as test animals. The rabbits were housed individually in suspended, wire-bottomed cages and maintained on a standard laboratory ration. Food and water were offered ad libitum.

Twenty-four hours prior to the dermal applications, the backs of the rabbits were shaved free of hair with electric clippers. The shaved area on each animal constituted about 30 percent of the total body surface area. The animals were then returned to their cages to await testing on the following day. The 24-hour waiting period allowed recovery of the stratum corneum from the disturbance which accompanied the close-clipping procedure and permitted healing of any microscopic abrasions possibly produced during the process.

The test material was applied at the highest reasonable dose level. The test site was covered by wrapping the trunk of the animal with impervious plastic sheeting which was securely taped in place. This plastic wrap insured close contact of the epidermis and test material. To prevent oral ingestion of the test material, each animal was fitted with a light-weight, flexible plastic collar which was worn throughout the observation period.

The test material remained in contact with the skin for 24 hours. At the end of this period the plastic sheeting was removed. The test material could not be completely washed off with tap water and Ivory Liquid and the residual material remained in contact with the skin for an unlimited period of time. The test sites were examined for local skin reactions and the animals were returned to their cages. Observations for mortality, local skin reactions, and behavioral abnormalities were continued for a total of 14 days following the skin applications. Initial, 7 and 14-day body weights were recorded. A necropsy examination was conducted on all animals.

In the case of significant mortality following the initial study, additional experiments were conducted at lower dose levels in order to obtain data sufficient to determine the acute dermal median lethal dose (LD₅₀), if possible, using the techniques of Weil*, Thompson**, and Thompson and Weil***. The test material was then assigned a classification. The classification system is presented in the following Table.

* Weil, Carrol S.: Tables for Convenient Calculation of Median-Effective Dose (LD₅₀ or ED₅₀) and Instructions in Their use. Biometrics, Sept. 1952.

** Thompson, William R.: Use of Moving Averages and Interpolation to Estimate Median-Effective Dose. Bact. Rev., Nov. 1947.

*** Thompson, William R. and Weil, Carrol S.: On the Construction of Tables for Moving Average Interpolation. Biometrics, March 1952.

TABLE

Acute Dermal Toxicity Study - Albino Rabbits

Classification of Test Materials
Based on Acute Dermal LD₅₀

Acute Dermal LD ₅₀ (Range of Values)	Classification	Probable lethal dose for a 70 kg man in commonly used measures
Less than 20 mg/kg	Extremely toxic	approximately 30 drops
20 - 200 mg/kg	Highly toxic	between 30 drops and 4 teaspoonfuls
200 - 500 mg/kg	Moderately toxic	between 4 teaspoonfuls and 1 ounce
500 - 3,000 mg/kg	Slightly toxic	between 1 ounce and 1 pint or 1 pound
3,000 - 10,000 mg/kg	Practically non-toxic	between 1 pint and 1 quart
Greater than 10,000 mg/kg	Relatively harmless	more than 1 quart

EYE IRRITATION TEST - ALBINO RABBITS

Young albino rabbits of the New Zealand strain were used to evaluate the eye irritating properties of the test material. The test method was patterned after that of Draize*.

The test material was instilled into the conjunctival sac of the right eye of each rabbit. The left eye of each animal served as a control. At each scoring interval the cornea, iris and palpebral conjunctiva were examined and graded for irritation and injury according to a standard scoring system*. The maximum possible score at any one examination and scoring period was 110 points, which indicated maximal irritation and damage to all three ocular tissues. Zero score indicated no irritation. The scoring system is presented in Table A. In this scoring system, special emphasis is placed upon irritation or damage to the cornea, while less emphasis is placed upon damage to the iris and conjunctiva.

After the completion of the test, the scores were analyzed and a descriptive eye irritation rating was assigned to the test material. The criteria used for assignment of the descriptive rating were the frequency, the extent and the persistence of irritation or damage which occurred to the three ocular tissues.

* Draize, John H.: Dermal Toxicity, "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics", Association of Food and Drug Officials of the U.S., 1959, pp. 49-51.

TABLE A

Eye Irritation Test - Albino Rabbits

Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading	
Cornea	<u>Opacity (D)</u>		
	Opacity - Degree of density (area which is most dense is taken for reading). Scattered or diffuse area, details of iris clearly visible.	1	
	Easily discernible translucent areas, details of iris slightly obscured.	2	
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3	
	Opaque, iris invisible.	4	
	<u>Area of Cornea Involved (A)</u>		
	One quarter (or less) but not zero.	1	
	Greater than one-quarter but less than one-half.	2	
	Greater than one-half but less than three-quarters.	3	
	Greater than three-quarters, up to whole area.	4	
	Score equals D x A x 5		Total maximum = 80
	Iris	<u>Values</u>	
		Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or a combination of any thereof), iris still reacting to light (sluggish reaction is positive).	1
		No reaction to light, hemorrhage, gross destruction (any or all of these).	2
Score equals value x 5		Total maximum = 10	

TABLE A continued

Eye Irritation Test - Albino Rabbits

Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading	
Conjunctiva	<u>Redness (R)</u>		
	Redness (refers to palpebral conjunctiva only). Vessels definitely injected above normal.	1	
	More diffuse, deeper crimson red, individual vessels not easily discernible.	2	
	Diffuse beefy red.	3	
	<u>Chemosis (S)</u>		
	Any swelling above normal (includes nictitating membrane).	1	
	Obvious swelling with partial eversion of the lids.	2	
	Swelling with lids about half-closed.	3	
	Swelling with lids about half-closed to completely closed.	4	
	<u>Discharge (D)</u>		
	Any amount different from normal (does not in- clude small amount observed in inner canthus of normal animals).	1	
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2	
	Discharge with moistening of the lids and hairs and considerable area around eye.	3	
	Score (R + S + D) x 2		Total maximum = 20

Note: The maximum total score is the sum of all scores obtained from the cornea, iris, and conjunctiva.

The rating is obtained by selecting the maximum mean irritation score at one, 24, 48 or 72 hours after instillation. If the rate of dissipation of injury does not meet the requirements defined for the descriptive rating appropriate for a particular numerical score, the descriptive rating was raised by one or more levels. The rating system is presented in Table B.

TABLE B

Eye Irritation Test - Albino Rabbits

Classification of Test Materials
Based on Eye Irritation Properties

Classification	Range	Definition
Non-Irritating	0.0 - 0.5	To maintain this rating, all scores at the 24-hour reading must be zero; otherwise, increase rating one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this rating, all scores at the 24-hour reading must be zero; otherwise increase rating one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this rating, all scores at the 72-hour reading must be zero; otherwise, increase rating one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this rating, all scores at the 7-day reading must be zero; otherwise, increase rating one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this rating, scores at 7 days must be less than or equal to 10 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 20. If 7-day mean score is less than or equal to 20 but less than 60% of animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if rating is to be maintained; otherwise, increase rating one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this rating, scores at 7 days must be less than or equal to 30 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 40. If 7-day mean score is less than or equal to 40 but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if rating is to be maintained; otherwise, increase rating one level.
Extremely Irritating	Greater than 80.0 - 110.0	

PRIMARY SKIN IRRITATION TEST - ALBINO RABBITS

Young albino rabbits of the New Zealand strain were used in the evaluation of the primary skin irritating properties of the test material. The test procedure was modeled after that of Draize*.

Prior to the application of the test material, the hair was clipped from the back and flanks of each rabbit. Two test sites located lateral to the midline of the back approximately ten centimeters apart were selected. One of the two sites was abraded by making four epidermal incisions, two perpendicular to the other two, while the other test site remained intact.

The test material was applied to each of the test sites on each rabbit and occluded with gauze patches which were secured with masking tape. The trunk of each animal was then wrapped with impervious plastic sheeting. The wrap held the patches in position and retarded evaporation of the test material during the 24-hour exposure period.

At the end of 24 hours, the plastic wrappings, patches and all residual test material were removed. The intact and abraded test sites were examined and scored separately for erythema and edema on a graded scale of 0 to 4. After 72 hours, the sites were again examined and scored.

* Draize, John H.: Dermal Toxicity, "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics", Association of Food and Drug Officials of the U.S., 1959, pp. 46-48.

In evaluating the average irritation present, the mean scores for erythema and edema of the intact test sites after 24 and 72 hours were added. Similarly, the mean scores for erythema and edema of the abraded test sites after 24 and 72 hours were added. These two values were totaled and divided by four to obtain the mean primary irritation score.

The following grading system was used to arrive at a descriptive primary skin irritation rating:

<u>Mean Primary Irritation Score</u> <u>(Range of Values)</u>	<u>Descriptive Rating</u>
0	Nonirritating
0.1 - 0.5	Minimally Irritating
0.6 - 1.5	Slightly Irritating
1.6 - 3.0	Mildly Irritating
3.1 - 5.0	Moderately Irritating
5.1 - 6.5	Severely Irritating
6.6 - 8.0	Extremely Irritating

The scoring criteria for erythema and edema are shown in the following table:

TABLE
 Primary Skin Irritation Test - Albino Rabbits
 Scoring Criteria for Skin Reactions

Reactions	Description	Score
Erythema	Barely perceptible (Edges of area not defined)	1
	Pale red in color and area definable	2
	Definite red in color and area well-defined	3
	Beet or crimson red in color	4
Edema	Barely perceptible (Edges of area not defined)	1
	Area definable but not raised more than 1 mm	2
	Area well-defined and raised approximately 1 mm	3
	Area raised more than 1 mm	4
Injury In Depth	Escharosis, Necrosis	8
	Maximum Primary Irritation Score =	8



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

Joseph A. LoMenzo, Ph.D.
Product Stewardship Director
Textile Products Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419-8300

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

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Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

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EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12140A



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Triage of 8(e) Submissions

Date sent to triage: _____

NON-CAP

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Submission number: 12140A

TSCA Inventory

Y

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D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

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CTOX/ONCO

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CYTO

NEUR

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entire document: 0 1 2 pages 1, 2 pages 1, 2, tab

Notes:

Contractor reviewer : LPS Date: 2/16/95

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHO: 0992-12140 SEQ. A
 TYPE: INT SUPP FLWP
 SUBMITTER NAME: Ciba-Geigy Corporation

INFORMATION REQUESTED: FLWP DATE:
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONALE)
 DISPOSITION:
 0639 REFER TO CHEMICAL SCREENING
 0678 CAP NOTICE

VOLUNTARY ACTIONS:
 0401 NO ACTION REPORTED
 0402 STUDIES PLANNED/IN PROGRESS
 0403 NOTIFICATION OF WORKER RIGHTS
 0404 LABEL/MSDS CHANGES
 0405 PROCESS/HANDLING CHANGES
 0406 APP/USE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

SUB. DATE: 09/04/92 OTS DATE: 09/10/92 CSRAD DATE: 01/31/95
 CHEMICAL NAME: Maxilon Blue 56
 CAS#: 55840-82-9

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL. TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY YES
 CAS SR NO (CONTINUE) YES
 Ongoing Review: YES (DROP/REFER) NO (CONTINUE) REFER
 SPECIES: RAT RBT
 TOXICOLOGICAL CONCERN: LOW acute dermal + dermal irritation
MED acute oral + eye irritation
 HIGH

12140A

M

Acute oral toxicity in rats is of moderate concern. Single oral doses of 266.7, 400, 600, 900, 1350, 2025, 4556, and 15380 mg/kg were administered to albino rats (2/sex/dose). The LD₅₀ values for males and females were 1,103 and 490 mg/kg, respectively. Clinical signs of toxicity included hypoactivity and salivation (4/4 at all dose levels), muscular weakness and labored breathing (4/4 at \geq 1350 mg/kg), and prostration (4/4 at 1350 mg/kg).

L

Acute dermal toxicity in rabbits is of low concern. A single dermal dose of 3,038 mg/kg was applied to the skin of albino rabbits (2/sex). No deaths or signs of compound-related toxicity resulted.

M

Primary eye irritation in rabbits is of moderate concern. Moderate irritation was observed following application of the substance into the right eye of six New Zealand white rabbits. The following were noted: corneal opacity (6/6) clearing by day 2 (4/6) or day 3 (2/6), iritis (6/6) clearing by day 2 (5/6) or day 3 (1/6), and conjunctival irritation (6/6) clearing by day 14 in 5/6.

L

Primary dermal irritation in rabbits is of low concern. Slight irritation was observed following application of the substance to the intact and abraded skin of six New Zealand albino rabbits. Mild erythema was noted at 24 hours in abraded (3/6 - other three could not be evaluated) and intact (1/6 - other five could not be evaluated), clearing by 72 hours in 5/6.