

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

# CIBA-GEIGY

Contains NO CBI

October 9, 1992

(A)

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

88920010525  
8EHQ-92-12315

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 the original and two 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. The information being submitted is not considered Confidential Business Information. 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:

1,3-Benzenediamine, 4,4'-{(4-methyl-1,3-phenylene)  
bis(azo)}bis{6-methyl-, dihydrochloride

also identified as: Brown AT Conc.; Bismark Brown R;

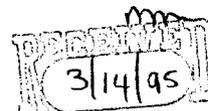
CAS No.: 5421-66-9

Report Title: Report on Rabbit Eye Irritation (Project Number:  
MB 78-3162 D, dated 12/4/78)

Summary: The test material was placed into the conjunctival sac of one eye of each of six rabbits. Scores for ocular irritation were recorded 1, 24, 28, and 72 hours after instillation according to the method of Kay and Calandra. Eyes not returning



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Textile Products Division



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to a score of zero by 72 hours were graded on the fourteenth day after instillation. Positive corneal, iridal, and conjunctival scores were noted in all animals. On day 14, corneal scores were present in 5/6, iridal scores in 2/5, and positive conjunctival scores in 6/6 treated eyes. This study is being submitted based on potential severe eye irritation and on potential human exposure.

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

MB Research Laboratories, Inc.

REC'D DR. J. SCHULZE MAY 9 1978

REPORT ON RABBIT EYE IRRITATION

FOR: TOMS RIVER CHEMICAL CORPORATION

steinsburg and wentz roads  
 post office box 203  
 spinnerstown, pennsylvania 18968  
 215-536-4110  
 Project Number: MB 78-3162 D  
 Date received : 10/02/78  
 Test started : 10/24/78  
 Test ended : 11/07/78  
 Description : Dark Brown Powder

Code Number : 5002-00  
 Product Name : Bismark Brown R  
 Concentration : 125%  
 Mix Number : 124  
 TR Number : 78-611

CG Name: Brown AT Conc.  
 CG No.: 44-175701-129-0

This study was designed to determine ocular irritation potential of a material when instilled in the rabbit eye.

Six New Zealand White rabbits weighing approximately 2.5 kg were housed individually in suspended wire mesh cages in temperature and light controlled rooms. Purina rabbit chow and water were available ad libitum.

The rabbits were equilibrated in this laboratory for at least seven days. Rabbits with irritated or damaged eyes were not used in this test.

The test material (0.1 ml liquid or 0.1 g solid) was instilled in the lower conjunctival sac of one eye of each rabbit and the lids held closed for approximately one second to insure even distribution of the test material over all surfaces of the eye. The other eye served as an untreated control.

The eyes were examined and graded for irritation and corneal damage at 1, 24, 48 and 72 hours after instillation. Eyes not returning to a score of zero by 72 hours were graded on the seventh day after instillation. Eyes still not returning to a score of zero were graded on the fourteenth day after instillation. All eyes were examined by applying 1 drop of 2% fluorescein sodium ophthalmic solution, U.S.P., to the cornea pre-test, 24, 72 hours and 7 and 14 days after instillation. The fluorescein is rinsed from the eye with physiological saline.

The ocular reactions were graded and interpreted as described in "Appraisal of the Safety of Food, Drugs, and Cosmetics", Association of Food and Drug Officials of the United States, 1959 with the assistance of the "Illustrated Guide for Grading Eye Irritation by Hazardous Substances". A copy of the score and interpreting system is attached.

The individual scores are presented on the attached pages.

The mean daily scores are:

Hour 1	28.7
Day 1	67.8
Day 2	67.7
Day 3	63.0
Day 7	47.7
Day 14	36.0

CLASSIFICATION: Extremely irritating.

Respectfully submitted,

*Oscar M. Moreno*  
 Oscar M. Moreno, Ph.D.  
 President

12/04/78



Rabbit Eye Irritation Study  
Individual Daily Scores

Project #: MB 78-3162D  
Material: 5002-00  
Page 2

An.No.	Item	Tissue	Reading	Day					
				Hour 1	1	2	3	7	14
1	A	Cornea	Opacity	3	4	4	4	4U	4U
	B		Area	1	4	4	3	2	2
		1.	Cornea Total = (AxB) x 5	15	80	80	60	40	40
	C	Iris		1 <sup>r</sup>	?	?	2 <sup>r</sup>	2 <sup>r</sup>	2 <sup>r</sup>
		2.	Iris Total = C x 5	5			10	10	10
	D	Conjunctiva	Redness	A	2*	2*	3*	3	3
	E		Chemosis	2	4	4	3	3	3
	F		Discharge	3	3	3	3	2	2
		3.	Conjunctiva Total = (D+E+F) x 2	10	18	18	18	16	16
		Totals added = 1 + 2 + 3			30	98	98	88	66
	UV Fluorescein scan				4		3	2	2
2	A	Cornea	Opacity	0	B	3	4	4	4
	B		Area	0	B	2	2	1	1
		1.	Cornea Total = (AxB) x 5	0		30	40	20	20
	C	Iris		1 <sup>r</sup>	B	1 <sup>r</sup>	1 <sup>r</sup>	1 <sup>r</sup>	0 <sup>r</sup>
		2.	Iris Total = C x 5	5		5	5	5	0
	D	Conjunctiva	Redness	A	2* <sup>w</sup>	3*	3*	2	1
	E		Chemosis	3	4	3	3	2	2
	F		Discharge	3	3	3	3	1	2
		3.	Conjunctiva Total = (D+E+F) x 2	12	18	18	18	10	10
		Totals added = 1 + 2 + 3			17	18	53	63	35
	UV fluorescein scan				B		1	0	1
3 V	A	Cornea	Opacity	2	4	3	3+	3+	0+
	B		Area	3	2	2	2	2	0
		1.	Cornea Total = (AxB) x 5	30	40	30	30	30	0
	C	Iris		1 <sup>r</sup>	1 <sup>r</sup>	1 <sup>r</sup>	1 <sup>r</sup>	1 <sup>r</sup>	0 <sup>r</sup>
		2.	Iris Total = C x 5	5	5	5	5	5	0
	D	Conjunctiva	Redness	A	2*	2*	2*	2	1
	E		Chemosis	2	4	3	3	2	2
	F		Discharge	3	3	2	2	1	1
		3.	Conjunctiva Total = (D+E+F) x 2	10	18	14	14	10	8
		Totals added = 1 + 2 + 3			45	63	49	49	45
	UV fluorescein scan				2		0	0	0

U = ulceration

r = areas of iris - red/orange

? = unable to determine due to extreme opacity

A = unable to determine due to color of material

\* = material remaining in eye

Rabbit Eye Irritation Study  
Individual Daily Scores

Project #: MB 78-3162D  
Material: 5002-00  
Page 3

An.No.	Item	Tissue	Reading	Hour					
				1	1	2	Day		7
4	A	Cornea	Opacity	2	4	3	3+	4	4
	B		Area	2	4	3	2	2	2
		1.	Cornea Total = (AxB) x 5	20	80	45	30	40	40
	C	Iris		1 <sup>r</sup>	?	1	1	2	1
		2.	Iris Total = C x 5	5		5	5	10	5
	D	Conjunctiva	Redness	A	A*	3*	3*	3	2
	E		Chemosis	2	4	4	3	3	3
	F		Discharge	3	3	3	2	2	2
		3.	Conjunctiva Total = (D+E+F) x 2	10	14	20	16	16	14
		Totals added = 1 + 2 + 3			35	94	70	51	66
	UV Fluorescein scan				3		2	1	1
5	A	Cornea	Opacity	2	4	4	4	4	C
	B		Area	2	3	4	3	s	3
		1.	Cornea Total = (AxB) x 5	20	60	80	60	20	15
	C	Iris		1 <sup>r</sup>	?	?	2	2	d
		2.	Iris Total = C x 5	5			10	10	
	D	Conjunctiva	Redness	A	A*	3*	3*	3	2
	E		Chemosis	2	4	4	3	3	3
	F		Discharge	3	3	3	3	2 <sup>o</sup>	3
		3.	Conjunctiva Total = (D+E+F) x 2	10	14	20	18	16	16
		Totals added = 1 + 2 + 3			35	74	100	88	46
	UV fluorescein scan				4		2	2	2
6	A	Cornea	Opacity	0	2	3	4	4	4
	B		Area	0	3	1	1	1	1
		1.	Cornea Total = (AxB) x 5	0	30	15	20	20	20
	C	Iris		0	2	1 <sup>r</sup>	1 <sup>r</sup>	0 <sup>r</sup>	0
		2.	Iris Total = C x 5	0	10	5	5	0	0
	D	Conjunctiva	Redness	A	3 <sup>C</sup>	3 <sup>C</sup>	2	1	0
	E		Chemosis	3	4	3	3	2	1
	F		Discharge	2	3	2	2	1	0
		3.	Conjunctiva Total = (D+E+F) x 2	10	20	16	14	8	2
		Totals added = 1 + 2 + 3			10	60	36	39	28
	UV fluorescein scan				3		1	1	1

+ = tiny brownish orange spots on cornea      A = unable to determine due to color of material  
r = areas of iris - red/orange  
? = unable to determine due to extreme opacity and area      \* = material remaining in eye  
FOOTNOTES CONTINUED ON BACK OF PAGE

SCALE OF SCORES FOR GRADING THE SEVERITY OF OCULAR LESIONS\*

OCULAR TISSUE	DESCRIPTION	GRADING	
CORNEA	A. OPACITY - Degree of Density - Area which is most dense is read	1	
	Scattered or diffuse area, details of iris clearly visible	2	
	Easily discernible translucent areas, details of iris slightly obscured	3	
	Opalescent areas, no details of iris visible, size of pupil barely discernible	4	
	Opaque, iris invisible		
	B. AREA OF CORNEA INVOLVED	1	
	One quarter or less but not zero	2	
	Greater than one quarter but less than one half	3	
	Greater than one half but less than three quarters	4	
	Greater than three quarters, up to whole area		
SCORE: A x B x 5 Total Maximum = 80			
IRIS	A. VALUES		
	Folds above normal, congestion, swelling, circumcorneal injection (any or all or 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: A x 5 Total Maximum = 10		
CONJUNCTIVA	A. REDNESS (refers to palpebral conjunctiva only excluding cornea and iris)		
	Vessels definitely injected above normal	1	
	More diffuse, deeper crimson red, individual vessels not easily discernible	2	
	Diffuse beefy red	3	
	B. CHEMOSIS		
	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	
	C. DISCHARGE		
Any amount different from normal (does not include 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: (A + B + C) x 2 Total Maximum = 20			

\*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

RATING OF TEST MATERIALS BASED ON EYE IRRITATION PROPERTIES\*

RATING	RANGE	DEFINITION
Non-irritating	0 - 0.5	To maintain this rating all scores at the 24 hour reading must be zero; otherwise, increase rating 1 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 1 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 1 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 1 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 the 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 1 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 scores 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 1 level.
Extremely Irritating	Greater than 80.0 - 110.0	

\*Kay, J.H., Calandra, J.C., J. Soc. Cos. Chem., 13:281 - 289, 1962.

SCALE OF SCORES FOR ULTRAVIOLET FLUORESCENCE SCAN

Reading	Grade
Negative	0
Positive with an area one quarter or less	1
Positive with an area greater than one quarter but less than one half	2
Positive with an area greater than one half but less than three quarters	3
Positive with an area greater than three quarters, up to whole area	4



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

MAY 08 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" .

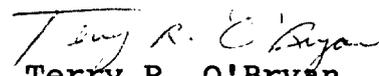
All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

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

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

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  
Risk Analysis Branch

Enclosure

12315A



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**Triage of 8(e) Submissions**

Date sent to triage: MAY 09 2007

NON-CAP

CAP

Submission number: 123/5A

TSCA Inventory: D N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO                      AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX                      SBTOX                      SEN                      w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX                      CTOX                      EPI                      RTOX                      GTOX  
STOX/ONCO                      CTOX/ONCO                      IMMUNO                      CYTO                      NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY**

<b>For Contractor Use Only</b>	
entire document <u>0</u> 1 2	pages <u>1,2</u> pages <u>1,2</u>
Notes:	
Contractor reviewer: <u>PM</u>	Date: <u>5/24/05</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:

Submission # 8EHQ-1192-12315 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 CONCERNS
- 0404 LABEL/MSDS CHANGES
- 0405 PROCESS/HANDLING CHANGES
- 0406 APP/USE DISCONTINUED
- 0407 PRODUCTION DISCONTINUED
- 0408 CONFIDENTIAL

SUB. DATE: 10/09/92 OTS DATE: 11/02/92 CSRAD DATE: 03/14/95

CHEMICAL NAME:

Brown AT Conc.  
Bismark Brown R

CAS#

none  
none  
5421-66-9

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	<u>0243</u> 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. OCCC/REL/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	<u>0223</u> RESPONSE REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	<u>0224</u> 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
<u>0211</u> CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
<u>0212</u> ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0239 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA NON-CBI INVENTORY

YES

CAS SR NO

IN TERMINI

ONGOING REVIEW

YES (DROP/REFER)

NO (CONTINUE)

REFER

SPECIES

RBT

TOXICOLOGICAL CONCERN:

LOW

MED

HIGH

USE:

PRODUCTION:

UNCLASSIFIED

-CPSS- 0927952113

0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>

8(E)-12315A

> <TOX CONCERN>

M

> <COMMENT>

EYE IRRITATION IN RABBITS IS MEDIUM CONCERN. 0.1 ML OF LIQUID OR 1.0 G OF SOLID TEST MATERIAL WAS PLACED INTO THE LEFT EYE OF 6 RABBITS. THE TEST MATERIAL IS CONSIDERED TO BE EXTREMELY IRRITATING WITH A MEAN IRRITATION SCORE OF 67.8 AT DAY 1. OBSERVATIONS INCLUDED POSITIVE CORNEAL (5/6), IRIDIAL (2/5), AND CONJUNCTIVAL (6/6) SCORES. CLINICAL SIGNS INCLUDED REDNESS, CHEMOSIS, AND DISCHARGE OF THE CONJUNCTIVA, RED/ORANGE AREAS OF THE IRIS, AND ULCERATIONS OF THE CORNEA.

\$\$\$\$