

CIBA-GEIGY

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

(A)

DOCUMENT RECEIPT OF

92 SEP 10 PM 1:21

8EHQ-92-12128
INIT
88920010366

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:

Benzenesulfonic acid, 4-{{5-methoxy-4-{{(4-methoxyphenyl)azo}-2-methylphenyl}azo}-, sodium salt;

also identified as:

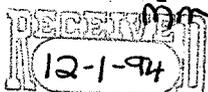
Acid Orange 2GN 100%

CAS No.: 68555-86-2

Report Title: Determination of the Approximate Lethal (Oral) Dose of Acid Orange 2GN 100%, Mix 12, 1201-00 (Report No. 49, UM No. 87, dated 1/31/77)

Summary:

Ten male and eleven female rats were treated with single oral doses ranging from 0.037 to 4.7 gm/kg. All animals survived doses up to 0.08 gm/kg whereas mortality was observed at doses



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Textile Products Division

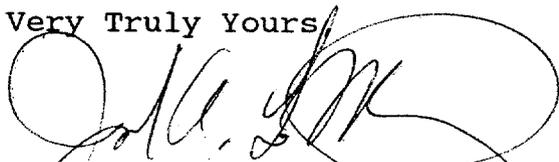
of 0.12 to 4.7 gm/kg. Lethargy, respiratory difficulties and asphyxial convulsions were observed. The approximate lethal dose was estimated to be 0.12 gm/kg. This report is submitted based on high acute oral toxicity potential of the test material.

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

Mailing Address:
RESEARCH AND TEACHING CENTER
OF TOXICOLOGY
SCHOOL OF MEDICINE
P. O. BOX 248216

Location:
SOUTH CAMPUS
BUILDING 6

Determination of the Approximate Lethal (Oral) Dose
of
Acid Orange 2GN, 100%, Standard Mix 12, 1201-00
(TRC 76-1016, UM 87)

Determination of the Approximate Lethal (oral) Dose
(ALD) by the method of Deichmann and LeBlanc (J. Ind.
Hyg. 25, 415, 1943), using nonstarved Osborne-Mendel
rats.

The material was administered as a 20% solution in 1% aqueous
carboxymethylcellulose. The surviving animals were discarded 14 days
after treatment.

No. of Rats Treated	Sex	Weight of Rats gm	Dose of Compound gm/kg	Fate of Animals	<u>A L D</u>
1	M	210	0.037	All rats survived	
1	F	170	0.037		
1	M	195	0.055		
1	F	170	0.055		
1	M	175	0.08		
1	F	155	0.08		
1	M	165	0.12		
1	F	152	0.12	Survived	
1	M	230	0.18	Died in from 5 to 22 hrs.	
1	F	168	0.18		
1	M	228	0.28		
1	F	189	0.28		
1	M	260	0.42		
1	F	190	0.42		
1	F	190	0.62		
1	F	203	0.62		
1	M	243	0.94		
1	F	185	2.1		
1	M	233	3.2		
1	F	163	4.7		
1	M	227	4.7		

The compound produced lethargy, followed by respiratory difficulties (increased rate of respiration followed by dyspnea) and asphyxial convulsions. Post mortem examination revealed marked hyperemia and hemorrhagic areas in the lungs, and a markedly congested liver.

The acutely lethal oral dose (ALD) of this compound administered as a 20% solution in 1% aqueous carboxymethylcellulose is 0.12 gm/kg, which, according to the "Tabulation of Toxicity Classes" following administration of a single oral dose to rats places this compound in the MODERATELY TOXIC group of chemicals.



Wm. B. Deichmann, PhD, MD(hon)
Professor of Pharmacology

WBD:bj

1/31/77



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

e Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances Compliance
Toxicology, Regulatory Auditing & Compliance
CIBA-GEIGY Corporation
444 Saw Mill River Road
Ardsley, New York 10502-2699

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

FEB 13 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
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12128A



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Triage of 8(e) Submissions

Date sent to triage: MAR 08 1995

NON-CAP

CAP

Submission number: 12128A

TSCA Inventory:

Y

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

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entire document: <u>0</u>	pages <u>1</u> - <u>4</u>
Notes:	
Contractor reviewer: <u>LPS</u>	Date: <u>1/25/95</u>

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8(e)-12128A

> <TOX CONCERN>

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> <COMMENT>

ACUTE ORAL TOXICITY IN RATS IS MEDIUM CONCERN. THE ALD IS 0.12 G/KG. ANIMALS (2/DOSE) WERE GIVEN NONLETHAL DOSAGES OF 0.037, 0.055, AND 0.08 G/KG; 1 OUT OF 2 DIED AT 0.12 G/KG; AND LETHAL DOSAGES OF 0.18, 0.28, 0.42, 0.62, AND 4.7 G/KG. 1 ANIMAL/DOSE WAS EXPOSED TO LETHAL DOSE LEVELS OF 2.1 AND 3.2 G/KG. CLINICAL SIGNS INCLUDED LETHARGY, INCREASED RESPIRATION RATE FOLLOWED BY DYSPNEA, AND ASPHYXIAL CONVULSIONS. AUTOPSY REVEALED MARKED HYPEREMIA AND HEMORRHAGIC AREAS IN THE LUNGS, AND A MARKEDLY CONGESTED LIVER.

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