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CIBA GEIGY CORP

Contractor

HAZLETON LABORATORIES

Document Title

LETTER FROM CIBA-GEIGY CORPORATION TO US EPA REGARDING ORAL GAVAGE STUDY IN THE RAT WITH 40% 2-PROPENOIC ACID MIXTURE WITH ATTACHMENT

Chemical Category

2-PROPENOIC ACID

CIBA-GEIGY Corporation
Ardsley, New York 10502-2699
Telephone 914 478 3131

CIBA-GEIGY

OTS Receipt 1/23/90

4-pages

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January 19, 1990

Document Processing Center (TS-790)
(Attn.: Section 8(e) Coordinator
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, SW
Washington, DC 20460

RE.: TSCA 8(e) Notice; CAS Registry No. 71050-62-9

Dear Sir or Madam:

CIBA-GEIGY Corporation claims the trade names and portion of the mixture bracketed in this letter and its attachment as Confidential Business Information. A sanitized copy of this letter is enclosed for the public file.

In accordance with EPA's March 16, 1978 policy statement on Section 8(e) reporting under the Toxic Substances Control Act, CIBA-GEIGY Corporation wishes to bring to the attention of the Environmental Protection Agency preliminary results from a 90-day oral gavage study in the rat with [ ]. Treatment related signs of osteomalacia associated with hyperphosphaturia and calciuria developed in animals of both sexes by week 8 of the study.

CIBA-GEIGY Limited of Basel, Switzerland, sponsored the above mentioned study, which is being conducted by Hazelton Laboratories, France. As of early December 1989, the study was at week 8 of treatment. Preliminary results were reported by the contractor to CIBA-GEIGY Limited on December 22, 1989. We enclose a copy of these preliminary results (two pages), which were received by CIBA GEIGY Corporation on January 4, 1990. The final report is expected during the second half of 1990.

[ ] is a 40% aqueous solution of 2-propenoic acid, polymer with sodium phosphinate, produced from a [ ] mixture by weight of acrylic acid and sodium hypophosphite (CAS Registry No. 71050-62-9).

This product is used in water treatment applications for calcium (scale) control in boilers. Although [ ] is manufactured in the U.S., all of it is exported to the United Kingdom. A similar product, [ ], which is a 50% aqueous solution of the same active ingredient, is manufactured and sold in the U.S. Additionally, CIBA-GEIGY Corporation submitted a PMN on 6/27/89 for Bellasol S 45/S 49, the sodium salt of the chemical substance in question (PMN No. P89-853).

CIBA-GEIGY Corporation will revise its label and Material Safety Data Sheet to reflect these new findings and notify its workers and customers in accordance with OSHA's Hazard Communication Standard, 29 CFR 1910.1200.

Yours truly,

A. Di Battista

Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances Compliance
Toxicology, Regulatory Auditing & Compliance

AD36.DOC/bt
Attachments

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CIBA-GEIGY LIMITED
CF Product Safety
Dr. H. P. Bernhard, PS 1.2

22. Dezember 1989

13 Week ORL (Gavage) Study in the Rat performed by Hazleton Laboratories France

Preliminary Results at Week 8

Project:	CG 884254, HF 380/560
Test Article:	TK 12964A
Study Title:	13 Week Oral (Gavage) Toxicity Study in the Rat followed by a 4 week free period Treatment
Batch No.:	2 (ARN 806579)
Purity:	40 % W/W

The test material was administered daily by gavage to Sprague-Dawley rats for 8 weeks at dose levels of 100 (group 2) 500 (group 3) and 2500 (mg/kg) (group 4). Dose groups consist of 40 animals (20M/20F). Control (group 1) and top dose (group 4) contain 20 additional animals (M/F) to be kept for a 4 week treatment free period.
The preliminary results of the ongoing study reveale treatment related signs of osteomalacia associated with hyperphosphate- and calciuria developing in animals of both sexes. The values of urinary calcium and inorganic phosphate obtained at week 4 and 8 are given in the attached table.
No significant changes are apparent in blood calcium and phosphate concentrations.
The possible nature of this response is presently under investigation. The full report of the study is expected to be available in July 1990.

PD Dr. H.P. Bernhard

Enclosure (1)

Enclosure (1

STUDY TITLE : TK 12964-A 13 week study in the rat (C.C. n° 88 4254 ; HF n° 380/560)

BLOOD LEVELS

PARAMETER			Group/sex 1M	2M	3M	4M	1F	2F	3F	4F
Ca (mg/l)	WEEK 4	m	99	101	101	106	103	103	103	108
		s	4	3	1	2	3	4	2	2
	WEEK 8	m	105	106	104	107	104	103	105	107
		s	2	2	2	2	3	3	2	2
P (mg/l)	WEEK 4	m	115	108	105	93	86	94	78	86
		s	4	11	8	3	5	6	4	9
	WEEK 8	m	83	80	86	72	57	61	60	61
		s	5	7	7	6	6	3	7	7

URINE ANALYSIS

PARAMETER			Group/sex 1M	2M	3M	4M	1F	2F	3F	4F
Volume (ml)	WEEK 4	m	11.1	10.5	9.6	9.3	6.6	7.4	5.9	5.6
		s	2.1	2.2	2.2	2.1	2.0	2.2	1.2	1.9
	WEEK 8	m	11.9	11.1	11.0	10.8	7.4	7.2	6.5	7.6
		s	2.4	1.0	1.0	3.2	3.2	2.1	1.7	2.7
Ca (mg/24h)	WEEK 4	m	1.57	0.65	0.20	1.84	0.87	1.17	0.32	1.09
		s	1.34	0.60	0.04	1.16	0.89	1.03	0.21	0.96
	WEEK 8	m	0.20	0.22	0.20	1.74	0.41	0.33	0.42	1.03
		s	0.07	0.05	0.11	0.61	0.30	0.17	0.26	0.58
P (mg/24h)	WEEK 4	m	0.52	3.75	9.49	22.84	2.68	1.51	4.65	12.58
		s	0.19	3.36	2.58	7.28	1.97	0.78	2.13	2.74
	WEEK 8	m	7.98	8.55	14.41	28.36	6.83	5.98	9.33	20.87
		s	1.05	1.92	2.75	5.67	4.32	2.77	2.43	2.36

m = mean S = standard deviation

CERTIFICATE OF AUTHENTICITY

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