

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

CIBA-GEIGY

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December 19, 1986

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RETURN RECEIPT REQUESTED

1-28-87
JTB

~~CONFIDENTIAL~~

Non-CBI
Per
Mr. D. Battista
BT
1/23/87

CONTAINS NO CBI

Document Control Officer
Chemical Information Division
Office of Toxic Substances (WH-557)
Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

Re: 28-Day Study in the Rat, Phenidone Derivative

CIBA-GEIGY Corporation wishes to inform the Environmental Protection Agency of certain preliminary information received in a "FLASH REPORT" entitled "TK 12850, 28-Day Study in the Rat". TK 12850 is a test code designation for Irgaform 1266, also known as Dimezone S, which is 4-(hydroxymethyl)-4-methyl-1-phenyl-3-pyrazolidinone, CAS. No. 13047-13-7.

Irgaform 1266 is a phenidone derivative used as a photographic developing agent. We have imported approximately 1,200 lbs. over the past two years, 880 lbs. of which is still in inventory. Three to five major potential customers in the U.S. are already using this chemical substance commercially. Additionally, there are many smaller photographic developing companies which would purchase developer chemicals containing this substance in solution. The total U.S. market for the substance, which has been in use commercially for about 20 years, is about 110,000 lbs.

A copy of the "FLASH REPORT" (in German) is attached, along with an English translation. The "FLASH REPORT" indicates that, in this study Irgaform 1266, has shown a dose-dependent toxic anemia with the formation of inclusion bodies. The animals were treated with 10, 40, and 150 mg/kg by gavage; 10 mg/kg proved to be the "no observable effect level". Spermatogenesis reduction with atrophy of the testicular canals in the highest dose group (150 mg/kg bw.) was also observed.

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The adverse effects in this 28-day study may be reportable under TSCA Section 8(e). However, until we receive and evaluate a full copy of the final report, we cannot judge the true significance of the findings and whether the data are 8(e) reportable. In the interim, we are sending you the preliminary findings in the "FLASH REPORT" for your information.

If you have any questions regarding this submission, please contact me.

Sincerely yours,

A. Di Battista

Anthony Di Battista
Manager, Toxic Substances Compliance
Safety, Health & Ecology

ADIB3/29/bt
Attachments

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Translation

ZF GU
GU 2
Prof. R. Hess

November 6, 1986
R-1066.342-74343

Dr. A. von Schulthess

FLASH REPORT

TK 12850 28-Day Study in the Rat
(850737)

The just prepared report, "Final Report for Audit" shows a dose-dependent toxic anemia with the formation of inclusion bodies, as well as spermatogenesis reduction with atrophy of the testicular canals in the highest dose group (150 mg/kg bw.). The animals were treated with 10, 40, and 150 mg/kg by gavage; 10 mg/kg proved to be the "no observable effect level."

The demonstrated findings, especially the spermatogenesis reduction, are toxicologically significant. They show great similarity to the findings which were obtained for an analogous product (TK 11267, Phenidone, Kodak). (1) Eastman-Kodak notified their product under TSCA 8(e) in 1984.

With friendly greetings,

/sg/ Prof. R. Hess

(1) J. L. O'Donogue, Subchronic Oral Toxicology of 1-Phenyl-3-Pyrazoldine (Phenidone; Acc. No. 902672) in the Rat, Toxicological Sciences, Health and Environment Laboratories, Eastman-Kodak Company, Rochester, New York 14650

cc: Dr. W. Gfeller

BS:ts:1759h

ZF GU

GU 2

PROF. R. HESS

1986

6. November 1986 / bth

R-1066.342 - 74343

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DEC 1 1986

PRODUCT SAFETY
AND ECOLOGY

Herrn Dr. A. von Schulthess

FLASH REPORT

TK 12 850 28-Tage-Studie an der Ratte
(85 0737)

Der soeben zur Vernehmlassung erstellte "Final Report for audit" ergibt das Vorliegen einer dosisabhängigen toxischen Anämie mit Innenkörperbildung, sowie in der höchsten Dosisgruppe (150 mg/kg/K.gew.), Spermatogenesehemmung mit Atrophie der Hodenkanälchen. Die Tiere wurden mit 10, 40 und 150 mg/kg per Schlundsonde behandelt; 10 mg/kg erwies sich als "no observable effect level".

Die vorliegenden Befunde, insbesondere die Spermatogenesehemmung, sind toxikologisch bedeutsam. Sie zeigen grosse Ähnlichkeit mit den Befunden, die mit einem analogen Produkt (TK 11 267, Phenidon, Kodak) erhalten wurden¹. Eastman Kodak hat 1984 ihr Produkt unter TSCA 8^e notifiziert.

Mit freundlichen Grüßen.



Prof. R. Hess

¹ J. L. O'Donogue, Subchronic Oral Toxicology of 1-Phenyl-3-Pyrazolidine (Phenidone; Acc. No. 902672) in the Rat, Toxicological Sciences, Health and Environment Laboratories, Eastman Kodak Company, Rochester, NY 14650

cc. Dr. W. Gfeller