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9/85

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

EPA-OTS

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CIBA–GEIGY

8EHQ-0287-0653 FLWP

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89-870000105

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February 6, 1987

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

Dear Madam/Sir:

Enclosed please find the Material Safety DataSheet and Label that were inadvertantly omitted from our non-confidential February 3,1987,8(e) submission regarding 28-Day Study in the Rat, Phenidone Derivative. (See copy of letter attached)

Sincerely,

Tony Di Battista

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

ADiB/bt
Enclosure

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

CIBA-GEIGY

Febr ary 3, 1987

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Re: TSCA Section 8(e) Notice; 28-Day Study in the Rat, Phenidone Derivative

Dear Madam/Sir:

This letter and the attached toxicity study contain no Confidential Business Information.

On December 19, 1986, CIBA-GEIGY Corporation submitted a "For Your Information" notice based on preliminary findings in a "FLASH REPORT" of a study entitled "TK 12850, 28-Day Study in the Rat". TK 12850 is a test code designation for IRGAFORM 1266, also known commercially 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. The vast majority of this chemical substance used in the U. S. is produced or imported by other companies. CIBA-GEIGY is a very minor supplier to this market.

We have now received and evaluated a copy of the aforementioned final report. In accordance with EPA's March 16, 1978 policy statement on Section 8(e) reporting under the Toxic Substances Control Act, CIBA-GEIGY Corporation herewith submits a copy of the subject 28-day study which indicates that anemia and testicular lesions were the primary effects induced in animals which received the highest doses (40 and 150 mg/kg/day) by gastric intubation. The NOEL was determined to be 10 mg/kg/day.

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Although we are reporting this information under TSCA Section 8(e), CIBA-GEIGY Corporation does not believe that the product constitutes a substantial risk of injury to human health or the environment for the following reasons:

a) The primary effects, while significant, were produced after administration by gastric intubation and mainly had a minimal grade of severity. In addition, the effects may be reversible.

b) Because the product is a skin sensitizer, the recommended handling precautions on our label and Material Safety Data Sheet would result in minimal exposure. These precautions are designed to avoid eye, skin, and inhalation exposure through engineering controls or the wearing of personal protective equipment; i.e. chemical goggles, impervious gloves, and a NIOSH approved respirator, if necessary.

c) Professional X-ray developing is the major use. Developer personnel wear impervious gloves, to the best of our knowledge, when handling the product either neat (powder form) or in solution.

d) The level of this product in commercial developer solutions is only 1 to 2 gms/Liter, i.e. 0.1 to 0.2%.

CIBA-GEIGY Corporation has already revised its MSDS and product label to incorporate the information obtained in this new study. Copies of each are enclosed.

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

ADIB4/03/bt
Attachments
bcc: R. Bernegger
J. Boehle
F. Koschier
M. McCusker
J. Munigle
R. Naidus
J. Schneller
J. Schulze
B. Schwemmer

F. Meier (GU-4, Basle)
A. von Schulthess (KA-2.9, Basle)

MATERIAL SAFETY DATA SHEET

CIBA-GEIGY CORPORATION
PLASTICS & ADDITIVES DIVISION
THREE SKYLINE DRIVE
HAWTHORNE, NEW YORK 105 2

EMERGENCY PHONE NUMBERS:
SAFETY/HEALTH: (914) 347-4700
AFTER HOURS : (800) 334-9481

SECTION I-IDENTITY INFORMATION

IDENTITY (TRADENAME): IRGAFORM 1266

FAMILY/CHEMICAL NAME:
4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-3-PYRAZOLIDINONE
PRODUCT TYPE:
PHOTODEVELOPING AGENT
IMPORTANT:

PLEASE NOTE: REVISION 04 - SECTIONS VI, VIII REVISED.

* *
* THIS MATERIAL WILL NOT BE SOLD FOR USE IN PRODUCTS *
* FOR WHICH PROLONGED CONTACT WITH MUCOUS MEMBRANES OR *
* ABRADED SKIN, OR IMPLANTATION WITHIN THE HUMAN BODY, IS *
* SPECIFICALLY INTENDED. BECAUSE OF THE WIDE RANGE OF *
* SUCH POTENTIAL USES, CIBA-GEIGY CORPORATION IS NOT ABLE *
* TO RECOMMEND THIS MATERIAL AS SAFE AND EFFECTIVE FOR *
* SUCH USES AND ASSUMES NO LIABILITY FOR ANY SUCH USES. *
* *

HAZARD STATEMENT :

* *
* THIS MATERIAL SAFETY DATA SHEET (MSDS) HAS BEEN *
* PREPARED IN COMPLIANCE WITH THE FEDERAL OSHA HAZARD *
* COMMUNICATION STANDARD 29 CFR 1910.1200. *
* THIS PRODUCT IS CONSIDERED TO BE A HAZARDOUS *
* CHEMICAL UNDER THAT STANDARD. *
* *

SECTION II-HAZARDOUS INGREDIENTS

SPECIFIC CHEMICAL NAME:
4-(HYDROXYMETHYL)-4-METHYL-1-PHENYL-3-PYRAZOLIDINONE,
CAS REG. NO. 13047-13-7
TRADE NAME: IRGAFORM 1266
PERCENT: PRODUCT PER SE
EXPOSURE LIMITS:

OSHA PEL: NONE ESTABLISHED
ACGIH TLV: NONE ESTABLISHED
CARCINOGENICITY:
THIS CHEMICAL IS NOT CONSIDERED TO BE CARCINOGENIC BY NTP, IARC, OR OSHA.

SECTION III-PHYSICAL DATA

APPEARANCE:
SOLID.
ODOR:
SLIGHT ODOR.
BOILING POINT:
NOT APPLICABLE.
MELTING POINT:
118-124C
DECOMPOSITION TEMPERATURE:
>130C (UNDER NITROGEN)
EVAPORATION RATE:
NOT APPLICABLE.
PERCENT VOLATILE:
NOT APPLICABLE
VAPOR DENSITY:
NOT APPLICABLE.
VAPOR PRESSURE:
AT 20C, <3 X 10(-7) (MM HG)
SOLUBILITY IN WATER:
AT 20C, 1000 PPM
PH:
NOT DETERMINED.
SPECIFIC GRAVITY:
1.25 (H2O = 1)

SECTION IV-FIRE AND EXPLOSION HAZARD DATA

FLASH POINT:
163F (PENSKY-MARTENS)
FLAMMABLE LIMITS IN AIR-LOWER:
NOT DETERMINED.
FLAMMABLE LIMITS IN AIR-UPPER:
NOT DETERMINED.
NFPA CODE:
NONE.
EXTINGUISHING MEDIA:
CARBON DIOXIDE, FOAM, DRY CHEMICAL, WATER SPRAY.
FIRE FIGHTING PROCEDURES-SPECIAL:
USE SELF-CONTAINED BREATHING APPARATUS.
UNUSUAL FIRE AND EXPLOSION HAZARDS:
DECOMPOSITION AND COMBUSTION PRODUCTS MAY BE TOXIC.

SECTION V-REACTIVITY DATA

STABILITY:

STABLE.
INCOMPATIBILITY:
NONE KNOWN.
HAZARDOUS DECOMPOSITION PRODUCTS:
THERMAL DECOMPOSITION AND BURNING MAY PRODUCE CARBON MONOXIDE, CARBON DIOXIDE AND NITROGEN OXIDES.
HAZARDOUS POLYMERIZATION:
WILL NOT OCCUR.

SECTION VI-HEALTH HAZARD DATA

PRIMARY ROUTES OF EXPOSURE:
DERMAL, INGESTION, AND INHALATION.
ORAL LD50:
(RATS) 1000 MG/KG
DERMAL LD50:
(RATS) >2000 MG/KG
SKIN IRRITATION:
(RABBITS) MINIMAL (DRAIZE SCORE 1/8)
EYE IRRITATION:
(RABBITS) MODERATE (DRAIZE SCORE 20/110)
SENSITIZATION:
(GUINEA PIGS) POSITIVE IN MODIFIED MAXIMIZATION TEST, WITH 2/20 POSITIVE AFTER FIRST CHALLENGE AND 3/19 POSITIVE AFTER SECOND CHALLENGE.
MUTAGENICITY:
AMES TEST: NEGATIVE
SUBCHRONIC ORAL FEEDING STUDIES:
DURING A 28-DAY ORAL (GAVAGE) STUDY IN RATS, DOSES OF 0, 10, 40, AND 150 MG/KG WERE ADMINISTERED. THE 150 MG/KG DOSE PRODUCED TOXIC EFFECT ON THE TESTIS AND BLOOD ANEMIA. THE NO OBSERVABLE EFFECT LEVEL (NOEL) FOR THE ANEMIA WAS 40 MG/KG; THE NOEL FOR THE TESTICULAR EFFECTS WAS 10 MG/KG, WITH MARGINAL EFFECTS SEEN AT THE 40 MG/KG DOSE; THE NOEL FOR THE ANEMIA WITH RELATED EFFECTS WAS 10 MG/KG.
THE ANEMIA WAS DEFINED AS MACROCYTIC AND HYPERCHROMIC ANEMIA WITH HEINZ BODIES WHICH OCCURRED AT 150 MG/KG. RELATED EFFECTS WERE SEEN IN THE SPLEEN WHERE CONGESTION, HEMOSIDEROSIS AND EXTRAMEDULLARY HEMATOPOIESIS WERE SEEN AT 40 AND 150 MG/KG. THE TESTICULAR EFFECTS INCLUDED LEYDIG CELL HYPERPLASIA, SPERMATOGENIC EPITHELIUM ATROPHY WITH A FEW GIANT CELLS AND SPERMATIC GRANULOMAS IN THE EPIDIDYMIS AT 150 MG/KG.
CELLULAR DEBRIS IN THE EPIDIDYMIS WAS PRESENT IN BOTH THE 40 AND 150 MG/KG GROUPS. A LIMITED EFFECT ON THE KIDNEY WAS OBSERVED AT 40 AND 150 MG/KG WHERE THERE WAS A MARGINAL INCREASE IN ORGAN WEIGHT AND A NON-SPECIFIC PARTIALLY PAS-POSITIVE EOSINOPHILIC BODIES IN THE PROXIMAL CONVULATED TUBULE.
SIGNS AND SYMPTOMS OF EXPOSURE-ACUTE/CHRONIC:
WARNING! SENSITIZER - MAY CAUSE SKIN SENSITIZATION OR OTHER ALLERGIC RESPONSES. MAY CAUSE EYE IRRITATION.
BASED UPON THE TEST IN ANIMALS CITED ABOVE, MAY CAUSE BLOOD AND TESTICULAR TISSUE CHANGES.
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:

ALLERGY, ACZEMA; INDIVIDUALS PREDISPOSED TO ANEMIA MAY HAVE CONDITION AGGRAVATED BY OVEREXPOSURE.

EMERGENCY AND FIRST AID PROCEDURES-EYES:
FLUSH EYES WITH WATER FOR AT LEAST 15 MINUTES.
GET MEDICAL ATTENTION.

EMERGENCY AND FIRST AID PROCEDURES-SKIN:
PROMPTLY WASH WITH MILD SOAP AND PLENTY OF WATER.

EMERGENCY AND FIRST AID PROCEDURES-INGESTION:
IF CONSCIOUS, GIVE LARGE QUANTITIES OF WATER. GET MEDICAL ATTENTION.

EMERGENCY AND FIRST AID PROCEDURES-INHALATION:
REMOVE TO FRESH AIR.

EMERGENCY AND FIRST AID PROCEDURES-OTHER:
REMOVE CONTAMINATED CLOTHING AND WASH BEFORE REUSE.

SECTION VII-SPILL OR LEAK PROCEDURES

SPILL PROCEDURES:
SWEEP OR VACUUM AND PLACE INTO CLOSABLE CONTAINER FOR DISPOSAL. WEAR PROTECTIVE EQUIPMENT SPECIFIED BELOW. THOROUGHLY FLUSH RESIDUE WITH WATER.

WASTE DISPOSAL METHODS:
DISPOSE IN ACCORDANCE WITH FEDERAL, STATE AND LOCAL REGULATIONS; INCINERATION RECOMMENDED.

EFFLUENT DATA-BOD:
MODIFIED STURM TEST: NOT BIODEGRADABLE

FISH TOXICITY:
RAINBOW TROUT, LC50 96 H: 32 PPM
ZEBRA FISH, LC50 96 H: 43 PPM

INVERTEBRATE TOXICITY:
DAPHNIA MAGNA, EC50 24 H: 7.1 PPM

SECTION VIII-SPECIAL PROTECTION INFORMATION

VENTILATION:
WORK IN WELL VENTILATED AREAS.

PROTECTIVE GLOVES:
WEAR IMPERVIOUS GLOVES.

EYE PROTECTION:
IN CASES WHERE THERE IS LIKELIHOOD OF EYE CONTACT, WEAR CHEMICAL GOGGLES.

RESPIRATORY PROTECTION:
USE NIOSH APPROVED RESPIRATOR WHERE DUST ARISES FROM USE.

OTHER PROTECTIVE EQUIPMENT:
WEAR COVERALLS.

SECTION IX-SPECIAL PRECAUTIONS

HANDLING PRECAUTIONS:
DO NOT GET IN EYES, ON SKIN OR ON CLOTHING. DO NOT TASTE OR SWALLOW. DO NOT INHALE DUST. USE ONLY WITH ADEQUATE VENTILATION. FOR INDUSTRIAL USE ONLY.

SHIPPING AND STORING PRECAUTIONS:

KEEP CONTAINER TIGHTLY CLOSED WHEN NOT IN USE AND DURING TRANSPORT.

PERSONAL HYGIENE:
WASH THOROUGHLY AFTER HANDLING.

SECTION X- REGULATORY INFORMATION

DOT CLASS:
NOT REGULATED.

DOT NUMBER:
NONE.

RCRA STATUS:
NOT A HAZARDOUS WASTE UNDER RCRA (40 CFR 261).

CERCLA STATUS:
NOT LISTED.

TSCA INVENTORY STATUS:
CHEMICAL COMPONENTS LISTED ON TSCA INVENTORY.

ISSUE DATE: 01/26/87 REVISION: 04
FOR FURTHER HEALTH/SAFETY INFORMATION, CONTACT : BRUCE SCHWEMMER
FOR TECHNICAL INFORMATION CONTACT YOUR TECHNICAL SALES REPRESENTATIVE.

THE INFORMATION AND RECOMMENDATIONS CONTAINED HEREIN ARE BASED UPON DATA BELIEVED TO BE CORRECT. HOWEVER, NO GUARANTEE OR WARRANTY OF ANY KIND EXPRESSED OR IMPLIED IS MADE WITH RESPECT TO THE INFORMATION CONTAINED HEREIN.

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LABEL PA-A 88 IRGAFORM 1266

Read Material Safety Data Sheet Before Handling

WARNING! Sensitizer - May cause skin sensitization or other allergic responses. May cause eye irritation. Blood anemia and toxic effects on the testis were seen in a feeding study conducted in laboratory animals.

Do not get in eyes, on skin, or on clothing. Do not taste or swallow. Do not inhale dust. Wear impervious gloves, and chemical goggles if eye contact is possible. Wear a NIOSH approved respirator, if required. Wash thoroughly after handling. Keep container tightly closed when not in use and during transport. Use with adequate ventilation.

First Aid, in case of contact:

Eyes: Flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Skin: Promptly wash with mild soap and plenty of water.

Inhalation: Remove to fresh air.

Ingestion: If conscious, give plenty of water. Get medical attention.

Clothing: Remove contaminated clothing and wash before reuse.

For Industrial Use Only.

0877h/109 1/22/87 BAS

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