ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-10-17920	88100000249	4/29/10

COMMENTS:

DOES NOT CONTAIN CBI

326542

DuPont Haskell Global Centers
for Health and Environmental Sciences
1090 Elkton Road, P.O. Box 50
Newark, DE 19714-0050

RECEIVED
OPPT CBIC
10 APR 29 AM 11:08

April 28, 2010

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

o-Phenylenediamine
CAS # 95-54-5

This letter is to inform you of the results of an Ames assay with the above referenced test substance. In addition, please find a copy of a report summarizing several acute toxicity studies (acute oral LD50 in male and female rats, acute subcutaneous LD50 in male and female rats, a test for skin compatibility, a mucous membrane irritation assay and skin sensitization with guinea pigs). DuPont became aware of these studies through REACH SIEF activity.

Ames Assay:

The test substance was tested for mutagenicity with the strains TA 100, TA 1535, TA 1537, TA 1538, TA 98 of Salmonella typhimurium and Escherichia coli WP2uvrA. The studies were conducted in the absence and in the presence of a metabolizing system derived from rat liver homogenate. A dose range of 5 different doses from 4 to 2500 µg/plate was used. The test substance proved to be not toxic for most of the bacterial strains at doses up to 2500 µg/plate. The dose level of 2500 µg/plate was chosen as the top dose level for the mutagenicity study.

In the absence of the metabolic activation system the test substance did not show a dose dependent influence in the number of revertants in any of the bacterial strains. In the presence of metabolic activation, treatment of the cells with the test substance resulted in relevant increases in the number of revertant colonies with the Salmonella strains TA 100, TA 1537, TA 1538 and TA 98.

This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, it is submitted as a precautionary measure and because it is information in which EPA may have an interest.

Sincerely,

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

8EHQ-10-17920

8EHQ-0410-17920A

AMK/BPS: clp
(302) 366-5260

Attachment: 10 pages

88100000249

DCN: 88100000249

CONTAINS NO CBI

Chemical Company I
Griesheim Site

Dr. Loskant
Dr. Bakowsky, Griesh. Site

Senders Your name and message from our name/ house call No. 6230 Frankfurt (M) - Hoochst

Pharmaceutical research
Toxicology

Dr. Wgd/B 7585 1.15.1971

Reference

O-Phenylenediamine

Enclosed we send the report about the toxicological examination of your product o-Phenylenediamine.

We have charged the developed expenses to your account NR, 62,059/Chemical Company I, Griesheim with the amount of DM 3.000.

Plant

PHARMA FORSCHUNG TOXIKOLOGIE D 528

Anlage

Chem. Betr.
-Nitro-
JAN. 1971

Dieses Blatt eignet sich zum Pausen auf Ozalid-Lichtpauspapier

Inks Hoechtst Co.

Pharmaceutical Research/Laboratory for tissue and drug toxicology

O-PHENYLENEDIAMINE

Toxicological analysis

Investigation of skin and mucous membrane compatibility
Sensitization experiment

SUMMARY

The analysis of the acute toxicity of o-phenylenediame on male and female SPF Wistar K-rats resulted in the following LD of 50 - values:

Oral LD 50 of male rats 1,418 mg/kg body weight

Oral LD 50 of female rats 1,365 mg/kg body weight

subcutaneous LD 50 of male rats 557 mg/kg body weight

subcutaneous LD 50 of female rats 496 mg/kg body weight

The testing of skin compatibility led only in the Barail test to reactions with injection of the 5% and 1% dilution.

The mucous membrane with application of the 10% dilution presented irritation features in two from five rabbits. The 5% dilution was nonreactive in all rabbits.

Sensitization experiment on guinea pigs: allergenic effect of o-Phenylenediamine could not be determined.

DISCLAIMER

Clariant

This report is the property of Clariant. Its content is confidential and not for general release. It is not allowed to cite and reveal the report or its content to a third party without prior written approval of Clariant.

O-PHENYLENEDIAMINE

We maintained a sample of the above mentioned product for toxicological testing (testing Chemical Company I, Griesheim on 8.20.69). The product is chemical clean and is present as brown, crystalline substance.

The examination carried out:

1. Acute oral toxicity in male rats
2. Acute oral toxicity in female rats
3. Acute subcutaneous toxicity in male rats
4. Acute subcutaneous toxicity in female rats
5. Skin and mucous membrane compatibility in rabbits
6. Sensitization experiments in guinea pigs

Our investigations led to the following results:

1. Acute oral toxicity in male SPF Wistar K-rats:

The product was given in a suspension in starch mucilage in different dosages with the throat probe to male SPF Wistar K-rats in the weight of 80 - 96 g (average yielded 85 g). Per dose 10 rats were used. The rats were given no more fodder at 16 hours before the application. The observation time after the application amounted to 7 days. During this time the rats were given the standard ALTROMIN from Altromin GmbH Lape/Lippe and tap water as fodder.

The determination of the LD50 took place according to the method from KÄHBER.

Results

Dosis mg/kg	Konzentration in %	Anzahl der gestorbenen Tiere/ Anzahl der eingesetzten Tiere
800	10	0 von 10 Ratten
1 000	10	0 von 10 Ratten
1 250	10	4 von 10 Ratten
1 600	10	7 von 10 Ratten
2 000	10	10 von 10 Ratten

The animals died under unbalanced equilibrium, as well as in abdomen and/or lateral within 1 - 24 hours after the application. The section of the dead animals resulted in macroscopically no remarkable findings:

The dose letalis median (LD 50) is to body weight of 1,418 mg/kg.

2. Acute oral toxicity in female SPF Wistar K-rats:

The product was given in a suspension in starch mucilage in different dosages with the throat probe in female SPF Wistar K-rats with a weight of 80 - 132 g (average weight 93 g). Per dose 10 rats were used. The rats were kept with no fodder 16 hours before the application. The observation time after the application, amounted to 7 days. During this time the rats were given the standard ALTROMIN from Altromin GmbH Lape/Lippe and tap water as fodder.

The determination of the LD50 took place according to the method from KÄHBER.

Results

Dosis mg/kg	Konzentration in %	Anzahl der gestorbenen Tiere/ Anzahl der eingesetzten Tiere
630	10	0 von 10 Ratten
1 000	10	0 von 10 Ratten
1 250	10	6 von 10 Ratten
1 600	10	8 von 10 Ratten
2 000	10	9 von 10 Ratten
2 500	10	10 von 10 Ratten

The animals died under unbalanced equilibrium and prone position within 1-24 hours after the application. In the highest dosage (2500 mg/kg body weight) in addition light cramps were observed. The section of the dead animals resulted in macroscopically no remarkable findings.

"The dose letalis median (LD 50) is to body weight of 1,365 mg/kg.

3. Acute subcutaneous toxicity in male SPF Wistar K-rats

The product was dissolved in water (warm) and were subcutaneously injected in different dosages uniquely in the neck area in male SPF Wistar K-rats in the weight from 104 - 160 g (average weight 136 g). Per dose 10 rats were used. The observation time after the application amounted to 7 days. During this time the rats were given the standard ALTROMIN from Altromin GmbH Lape/Lippe and tap water as fodder.

The determination of the LD50 took place according to the method from KÄHBER.

Results

Dosis mg /kg	Konzentration in %	Anzahl der gestorbenen Tiere/ Anzahl der eingesetzten Tiere
400	4	o von 10 Ratten
500	4	2 von 10 Ratten
630	4	9 von 10 Ratten
800	4	10 von 10 Ratten

The animals died the following night after the application under unbalanced equilibrium, accelerated respiration and prone position.

The dose letalis median (LD 50) is to body weight with 5.57 mg/kg.

4. Acute subcutaneous toxicity in female SPF Wistar K-rats:

The product was dissolved in water (warm) and were subcutaneously injected in different dosages uniquely in the neck area in female SPF Wistar K-rats in the weight from 88 - 120 g (average weight 105 g). Per dose 10 rats were used. The observation time after the application amounted to 8 days. During this time the rats were given the standard ALTROMIN from Altromin GmbH Lape/Lippe and tap water as fodder.

The determination of the LD50 took place according to the method from KÄHBER.

Results

Dosis mg/kg	Konzentration in %	Anzahl der gestorbenen Tiere/ Anzahl der eingesetzten Tiere
250	4	0 von 10 Ratten
400	4	0 von 10 Ratten
500	4	6 von 10 Ratten
630	4	10 von 10 Ratten
800	4	10 von 10 Ratten

The animals died at the following night after the application under unbalanced equilibrium, accelerated respiration and prone position.

The dose letalis media (LD 50) is to body weight with 496 mg/kg.

5. Skin and mucosa tolerance in rabbits

As experimental animals per experiment 5 rabbits of the yellow silver race were used. The animals were held in individual cages and fed with ALTROMIN K from Altromin GmbH Alge/Lippe and tap water as standard fodder. For the dilution for all tests 0.9% NaCl solution was used.

a) The examination of the product on skin tolerance took place in the Barail test via intra-cutaneous injection of
0.02 ml 5% -; 1% -; 0; 1% -; 0.01% - and 0.001% solution (warm) into the shaved flank skin. As a control 0.02 ml 0.9% NaCl solution were injected.

Results

The injection of the 5% dilution led all rabbits to present at the injection points a central necroses with red halo. The use of a 1% solution resulted in a complete redness of the injection points. The remaining injections were non-reactive.

b) In a further experiment with 10% and 5% diluted product 5-times in 5 days (Mondays - to Fridays, once daily) in a quantity of over 0,5 ml on the shaved und uninjured flank skin laid on by rabbits.

Results

No aggravated appearance was observed.

c) The mucosa compatibility of the product was examined with the 10% and 5% by unique application of 0.1 each ml diluted sample in the conjunctiva sack at the rabbit eye. Control for possibly arising attraction features took place 1, 3, 7 and 24 hours after the application.

Results

The application of the 10% dilution led only with two from five rabbits for approximately 7 hours to a complete reddening of the conjunctiva skin. The 5% dilution was in all rabbits non-reactive.

6. Sensitization experiments in guinea pigs:

TESTING PROCEDURE:

The experiments were accomplished on 10 young Albino guinea pigs and 10 full-grown Albino guinea pigs (Perbright). The guinea pigs were held to 5 animals in plastic cages on wood shavings. During the experiment and observation time the animals were kept on the standard ALTROMIN MS from Altromin GmbH Lage/Lippe and tap water as fodder. In addition addition greens and carrots were fed.

The mechanically shaving of intact flank skin was treated on a side with 5% an aqueous solution, 3-times per week (Mondays, Wednesdays, Fridays) during 3 weeks (i.e. altogether 9 treatments).

On the other side with beginning of experiment the Barail test was accomplished by intracutaneous injection by 0,02 ml 5 %, 1%, 0.1%, 0.01% .und 0.001% solution. As a control 0.02 ml 0.9% NaCl solution were injected.

At 2 and/or 3 weeks after the last treatment the sides of each 5 young Albino guinea pigs and 5 full-grown Albino guinea pigs was treated l-times with 0,5 ml the 5% solution as well as the Barail test in the above mentioned concentrations examined.

RESULTS:

An allergenic effect of o-Phenylenediamine could not be determined.

Pharmaceutical research toxicology from

Inks Hoechst CO.

Dr. Wgd/Wo
15. 1. 1971

Dr. Scholz

Dr. Weigand

FedEx Express *US Airbill*

FedEx Tracking Number 8715 4863 9661

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records

Date 1-26-10 FedEx Tracking Number 871548639661

Sender's Name [illegible] Phone [illegible]

Company [illegible]

Address [illegible] Dept./Floor/Suite/Room

City [illegible] State [illegible] ZIP [illegible]

2 Your Internal Billing Reference

3 To

Recipient's Name [illegible] Phone [illegible]

Company [illegible]

☐ HOLD Weekday — Print FedEx location address below. **NOT available for** FedEx First Overnight.

☐ HOLD Saturday — Print FedEx location address below. ***Available ONLY for*** FedEx Priority Overnight and FedEx 2Day to select locations.

Address [illegible]

We cannot deliver to PO boxes or PO ZIP codes. Dept./Floor/Suite/Room

Address

Print FedEx location address here if HOLD option is selected

City [illegible] State [illegible] ZIP [illegible]

8715 4863 9661

SPH32

0215

4a Express Package Service * To most locations. ***Packages up to 150 lbs.***

☐ FedEx Priority Overnight — Next business morning * Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected

☐ FedEx Standard Overnight — Next business afternoon * Saturday Delivery NOT available

☐ FedEx First Overnight — Earliest next business morning delivery to select locations * Saturday Delivery NOT available

☐ FedEx 2Day — Second business day * Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected

☐ FedEx Express Saver — Third business day * Saturday Delivery NOT available

4b Express Freight Service ** To most locations. ***Packages over 150 lbs.***

☐ FedEx 1Day Freight — Next business day ** Friday shipments will be delivered on Monday unless SATURDAY Delivery is selected

FedEx 1Day Freight Booking No.

☐ FedEx 2Day Freight — Second business day ** Thursday shipments will be delivered on Monday unless SATURDAY Delivery is selected

☐ FedEx 3Day Freight — Third business day ** Saturday Delivery NOT available

5 Packaging * Declared value limit $500.

☐ FedEx Envelope* ☐ FedEx Pak* — Includes FedEx Small Pak, FedEx Large Pak, and FedEx Sturdy Pak. ☐ FedEx Box ☐ FedEx Tube ☐ Other

6 Special Handling and Delivery Signature Options

☐ SATURDAY Delivery — **NOT available for** FedEx Standard Overnight, FedEx First Overnight, FedEx Express Saver, or FedEx 3Day Freight.

☐ No Signature Required — Package may be left without obtaining a signature for delivery

☐ Direct Signature — Someone at recipient's address may sign for delivery. ***Fee applies.***

☐ Indirect Signature — If no one is available at recipient's address, someone at a neighboring address may sign for delivery. For residential deliveries only. ***Fee applies.***

Does this shipment contain dangerous goods?

One box must be checked

☐ No ☐ Yes — As per attached *Shipper's Declaration* ☐ Yes — Shipper's Declaration *not required* ☐ Dry Ice — Dry ice, 9, UN 1845 ____ x ____ kg

Dangerous goods (including dry ice) cannot be shipped in FedEx packaging or placed in a FedEx Express Drop Box.

☐ Cargo Aircraft Only

7 Payment ***Bill to:***

Enter FedEx Acct. No. or Credit Card No. below.

☐ Sender — Acct. No. in Section 1 will be billed. ☐ Recipient ☐ Third Party ☐ Credit Card ☐ Cash/Check

Total Packages ____ Total Weight ____ lbs. Credit Card Auth ____

†Our liability is limited to $100 unless you declare a higher value. See the current FedEx Service Guide for details.

553

Rev. Date 2/08•Part #158279•©1994–2008 FedEx•PRINTED IN U.S.A.•SRS

fedex.com 1800 GoFedEx 1800 463 3339