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DuPont Specialty Chemicals
1007 Market Street
Wilmington, DE 19898



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SP001 02/13/95

CERTIFIED MAIL--RETURN RECEIPT REQUESTED.

Document Processing Center (7407)
Attention: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460-0001

ORIGINAL



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Dear Coordinator:

8EHQ-93-12761

This letter is in response to EPA's request of December 8, 1994, addressed to Dr. C. F. Reinhardt, MD, Haskell Laboratory, DuPont, asking for information on voluntary actions taken as a consequence of our TSCA section 8(e) filing of November 12, 1993 on o-Toluidine (CAS #95-53-4).

The following actions have been completed or are underway:

1. Based on all available toxicity data, including the new findings, the existing worker exposure limit (Acceptable Exposure Limit, AEL) was reviewed and its validity at 5 ppm, 8- and 12-hr. time weighted average, confirmed. The Unscheduled DNA Synthesis (UDS) assay showed a statistically significant elevation in nuclear grain count over corresponding controls in rat bladder epithelial cells only at the highest dose tested (6000ppm). While this finding triggered the 8(e) notification, no UDS effects were observed at the two lower doses studied (500 and 3000 ppm). Therefore, the existing AEL of 5 ppm, 8- and 12-hr time weighted average, was considered to be sufficiently protective against the potential for this type of genetic damage in humans.
2. The MSDS was updated. It now states that o-Toluidine has caused genetic damage in animals. A copy is attached.
3. Following receipt of additional test results an employee communication was developed for workers at Chambers Works, DuPont's only producing and handling site for o-Toluidine. Site-wide notification was initiated on January 13, 1994 and completed by January 17, 1994. DuPont has since ceased manufacture of o-Toluidine and now only imports the chemical to manufacture 2-Aminotoluene-5-sulfonic acid and for resale into merchant markets.
4. Prior to the conclusion of the UDS assay a biomonitor to measure

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o-Toluidine in urine was developed. This involved extensive pharmacokinetic and analytical chemistry development. Under TSCA 8(d) EPA was notified of the initiation of this work and provided a copy of the final report. However, because DuPont ceased manufacture of o-Toluidine before the method could be validated and lacking a large enough internal cohort to permit validation, the method was offered to a major customer (Goodyear) and to a co-producer (First Chemical Company) for validation studies. A technical paper describing the method has been accepted for publication in "Analytical Toxicology".

5. A 14-day feeding study designed to determine urinary bladder toxicity was completed. A copy of the final report was submitted to EPA under TSCA 8(d) on June 21, 1994.

6. A case-control epidemiology study, comparing bladder cancer incidence rates between DuPont workers exposed to the compound against those who did not handle it and the general population, is in progress. EPA was notified on August 6, 1990, under TSCA 8(d), of the initiation of this study. A copy of the final report will be submitted when it issues.

You may contact me on 302/774-6467 if there are any questions.

Yours truly,



K. D. Dastur
Manager, Product Toxicology
and Chemical Regulations

HAZARDS IDENTIFICATION

Potential Health Effects

Causes eye burns. Causes skin irritation. Harmful if inhaled, swallowed, or absorbed through skin; reduces blood's oxygen carrying capacity. Symptoms may be delayed. May cause cancer based on tests with laboratory animals.

HUMAN HEALTH EFFECTS:

Human health effects of overexposure to the product by eye or skin contact may include eye corrosion with corneal or conjunctival ulceration; or skin irritation with discomfort or rash. Evidence suggests that skin permeation can occur in amounts capable of producing systemic toxicity. By inhalation or ingestion, the effects of overexposure may include nonspecific discomfort such as nausea, headache, or weakness; abnormal kidney function as detected by laboratory tests; abnormal kidney function with bloody urine or flank pain. Higher exposures may cause methemoglobinemia (reduced oxygen carrying capacity of the blood) with headache, weakness, or cyanosis (bluish discoloration of the skin) possibly progressing to dizziness, incoordination, shortness of breath, increased pulse rate, and loss of consciousness.

Results of epidemiology studies do not show a clear association between exposure to o-toluidine and bladder cancer. There have been reports of excess bladder cancer risk in workers exposed to o-toluidine in combination with other dyestuffs and intermediates, although it is not clear which of these materials (or combination) may have accounted for a higher incidence of bladder cancer.

Individuals with preexisting diseases of the cardiovascular system, bone marrow, or kidneys may have increased susceptibility to the toxicity of excessive exposures.

Carcinogenicity Information

The following components are listed by IARC, NTP, OSHA or ACGIH as carcinogens. A "P" indicates a proposed carcinogen.

Material	IARC	NTP	OSHA	ACGIH
o-Toluidine	X	X		X
P-TOLUIDINE				X

Du Pont controls the following materials as potential carcinogens:
o-Toluidine.

FIRST AID MEASURES

First Aid

INHALATION

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SKIN CONTACT

In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Call a physician. Wash contaminated clothing before reuse.

EYE CONTACT

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INGESTION

If swallowed, immediately give 2 glasses of water and induce vomiting. Never give anything by mouth to an unconscious person. Call a physician.

Notes to Physicians

Absorption of this product may lead to the formation of methemoglobin which, in sufficient concentration, causes cyanosis. Thorough cleansing of the entire contaminated area including scalp and nails, is of utmost importance. Moderate cyanosis can be treated by supportive measures such as bed rest and oxygen inhalation. Severe cyanosis may require intravenous injection of methylene blue, one milligram per kilogram of body weight. Cyanocobalamin (Vitamin B12), One milligram intramuscularly, may speed recovery. Intravenous fluids and blood transfusions may be indicated in very severe exposure. Methylene blue is contraindicated if the patient has confirmed or suspected glucose-6-phosphate dehydrogenase deficiency. Ascorbic acid has been suggested in such cases.

FIRE FIGHTING MEASURES

Flammable Properties

Flash Point	: 85 C (185 F)
Method	: SFCC
Flammable limits in Air, % by Volume	
LEL	: 1.5
Autoignition	: 482 C (900 F)

(FIRE FIGHTING MEASURES - Continued)

Actual Autoignition Temperature (AIT) can be affected by the concentration of vapors and oxygen, vapor/air contact time, pressure, volume, catalytic impurities, etc. Process conditions should be analyzed to determine if the AIT's may be higher or lower.

Combustible liquid. Follow appropriate National Fire Protection Association (NFPA) codes.

Extinguishing Media

Small fires: Dry Chemical. Carbon Dioxide (CO₂).

Large fires: Water Spray. Fog. Foam.

Fire Fighting Instructions

Evacuate personnel to a safe area. Keep personnel removed and upwind of fire. Cool tank/container with water spray.

Fight fire from maximum distance. If smoke and fumes cannot be avoided, wear chemical-proof suit with hood and breathing air supply. Run-off from fire may cause pollution.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Accidental Release Measures

Evacuate area and keep upwind of spill. Contain spill with sand or earth dam, soak up with sand or other noncombustible absorbant and transfer to a covered metal container for disposal. Flush area with detergent and water. Water spray may be used to control and disperse vapors. Comply with Federal, State, and local regulations on reporting releases.

The EPA Reportable Quantity is 100 lbs.

HANDLING AND STORAGE

Handling (Personnel)

Do not breathe vapor or mist. Do not get in eyes, on skin, or on clothing. Wash thoroughly after handling.

Storage

Store in a well ventilated place. Keep container tightly closed.

(HANDLING AND STORAGE - Continued)

Store away from heat, sparks, and flame. Keep container upright and handle in a manner to prevent human contact.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Use ventilation that is adequate to keep airborne vapor concentration below the exposure limits.

Personal Protective Equipment

Have available and wear as appropriate for exposure conditions: chemical splash goggles, safety glasses (side shields preferred); face shield; butyl rubber footwear; butyl rubber pants, jacket, apron; neoprene or neoprene coated gloves (for routine work) or butyl rubber gauntlet gloves (for possible liquid contact); or flame resistant work clothing if handling material above its flashpoint; and NIOSH/MSHA approved respiratory protection. If there is potential for direct exposure, wear a chemical proof suit with hood and breathing air supply.

Exposure Guidelines

Exposure Limits

o-Toluidine

PEL (OSHA)	: 5 ppm, 22 mg/m ³ , 8 Hr. TWA, Skin
TLV (ACGIH)	: 2 ppm, 8.8 mg/m ³ , A2, 8 Hr. TWA, Skin
AEL * (Du Pont)	: 5 ppm, 8 Hr. TWA, Skin

Other Applicable Exposure Limits

P-TOLUIDINE

PEL (OSHA)	: None Established
TLV (ACGIH)	: 2 ppm, A2, 8.8 mg/m ³ , A2, Skin 8 Hr. TWA
AEL * (Du Pont)	: None Established

* AEL is Du Pont's Acceptable Exposure Limit. Where governmentally imposed occupational exposure limits which are lower than the AEL are in effect, such limits shall take precedence.

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Boiling Point	: 200 C (392 F) @ 760 mm Hg
Vapor Pressure	: 0.26 mm Hg @ 25 C (77 F) 0.66 mm Hg @ 38 C (100 F)
Vapor Density	: 3.7 (Air=1.0)
Freezing Point	: -16 C (3 F)
Evaporation Rate	: <1 (Butyl Acetate=1.0)
Solubility in Water	: 1.5 WT% @ 25 C (77 F)
pH	: 8 (Water Extract)
Odor	: Aromatic amine
Form	: Oily liquid
Color	: Pale yellow (straw color)
Specific Gravity	: 1.0 @ 20 C (68 F)
Octanol-Water Partition Coefficient:	1.32

STABILITY AND REACTIVITY

Chemical Stability

Stable at normal temperatures and storage conditions.

Incompatibility with Other Materials

Incompatible with oxidizing agents; reacts vigorously with acids.

Decomposition

Decomposes if overheated; may release hazardous nitrogen oxide gases.

Polymerization

Polymerization will not occur.

TOXICOLOGICAL INFORMATION

Animal Data

O-TOLUIDINE

Inhalation 4-hour LC50:	862 ppm in rats
Skin absorption LD50	: 3,250 mg/kg in rabbits
Oral LD50	: 940 mg/kg in rats

The compound is a severe eye irritant and a mild skin irritant. Toxic effects described in animals from a single inhalation exposure included lethargy, prostration, weight loss, labored breathing, tremors and cyanosis. By ingestion, the effects included restlessness, depression,

(TOXICOLOGICAL INFORMATION - Continued)

accelerated respiration, methemoglobinemia, reticulocytosis, and anemia. The effects of repeated ingestion exposures included blood changes (methemoglobinemia, reticulocytosis, erythropenia), congestion of the spleen, and bone marrow hyperplasia.

A carcinogenic response has been noted in some animals. One study suggested an association between skin absorption of o-toluidine and developmental effects in rats. However, because of the lack of detail, the developmental toxicity cannot be evaluated. Tests for reproductive effects in animals have not been performed.

In some tests, o-toluidine produced genetic damage in bacterial and mammalian cell cultures, as well as in tests on animals. In other tests, using the same procedures, no genetic damage was reported. This material has caused genetic damage in animals. It has not been tested for heritable genetic damage.

P-TOLUIDINE

Inhalation 1-hour ALC: >0.64 mg/L in rats
Skin absorption LD50 : 890 mg/kg in rabbits
Oral LD50 : 326 mg/kg in rats

The compound is a severe eye and skin irritant, but is not a skin sensitizer in animals. Toxic effects described in animals from single exposures by inhalation, ingestion, or skin contact include liver, kidney, and bladder effects and irritation of mucosal surfaces. No carcinogenic response has been observed in most animal studies, but a weak carcinogenic response has been observed in one study with mice. Tests in bacterial or mammalian cell cultures demonstrate no mutagenic activity.

ECOLOGICAL INFORMATION

Ecotoxicological Information

Aquatic Toxicity

96-hour LC50, fathead minnows: 1-10 mg/L

DISPOSAL CONSIDERATIONS

Waste Disposal

This material may be a RCRA Hazardous Waste on disposal. Comply with Federal, State, and local regulations. If approved, may be incinerated, sent to an approved hazardous material disposal area, or transferred to a disposal contractor. Very dilute solutions are biodegradable by specially acclimated bacteria.

TRANSPORTATION INFORMATION

Shipping Information

DOT/IMO
Proper Shipping Name : TOLUIDINE
Hazard Class : 6.1
UN No. : 1708
DOT/IMO Label : POISON
Packing Group : II
Reportable quantity : 100 lb (45.4 kg)

Shipping Containers

Tank Cars.
Tank Trucks.
Drums.

REGULATORY INFORMATION

U.S. Federal Regulations

TSCA Inventory Status : Reported/Included.

TITLE III HAZARD CLASSIFICATIONS SECTIONS 311, 312

Acute : Yes
Chronic : Yes
Fire : Yes
Reactivity : No
Pressure : No

HAZARDOUS CHEMICAL LISTS

SARA Extremely Hazardous Substance: No
CERCLA Hazardous Substance : Yes
SARA Toxic Chemical : Yes

Canadian Regulations

CLASS B Division 3 - Combustible Liquid.

(REGULATORY INFORMATION - Continued)

CLASS D Division 1 Subdivision A - Very Toxic Material/Acute Lethality.

CLASS D Division 2 Subdivision A - Very Toxic Material. Carcinogen.

CLASS D Division 2 Subdivision B - Toxic Material. Skin or Eye Irritant.

OTHER INFORMATION

NFPA, NPCA-HMIS

NFPA Rating
Health : 3
Flammability : 2
Reactivity : 0

NPCA-HMIS Rating
Health : 2
Flammability : 2
Reactivity : 0

Personal Protection rating to be supplied by user depending on use conditions.

Additional Information

WARNING:

The State of California lists o-toluidine and p-toluidine as substances known to cause cancer.

The ACGIH has established a BEI (Biological Exposure Indices) for methemoglobin inducers of 1.5% methemoglobin in blood.

The "Skin" notations indicate that ortho and para-toluidine can penetrate skin and mucous membranes. Therefore, control of inhalation alone may not be sufficient to prevent an excessive dose.

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

Responsibility for MSDS : DuPont Chemicals
Address : Engineering & Product Safety
> : P.O. Box 80709, Chestnut Run
> : Wilmington, DE 19880-0709
Telephone : (302) 999-4946

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DuPont
Material Safety Data Sheet

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(Continued)

Indicates updated section.

End of MSDS