



SAFETY DATA SHEETS

According to the UN GHS revision 9

Version: 1.0
Creation Date: July 15, 2019
Revision Date: July 15, 2019

SECTION 1: Identification

1.1 GHS Product identifier

Product name Mitotane

1.2 Other means of identification

Product number -
Other names 2,4'-Ddd; Khlodithan; Chlodithan

1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research use.
Uses advised against no data available

1.4 Supplier's details

Company Shanghai Yien Chemical Technology Co., Ltd
Address Building 6, 28 Yingong Road, Fengxian District, Shanghai
Chemical Industry Zone, Shanghai, 201400, China
Telephone +86-400-133-2688

1.5 Emergency phone number

Emergency phone number +86-400-133-2688
Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

SECTION 2: Hazard identification

2.1 Classification of the substance or mixture

Carcinogenicity, Category 2

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word Warning
Hazard statement(s) H351 Suspected of causing cancer
Precautionary statement(s)
Prevention P203 Obtain, read and follow all safety instructions before use.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
Response P318 IF exposed or concerned, get medical advice.

Storage
Disposal

P405 Store locked up.
P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.

2.3 Other hazards which do not result in classification

no data available

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Mitotane	Mitotane	53-19-0	200-166-6	100%

SECTION 4: First-aid measures

4.1 Description of necessary first-aid measures

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: This compound has been shown to be an inhibitor of adrenal steroid biosynthesis. ACUTE/CHRONIC HAZARDS: This compound is toxic by ingestion, inhalation, and skin absorption. When heated to decomposition it emits toxic fumes. (NTP, 1992)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

If shock or trauma occurs during treatment, administration of exogenous corticosteroids is mandatory to compensate for drug-induced depression of adrenocortical function. Supplemental corticosteroids may also be necessary if acute adrenocortical insufficiency develops during treatment.

SECTION 5: Fire-fighting measures

5.1 Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available. It is probably combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Spill kits containing all materials needed to clean up spills of hazardous drugs should be assembled or purchased. These kits should be readily available in all areas where hazardous drugs are routinely handled. If hazardous drugs are being prepared or administered in a nonroutine area (home setting or unusual patient-care area), a spill kit should be obtained by the drug handler. The kit should include two pairs of disposable gloves (one outer pair of utility gloves and one inner latex pair); low-permeability, disposable protective garments (coveralls or gown and shoe covers); safety glasses or splash goggles; respirator; absorbent, plastic-backed sheets or spill pads; disposable toweling; at least 2 sealable thick plastic hazardous waste disposal bags (prelabeled with an appropriate warning label); a disposable scoop for collecting glass fragments; and a puncture-resistant container for glass fragments. All individuals who routinely handle hazardous drugs must be trained in proper spill management and cleanup procedures. Spills and breakages must be cleaned up immediately according to the following procedures. If the spill is not located in a confined space, the spill area should be identified and other people should be prevented from approaching and spreading the contamination. Wearing protective apparel from the spill kit, workers should remove any broken glass fragments and place them in the puncture-resistant container. Liquids should be absorbed with a spill pad; powder should be removed with damp disposable gauze pads or soft toweling. The hazardous material should be completely removed and the area rinsed with water and then cleaned with detergent. The spill cleanup should proceed progressively from areas of lesser to greater contamination. The detergent should be thoroughly rinsed and removed. All contaminated materials should be placed in the disposal bags provided and sealed and transported to a designated containment receptacle. Spills occurring in the biohazard cabinet should be cleaned up immediately; a spill kit should be used if the volume exceeds 150 ml or the contents of one drug vial or ampule. If there is broken glass, utility gloves should be worn to remove it and place it in the puncture-resistant container located in the biohazard cabinet. The biological safety cabinet, including the drain spillage trough, should be thoroughly cleaned. If the spill is not easily and thoroughly contained, the biological safety cabinet should be decontaminated after cleanup. If the spill contaminates the high efficiency particulate air filter, use of the biological safety cabinet should be suspended until the cabinet has been decontaminated and the high efficiency particulate air filter replaced. Antineoplastic agents

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Commercially available mitotane tablets should be stored in tight, light-resistant containers. Mitotane tablets should be stored at 25 deg C, but excursions to 15 -30 deg C are permitted.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

Biological limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

SECTION 9: Physical and chemical properties and safety characteristics

Physical state	PHYSICAL DESCRIPTION: Colorless powder. (NTP, 1992)
Colour	Crystals from pentane or methanol
Odour	no data available
Melting point/freezing point	76-78°C
Boiling point or initial boiling point and boiling range	398.9°C at 760 mmHg
Flammability	no data available
Lower and upper explosion limit/flammability limit	no data available
Flash point	194.2°C
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 75° F (NTP, 1992)
Partition coefficient n-octanol/water	no data available
Vapour pressure	1.94X10 ⁻⁶ mm Hg at 25 deg C
Density and/or relative density	1.372 g/cm ³
Relative vapour density	no data available
Particle characteristics	no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

no data available

10.3 Possibility of hazardous reactions

O,P'-DDD dehydrohalogenates with strong alkalis. (NTP, 1992) Simple aromatic halogenated organic compounds are very unreactive; halogenated aliphatic compounds are moderately or very reactive. Both subgroups generally become less reactive as more of their hydrogen atoms are replaced with halogen atoms. Materials in this group are incompatible with strong oxidizing and reducing agents. Also, they are incompatible with many amines, nitrides, azo/diazo compounds, alkali metals, and epoxides.

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

no data available

SECTION 11: Toxicological information

Acute toxicity

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

SECTION 12: Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

An estimated BCF of 3,500 was calculated in fish for mitotane(SRC), using an estimated log Kow of 5.9(1) and a regression-derived equation(2). According to a classification scheme(3), this BCF suggests the potential for bioconcentration in aquatic organisms is very high(SRC), provided the compound is not metabolized by the organism(SRC). Mitotane bioaccumulation factors for bivalves in Arcachon Bay, France sampled from were 26.5 in Razer shell; 30.7 in Carpet shell; 28.5 in Mussel; 34.8 in Oyster water; 24.0 in Oysterwater sediment(4).

12.4 Mobility in soil

Using a structure estimation method based on molecular connectivity indices(1), the Koc of mitotane can be estimated to be 1.2×10^5 (SRC). According to a classification scheme(2), this estimated Koc value suggests that mitotane is expected to immobile.

12.5 Other adverse effects

no data available

SECTION 13: Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

SECTION 14: Transport information

14.1 UN Number

ADR/RID: UN3249 (For reference only, please check.)

IMDG: UN3249 (For reference only, please check.)

IATA: UN3249 (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: MEDICINE, SOLID, TOXIC, N.O.S. (For reference only, please check.)

IMDG: MEDICINE, SOLID, TOXIC, N.O.S. (For reference only, please check.)

IATA: MEDICINE, SOLID, TOXIC, N.O.S. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: 6.1 (For reference only, please check.)

IMDG: 6.1 (For reference only, please check.)

IATA: 6.1 (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: II (For reference only, please check.)

IMDG: II (For reference only, please check.)

IATA: II (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No

IMDG: No

IATA: No

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to IMO instruments

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Mitotane	Mitotane	53-19-0	200-166-6
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Not Listed.
Vietnam National Chemical Inventory			Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Not Listed.
Korea Existing Chemicals List (KECL)			Not Listed.

SECTION 16: Other information

Information on revision

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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>

- Germany GESTIS-database on hazard substance, website:
<http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Any questions regarding this SDS, Please send your inquiry to sds@xixisys.com

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