

## Chemical Safety Data Sheet MSDS / SDS

## Mitotane SDS

Revision Date:2024-04-25 Revision Number:1

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****Product identifier**

Product name: Mitotane  
CAS: 53-19-0

**Relevant identified uses of the substance or mixture and uses advised against**

Relevant identified uses: For R&D use only. Not for medicinal, household or other use.  
Uses advised against: none

**Company Identification**

Company: Chemicalbook.in  
Address: 5 vasavi Layout Basaveswara Nilayam Pragathi Nagar Hyderabad, India -500090  
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**SECTION 2: Hazards identification****Classification of the substance or mixture**

Carcinogenicity, Category 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

P405 Store locked up.

### Disposal

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.

### Other hazards which do not result in classification

no data available

## SECTION 3: Composition/information on ingredients

### Substance

Chemical name: Mitotane

Common names and synonyms: Mitotane

CAS number: 53-19-0  
EC number: 200-166-6  
Concentration: 100%

## SECTION 4: First aid measures

### 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.

#### 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)

#### 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: Firefighting measures

### Suitable extinguishing media

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

#### **Specific hazards arising from the chemical**

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

#### **Special protective actions for fire-fighters**

Wear self-contained breathing apparatus for firefighting if necessary.

### **SECTION 6: Accidental release measures**

#### **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.

#### **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.

#### **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**

### **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.

### **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**

### **Control parameters**

#### **Occupational Exposure limit values**

no data available

#### **Biological limit values**

no data available

### **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.

### **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 <sup>3</sup>
Relative vapour density:	no data available
Particle characteristics:	no data available

## SECTION 10: Stability and reactivity

### Reactivity

no data available

### Chemical stability

no data available

### 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.

### Conditions to avoid

no data available

**Incompatible materials**

no data available

**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****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

**Persistence and degradability**

no data available

**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).

**Mobility in soil**

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

#### **Other adverse effects**

no data available

### **SECTION 13: Disposal considerations**

#### **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**

#### **UN Number**

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

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

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

#### **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.)

#### **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.)

**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.)

**Environmental hazards**

ADR/RID: No

IMDG: No

IATA: No

**Special precautions for user**

no data available

**Transport in bulk according to IMO instruments**

no data available

**SECTION 15: Regulatory information**

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

**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.

### **(PICCS)**

Not Listed.

### **Vietnam National Chemical Inventory**

Listed.

### **IECSC)**

Not Listed.

### **Korea Existing Chemicals List (KECL)**

Not Listed.

## **SECTION 16: Other information**

### **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](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/>

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