

Mitotane SDS/MSDS (Safety Data Sheet)

1. PRODUCT AND COMPANY IDENTIFICATION

Product identifier

* Product Name: Mitotane

* Catalog Number: S1732

* CAS Number: 53-19-0

* IUPAC Name: 1,1-dichloro-2-(2-chlorophenyl)-2-(4-chlorophenyl)ethane

Relevant identified uses and uses advised against

* Identified uses: For research and development use only; laboratory chemicals; manufacture of substances.

* Uses advised against: Not for pharmaceutical, household, or other unapproved uses.

Details of the supplier

* Company: Selleck Chemicals

* TollFree: +1 877 796-6397

* Tel: +1 832 582-8158

* Fax: +1 832 582-8590

Emergency telephone number

* Emergency phone #: +1 832 582-8158

2. HAZARDS IDENTIFICATION

2.1 GHS classification in accordance with 29 CFR 1910 (OSHA HCS):

Specific target organ toxicity (single exposure): Category 3. H336

Carcinogenicity: Category 2. H351

Specific target organ toxicity (single exposure): Category 1. H370

Specific target organ toxicity (repeated exposure): Category 1. H372

2.2 GHS Label elements, including precautionary statements

Hazard Pictogram(s)



Signal Word

Danger

Hazard statement(s)

H336: May cause drowsiness or dizziness

H351: Suspected of causing cancer

H370: Causes damage to organs

H372: Causes damage to organs through prolonged or repeated exposure

Precautionary statement(s)

None.

Prevention	P203: Obtain, read and follow all safety instructions before use. P260: Do not breathe dust/fume/gas/mist/vapors/spray. P261: Avoid breathing dust/fume/gas/mist/vapors/spray. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
Response	P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P308+P316: IF exposed or concerned: Get emergency medical help immediately. P318: if exposed or concerned, get medical advice. P319: Get medical help if you feel unwell. P321: Specific treatment (see information on this label and safety datasheet)).
Storage	P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up.
Disposal	P501: P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Mitotane

CAS Number: 53-19-0

PubChem CID: 4211

Molecular formula: C₁₄H₁₀Cl₄

Molecular weight: 320.0 g/mol

IUPAC name: 1-chloro-2-[2,2-dichloro-1-(4-chlorophenyl)ethyl]benzene

3.2 Mixtures

Not applicable (pure substance).

4. FIRST-AID MEASURES

4.1 Description of first aid measures

Inhalation: INHALATION: IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. IMMEDIATELY call a physician and be prepared to transport the victim to a hospital even if no symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater

Skin contact: SKIN: IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. IMMEDIATELY call a hospital or poison control center even if no symptoms (such as redness or irritation) develop. IMMEDIATELY transport the victim to a hospital for treatment after washing the affected areas.

Eye contact: EYES: First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician.

IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.

Ingestion: INGESTION: DO NOT INDUCE VOMITING. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious, do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. IMMEDIATELY transport

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 (Toxicological Information).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Contact a poison control center or physician for severe exposure.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Suitable: Water spray, dry chemical, carbon dioxide (CO₂), alcohol-resistant foam.

Unsuitable: None known.

5.2 Specific hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Wear self-contained breathing apparatus (SCBA) and full protective clothing.

Fight fire from upwind. Cool containers with water spray until fire is extinguished.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate personal protective equipment (see Section 8).

Avoid breathing dust/vapor. Ensure adequate ventilation.

Evacuate personnel to safe areas. Keep people away from and upwind of spill.

6.2 Environmental precautions

Prevent product from entering drains, waterways, or soil.

Contain spill with inert absorbent material.

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/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ If hazardous drugs are routinely prepared or administered in carpeted areas, special equipment is necessary to remove the spill. Absorbent powder should be substituted for pads or sheets and left in place on the spill for the time recommended by the manufacturer. The powder should then be picked up with a small vacuum unit reserved for hazardous drug cleanup. The carpet should then be cleaned according to usual procedures. The vacuum bag should be removed and discarded or cleaned, and the exterior of the vacuum cleaner should be washed with detergent and rinsed before being covered and stored. The contaminated powder should be discarded into a sealable plastic bag and segregated with other contaminated waste materials. Alternatively, inexpensive wet or dry vacuum units may be purchased for this express use and used with appropriate cleaners. All such units are contaminated, once used, and must be cleaned, stored, and ultimately discarded /properly/ ... The circumstances and handling of spills should be documented. Health-care personnel exposed during spill management should also complete an incident report or exposure form. /Antineoplastic agents/

SRP: At the time of review, criteria for land treatment or burial (sanitary landfill) disposal practices are subject to significant revision. Prior to implementing land disposal of waste residue (including waste sludge), consult with environmental regulatory agencies for guidance on acceptable disposal practices.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ All contaminated disposables should be contained in sealable bags for transfer to larger waste containers. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ All bottles must be discarded as contaminated waste after decontamination of the biohazard cabinet. All protective apparel (gown, gloves, goggles, and respirator) should be discarded as contaminated waste. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The contaminated filters must be removed, bagged in thick plastic and prepared for disposal in a hazardous waste dump site or incinerator licensed by the Environmental Protection Agency (EPA). /Antineoplastic agents/

For more Disposal Methods (Complete) data for MITOTANE (8 total), please visit the HSDB record page.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Accidental contamination of the health-care environment, resulting in exposure of personnel, patients, visitors, and family members to hazardous substances, is prevented by maintaining the physical integrity and security of packages of hazardous drugs. 1. Access to all areas where hazardous drugs are stored is limited to specified authorized staff. 2. A method should be present for identifying to personnel those drugs that require special precautions (eg, cytotoxics). One way to accomplish this is to apply appropriate warning labels to all hazardous drug containers, shelves, and bins where the drug products are stored. ... 3. A method of identifying, for patients and family members, those drugs that require special precautions in the

home should be in place. This may be accomplished in the health-care setting, by providing specific labeling for discharge medications, along with written instructions. 4. Methods for identifying shipping cartons of hazardous drugs should be required from manufacturers and distributors of these drugs. 5. Written procedures for handling damaged packages of hazardous drugs should be maintained. Personnel involved in shipping and receiving hazardous drugs should be trained in these procedures, including the proper use of protective garments and equipment. Damaged shipping cartons of hazardous drugs should be received and opened in an isolated area (eg, in a laboratory fume hood, if available, not in a vertical laminar airflow biological safety cabinet used for preparing sterile products). /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Facilities (eg, shelves, carts, counters, and trays) for storing hazardous drugs are designed to prevent breakage and to limit contamination in the event of leakage. Bins, shelves with barriers at the front, or other design features that reduce the chance of drug containers falling to the floor should be used. Hazardous drugs requiring refrigeration should be stored separately from nonhazardous drugs in individual bins designed to prevent breakage and to contain leakage. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Until the reproductive risks (or lack thereof) associated with handling hazardous drugs within a safety program have been substantiated, staff who are pregnant or breast-feeding should be allowed to avoid contact with these drugs. Policies should be in effect that provide these individuals with alternative tasks or responsibilities if they so desire. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The pharmacy should provide access to information on toxicity, treatment of acute exposure (if available), chemical inactivators, solubility and stability of hazardous drugs (including investigational agents) used in the workplace. /Antineoplastic agents/

For more Preventive Measures (Complete) data for MITOTANE (19 total), please visit the HSDB record page.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

SMALL SPILLS AND LEAKAGE: Should a spill occur while you are handling this chemical, FIRST REMOVE ALL SOURCES OF IGNITION, then you should dampen the solid spill material with 60-70% ethanol and transfer the dampened material to a suitable container. Use absorbent paper dampened with 60-70% ethanol to pick up any remaining material. Seal the absorbent paper, and any of your clothes, which may be contaminated, in a vapor-tight plastic bag for eventual disposal. Solvent wash all contaminated surfaces with 60-70% ethanol followed by washing with a soap and water solution. Do not reenter the contaminated area until the Safety Officer (or other responsible person) has verified that the area has been properly cleaned.

STORAGE PRECAUTIONS: You should store this material in a refrigerator. (NTP, 1992)

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

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 °C, but excursions to 15 -30 °C are permitted.

Store away from incompatible materials (see Section 10).

[Note: Specific storage temperature not available in public databases. Refer to supplier Certificate of Analysis (COA) for exact storage conditions.]

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure controls

8.1.1 Occupational exposure limits (OEL)

OSHA PEL: Not established.

ACGIH TLV: Not established.

NIOSH REL: Not established.

No occupational exposure limit values are established for this substance.

Use the lowest feasible exposure level (ALARA principle).

8.1.2 Appropriate engineering controls

Use only in a chemical fume hood or with local exhaust ventilation.

Ensure adequate ventilation to keep airborne concentrations below exposure limits.

8.2 Individual protection measures

8.2.1 Eye/face protection

Wear safety glasses with side shields.

8.2.2 Skin protection

Wear protective gloves. Recommended material: Nitrile rubber.

Wear suitable protective clothing (lab coat).

8.2.3 Respiratory protection

Use NIOSH-approved dust/mist respirator (N95 or higher) if ventilation is inadequate.

8.2.4 Thermal hazards

Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- a) Appearance: O,p'-ddd is a colorless powder. (NTP, 1992)
- b) Odor: No data available
- c) Odor threshold: No data available
- d) pH: No data available
- e) Melting point/freezing point: 171 to 172 °F (NTP, 1992)
- f) Initial boiling point and boiling range: No data available
- g) Flash point: No data available
- h) Evaporation rate: No data available
- i) Flammability (solid, gas): No data available
- j) Upper/lower flammability or explosive limits: No data available
- k) Vapor pressure: 1.94×10^{-6} mm Hg at 25 °C
- l) Vapor density: No data available
- m) Relative density: No data available
- n) Water solubility: less than 1 mg/mL at 75 °F (NTP, 1992)
- o) Partition coefficient: n-octanol/water: Log P (n-octanol/water): 6.2
- p) Auto-ignition temperature: No data available
- q) Decomposition temperature: No data available
- r) Viscosity: No data available
- s) Explosive properties: No data available
- t) Oxidizing properties: No data available

9.2 Other information

Complexity: 248

10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific reactivity hazards identified under normal handling conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions under normal conditions.

10.4 Conditions to avoid

Avoid heat, sparks, open flames, direct sunlight, and moisture.

Avoid strong oxidizing agents, strong acids, and strong bases.

10.5 Incompatible materials

Strong oxidizing agents, strong acids, strong bases.

10.6 Hazardous decomposition products

Thermal decomposition may produce: Carbon monoxide (CO), Carbon dioxide (CO₂), Hydrogen chloride (HCl).

See also Section 5 (Fire-fighting measures) for combustion products.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

No acute toxicity data available.

Skin corrosion/irritation:

No data available.

Serious eye damage/eye irritation:

No data available.

Respiratory or skin sensitization:

No data available.

Germ cell mutagenicity:

No data available.

Carcinogenicity:

Suspected of causing cancer (H351).

Reproductive toxicity:

No data available.

Specific target organ toxicity (single exposure):

H370, H372

Specific target organ toxicity (repeated exposure):

No data available.

Aspiration hazard:

No data available.

11.2 Additional information

Carcinogen classification:

Not directly listed by IARC, but carcinogenicity studies of this DDT metabolite are discussed in connection with DDT (L2151).

Exposure routes:

Oral (L85); about 40% oral Lysodren is absorbed.

Signs and symptoms of exposure:

DDT exposure causes ataxia and abnormal stepping. Acute signs of DDT poisoning include paresthesia after oral ingestion. Studies have shown that a mammal poisoned with DDT-type agents displays periodic persistent tremoring and/or convulsive seizures that are suggestive of repetitive discharges in neurons. These repetitive tremors and seizures can be initiated by tactile and auditory stimuli. (T10)

Data source: Hazardous Substances Data Bank (HSDB) via PubChem.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Mitotane's production and use as in the treatment of adrenal tumors may result in its release to the environment through various waste streams. Mitotane is a metabolite of DDT. If released to air, a vapor pressure of 1.94×10^{-6} mm Hg at 25 °C indicates mitotane will exist in both the vapor and particulate phases in the atmosphere.

Vapor-phase mitotane will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals; the half-life for this reaction in air is estimated to be 90 days. Particulate-phase mitotane will be removed from the atmosphere by wet or dry deposition. Mitotane does not contain chromophores that absorb at wavelengths >290 nm and therefore is not expected to be susceptible to direct photolysis by sunlight. If released to soil, mitotane is expected to be immobile based upon an estimated Koc of 1.2×10^5 . Volatilization from moist soil surfaces is expected to be an important fate process based upon an estimated Henry's Law constant of 8.2×10^{-6} atm-cu m/mole. However, adsorption to soil is expected to attenuate volatilization. Mitotane may not volatilize from dry soil surfaces based upon its vapor pressure. Biodegradation data were not available. If released into water, mitotane is expected to adsorb to suspended solids and sediment based upon the estimated Koc. Volatilization from water surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant. Estimated volatilization half-lives for

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Log P (n-octanol/water): 6.2

Potential for bioaccumulation exists (Log P > 3).

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available.

12.6 Other adverse effects

No other adverse ecological effects identified.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Treatment Methods: Waste material must be disposed of in accordance with national and local regulations. Leave chemicals in original containers and do not mix with other waste. Handle uncleaned containers in the same manner as the product itself.

14. TRANSPORT INFORMATION

14.1 UN number

Not regulated as dangerous goods (research quantities typically exempt).

14.2 UN proper shipping name

Not subject to transport regulations (small quantities for research use).

14.3 Transport hazard class(es)

Not classified as dangerous goods for transport (research quantities).

14.4 Packing group

Not applicable (not regulated as dangerous goods in typical research quantities).

14.5 Environmental hazards

Marine pollutant: No (not classified as environmentally hazardous per GHS).

14.6 Special precautions for user

Transport in original packaging. Ensure containers are tightly sealed.

For bulk or commercial quantities, consult applicable transport regulations (DOT, IATA, IMDG).

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

US EPA / TSCA: Subject to EPA TSCA regulations

EU ECHA / REACH: Not available in public databases.

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

Acute (short-term) health hazard

Chronic (long-term) health hazard

Massachusetts Right To Know Components:

This material contains components subject to the Massachusetts Right to Know Act. See Section 2 for hazard classification.

Pennsylvania Right To Know Components:

This material contains components subject to the Pennsylvania Right to Know Act. See Section 2 for hazard classification.

New Jersey Right To Know Components:

This material contains components subject to the New Jersey Right to Know Act. See Section 2 for hazard classification.

California Prop. 65 Components:

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulatory listings:

- California Safe Cosmetics Program (CSCP) Reportable Ingredient: Hazard Traits - Bioaccumulation; Environmental Persistence; Environmental tox Authoritative List - Canada PBiTs Report - if used as a fragrance or flavor ingredient
- EFSA Legal Basis: Regulation (EC) No 178/2002 (amended)
- FDA Requirements: The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed prescription drug products, incl mitotane, approved on the basis of safety and effectiveness by FDA under sections 505 of the Federal Food, Drug, and Cosmetic Act.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this substance.

For research-use-only compounds, no CSA is required under REACH Annex I.

16. OTHER INFORMATION

Revision Date: 2026/09/08

Further Information: The information provided is believed to be correct but is not exhaustive and should be used only as a guideline based on current knowledge. It does not represent a guarantee of the properties of the product.

Selleck Chemicals Corporation and its Affiliates shall not be held liable for any damage resulting from handling or contact with the product.