

Safety Data Sheet



1. Identification

Product Identifier	Clomiphene Citrate
Other means of identification	
Internal item number	82393-0309
CAS number	50-41-9
Chemical name	Ethanamine, 2-[4-(2-chloro-1,2-diphenylethenyl)phenoxy]-N,N-diethyl-,2-hydroxy-1,2,3-propanetricarboxylate (1:1)
Relevant use and restrictions:	No further information available.
Application of substance:	Active pharmaceutical ingredient.
Manufacturer/Supplier information	
Company name	Pharma Source Direct
Address	8591 Prairie Trail Drive, Ste C-600 Englewood, CO 80112
Website	www.pharmasd.com
Emergency phone number	Infotrac: 1-800-535-5053

2. Hazard(s) Identification

Physical hazards	Not classified	
Health hazards	Reproductive toxicity	Category 1
Environmental hazards	Not classified	
OSHA defined hazards	Not classified	
Label elements		



Signal word	Danger
Hazard statement	May damage fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazards not otherwise classified (HNOC)	None known.
Supplemental information	Pharmacologically active material.

3. Composition/Information on Ingredients

Safety Data Sheet



Substance

Chemical name	Common name and synonyms	CAS number	%
Clomiphene Citrate		50-41-9	100

4. First-aid Measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Reproductive system effects. Pharmacologically active material. Occupational exposure may cause physiological effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically.
General Information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting Measures

Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental Release Measures

Safety Data Sheet



Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

Precautions for safe handling

As a general rule, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure Controls & Personal Protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Safety Data Sheet



Thermal hazards
General hygiene considerations

Wear appropriate thermal protective clothing, when necessary.
Not available.

9. Physical and Chemical Properties

Appearance	Appearance descriptions are general information and not specific to any lot.
Physical state	Solid.
Form	Powder.
Color	White.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	240.8 – 244.4 °F (116 - 118 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	<0.0000001 kPa (77°F (25°C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slightly soluble.
Solubility (other)	Chloroform: Slightly soluble. Methanol: Freely soluble. Ethanol: Soluble. Acetone: Slightly soluble.
Auto-ignition temperature	932°F (500°C)
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Stilbene derivative.
Molecular formula	C ₂₆ H ₂₈ ClNO.C ₆ H ₈ O ₇
Molecular weight	598.08

10. Stability and Reactivity

Safety Data Sheet



Reactivity	The product is stable and non-reactive under normal conditions of use, storage, and transport.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Oxidizing agents.
Hazardous decomposition products	NO _x . Cl ₂ . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological Information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Based on information from therapeutic use, this material may cause: Reproductive effects.

Symptoms related to the physical, chemical, and toxicological characteristics

Hot flashes. Abdominal pain. Bloating. Pelvic pain. Weight gain. Troubled breathing. Decreased urination. Yellow eyes and/or skin. Headache. Vision disturbances. Increased sensitivity of eyes to light. Tiredness. Trouble sleeping. Restlessness. Nervousness. Nausea. Vomiting. Breast pain or tenderness. Dizziness. Breast enlargement. Abnormal uterine bleeding. Mental depression.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product	Species	Test Results
----------------	----------------	---------------------

Clomiphene Citrate (CAS 50-41-9)

Oral

LD50

Rat

5750 mg/kg

Skin corrosion/irritation

Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation

Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about health hazard is incomplete.

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Clomiphene Citrate (CAS 50-41-9)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Safety Data Sheet



Reproductive toxicity	May damage fertility or the unborn child. There have been reports of birth defects and fetal death associated with clomiphene administration in humans, although a direct causal relationship has not been established. The therapeutic use of clomiphene is associated with an increased incidence of multiple births (twinning) and possible premature deliveries, as well as ectopic and heterotopic pregnancy. Clomiphene is intended to stimulate ovulation in women and increase testosterone in men. Increased fertility and adverse effects have occurred with therapeutic use. Studies in rats, mice, and rabbits have shown clomiphene to cause impaired fertility and birth defects or adverse effects in the fetus.
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.
Aspiration hazard	Based on available data, the classification criteria are not met.
Further information	Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological Information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal Considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport Information

Safety Data Sheet



DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

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

Not applicable

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory Information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Clomiphene Citrate (CAS-50-41-9) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Reproductive toxicity

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Clomiphene Citrate
(CAS-50-41-9)

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

Safety Data Sheet



WARNING: This product can expose you to Clomiphene Citrate, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 – CRT: Listed date/Carcinogenic substance

Clomiphene Citrate (CAS 50-41-9) Listed: May 24, 2013

California Proposition 65 – CRT: Listed date/Developmental Toxin

Clomiphene Citrate (CAS 50-41-9) Listed: April 1: 1990

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a))

Clomiphene Citrate (CAS 50-41-9)

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
Unites States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other Information

Disclaimer

The information in this SDS has been compiled from sources considered dependable but has not been independently verified. The company cannot guarantee the accuracy of information herein, and the statements contained should not be considered an official expression. The company will not assume liability for any loss, damage, and/or expense resulting from the use and/or misuse of this product regarding handling, storage, and/or disposal.

Issue date

22 Nov 2023

Safety Data Sheet



Version 1.0
Issued by Pharma Source Direct – Quality Assurance