SAFETY DATA SHEET



1. Identification

Product identifier Chloramphenicol Palmitate Polymorph A

Other means of identification

Catalog number1107503CAS number530-43-8

Chemical name Hexadecanoic acid, 2-[(2,2-dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl) propyl ester,

[R-(R*,R*)]-

Recommended use For analytical laboratory use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company name U. S. Pharmacopeia
Address 12601 Twinbrook Parkway

Rockville

MD

20852-1790 United States

Telephone Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Sensitization, skin Category 1

Carcinogenicity Category 2
Reproductive toxicity Category 1

Specific target organ toxicity, repeated Category 2 (blood, bone marrow)

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement May cause an allergic skin reaction. Suspected of causing cancer. May damage fertility or the

unborn child. May cause damage to organs (bone marrow, blood) through prolonged or repeated

exposure.

Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wear protective

gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be

allowed out of the workplace.

Response If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse. If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

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USP SDS US

Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information

Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Chloramphenicol Palmitate		530-43-8	100
Polymorph A			

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Remove contaminated clothing immediately and wash skin with soap and water. In case of Skin contact

eczema or other skin disorders: Seek medical attention and take along these instructions. For

minor skin contact, avoid spreading material on unaffected skin.

Rinse with water. Get medical attention if irritation develops and persists. Eye contact

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important

symptoms/effects, acute and

delayed

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects. Related material: May cause allergic skin reaction. Reproductive system effects. Bone marrow depression.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Treatment of chloramphenicol overdose may include the following: Administer activated charcoal as a slurry and saline cathartic. Obtain a baseline CBC and ABG (or venous blood gas), and monitor patient closely. Administer vitamins B6 and B12 for neuritis. For hypothermia, rewarm slowly using blankets, warm IV fluids, and/or warmed mist inhalation. Manage anaphylaxis by conventional symptomatic and supportive measures. For toxic bone marrow effects, L-phenylalanine has been administered experimentally. To remove chloramphenicol from plasma, use charcoal hemoperfusion. Hemodialysis is not

effective in removing chloramphenicol.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from **General information**

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

Specific methods

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.

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted. General fire hazards

6. Accidental release measures

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.

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7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, 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

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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

Consider double gloves. 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 disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.
Form Powder.
Color Off-white.

Odor Odorless. Faint odor.

Odor threshold Not available.
pH Not available.

Melting point/freezing point 197.6 - 201.2 °F (92 - 94 °C)

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.

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Vapor pressure < 0.0000001 kPa (77 °F (25 °C))

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Practically insoluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical family Phenethylamine derivative.

Molecular formula C27H42Cl2N2O6

Molecular weight 561.54

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Stable at normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoidContact with incompatible materials.

Incompatible materials Acids. Acid chlorides. Acid anhydrides. Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx, Cl-.

11. Toxicological information

Information on likely routes of exposure

Inhalation Knowledge about health hazard is incomplete.

Skin contact May cause an allergic skin reaction.

Eye contact Knowledge about health hazard is incomplete. **Ingestion** Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics

Related material: Unusual bleeding or bruising. Gastrointestinal disturbances. Pale skin. Sore throat. Fever. Chills. Severe headache. Depression. Unusual tiredness or weakness. Swollen abdomen. Dizziness. Shivering. It is not known if this material causes the same effects.

Information on toxicological effects

Acute toxicity A related material showed low oral toxicity in animals.

Product Species Test Results

Chloramphenicol Palmitate Polymorph A (CAS 530-43-8)

Oral

LD50 Mouse 2640 mg/kg (chloramphenicol palmitate)

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

3

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Carcinogenicity Suspected of causing cancer.

Related material IARC: Group 2A; Probably carcinogenic to humans. It is not known if this

material causes the same effects.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

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US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

May damage fertility or the unborn child. Reproductive toxicity

Based on a related material, may cause: Fetal toxicity. It is not known if this material causes the

same effects.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

May cause damage to organs (blood, bone marrow) through prolonged or repeated exposure.

Based on available data, the classification criteria are not met. **Aspiration hazard**

Pharmaceutical related compound of unknown potency. It is not known if occupational exposure **Further information**

may cause physiological effects.

12. Ecological information

Ecotoxicity

Mobility in soil

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 substance.

Bioaccumulative potential

No data available. 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

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.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

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Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

Classified hazard

categories

Respiratory or skin sensitization

Carcinogenicity

Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

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

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

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)	No
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	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United 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, including date of preparation or last revision

Issue date 12-06-2006 02-10-2021 Revision date

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