

1. Identification

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| Product identifier | Chloramphenicol Palmitate Nonpolymorph A | |
| Other means of identification | | |
| Catalog number | 1107401 | |
| Chemical name | Hexadecanoic acid, 2-[(2,2-dichloroacetyl)amino]-3-hydroxy-3-(4-nitrophenyl) propyl ester, [R-(R*,R*)]- | |
| Recommended use | Specified quality tests and assay use only. | |
| Recommended restrictions | Not for use as a drug. Not for administration to humans or animals. | |
| Manufacturer/Importer/Supplier/Distributor information | | |
| Company name | U. S. Pharmacopeia | |
| Address | 12601 Twinbrook Parkway Rockville MD 20852-1790 US | |
| Telephone | RS Technical Services | 301-816-8129 |
| Website | www.usp.org | |
| E-mail | RSTECH@usp.org | |
| Emergency phone number | CHEMTREC within US & Canada | 1-800-424-9300 |
| | CHEMTREC outside US & Canada | +1 703-527-3887 |

2. Hazard(s) identification

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|-------------------------|---|---------------------------------|
| Physical hazards | Not classified. | |
| Health hazards | Sensitization, skin | Category 1 |
| | Germ cell mutagenicity | Category 2 |
| | Carcinogenicity | Category 1 |
| | Reproductive toxicity | Category 2 |
| | Specific target organ toxicity, repeated exposure | Category 2 (blood, bone marrow) |
| OSHA hazard(s) | Not classified. | |
| Label elements | | |



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| Signal word | Danger |
| Hazard statement | May cause an allergic skin reaction. Suspected of causing genetic defects. May cause cancer. Suspected of damaging 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. Avoid breathing dust. Do not handle until all safety precautions have been read and understood. 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. |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. |
| Hazard(s) not otherwise classified (HNOC) | Not classified. |

3. Composition/information on ingredients

Substance

Hazardous components

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

4. First-aid measures

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| Inhalation | Move to fresh air. Call a physician if symptoms develop or persist. |
| Skin contact | Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention. |
| Eye contact | Rinse with water. Get medical attention if irritation develops and persists. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| Most important symptoms/effects, acute and delayed | May cause allergic skin reaction. Reproductive system effects. Bone marrow depression. |
| Indication of immediate medical attention and special treatment needed | Treatment of chloramphenicol overdose should be symptomatic and supportive and may include the following: 1. Administer activated charcoal as a slurry and saline cathartic. 2. Obtain a baseline CBC and ABG (or venous blood gas), and monitor patient closely. 3. Administer vitamins B6 and B12 for neuritis. 4. For hypothermia, rewarm slowly using blankets, warm IV fluids, and/or warmed mist inhalation. 5. Manage anaphylaxis by conventional symptomatic and supportive measures. 6. For toxic bone marrow effects, L-phenylalanine has been administered experimentally. 7. To remove chloramphenicol from plasma, use charcoal hemoperfusion. 8. Hemodialysis is not effective in removing chloramphenicol. [Meditext 2006] |
| 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

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| Suitable extinguishing media | Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ . |
| 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. |

6. Accidental release measures

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| Personal precautions, protective equipment and emergency procedures | Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment. |
| Methods and materials for containment and cleaning up | Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination. |

7. Handling and storage

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| Precautions for safe handling | As a general rule, when handling USP Reference Standards, 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. Use of a designated area is recommended for handling of potent materials. Wear personal protective equipment. |
| Conditions for safe storage, including any incompatibilities | Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. |

8. Exposure controls/personal protection

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| Biological limit values | No biological exposure limits noted for the ingredient(s). |
| Exposure guidelines | No exposure standards allocated. |

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| Appropriate engineering controls | Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment. |
| Individual protection measures, such as personal protective equipment | |
| Eye/face protection | Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area. |
| Skin protection | |
| Hand protection | Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment. |
| Other | For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination. |
| Respiratory protection | Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134). |
| Thermal hazards | Not available. |
| General hygiene considerations | Handle in accordance with good industrial hygiene and safety practice. |

9. Physical and chemical properties

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| Appearance | White powder. |
| Physical state | Solid. |
| Form | Powder. |
| Odor | Not available. |
| Odor threshold | Not available. |
| pH | Not available. |
| Melting point/freezing point | 190.4 - 192.2 °F (88 - 89 °C) |
| Initial boiling point and boiling range | Not available. |
| Flash point | Not available. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not applicable. |
| 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 at 25 °C |
| Vapor density | Not available. |
| Relative density | Not available. |
| Solubility in water | Practically insoluble. |
| Partition coefficient (n-octanol/water) | Not available. |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |

Other information

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| Chemical family | Phenethylamine derivative. |
| Molecular formula | C27H42Cl2N2O6 |
| Molecular weight | 561.54 |
| Solubility (other) | Freely soluble in acetone; sparingly soluble in alcohol. |

10. Stability and reactivity

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| Reactivity | No reactivity hazards known. |
| Chemical stability | Stable at normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | None known. |
| Incompatible materials | Acids, acid chlorides or anhydrides, and 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

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| Ingestion | Based on available data, the classification criteria are not met. |
| Inhalation | Due to lack of data the classification is not possible. |
| Skin contact | May cause an allergic skin reaction. |
| Eye contact | Due to lack of data the classification is not possible. |

Symptoms related to the physical, chemical, and toxicological characteristics Bland, mild taste. Unusual bleeding or bruising. Diarrhea. Nausea. Vomiting. Pale skin. Sore throat. Fever. Chills. Severe headache. Depression. Unusual tiredness or weakness. Swollen abdomen. Dizziness. Shivering.

Delayed and immediate effects of exposure Hypothermia. Anemia or leukopenia. Inflammation of the peripheral or optic nerve. Low blood pressure. Cardiovascular collapse. Coma.

Medical conditions aggravated by exposure Bone marrow depression. Impaired liver function. Impaired kidney function. Blood disorders. Treatment with cytotoxic drugs or radiation.

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

Skin corrosion/irritation Due to lack of data the classification is not possible.

Serious eye damage/eye irritation Due to lack of data the classification is not possible.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity Suspected of causing genetic defects.

Carcinogenicity May cause cancer. IARC: Group 1; Carcinogenic to humans. NTP: Known to be a human carcinogen.

Reproductive toxicity Suspected of damaging fertility or the unborn child.

Specific target organ toxicity - single exposure Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure May cause damage to organs (blood, bone marrow) through prolonged or repeated exposure.

Aspiration hazard Not classified.

12. Ecological information

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| Ecotoxicity | No ecotoxicity data noted for the ingredient(s). |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulative potential | Not available. |
| Mobility in soil | Not available. |
| Other adverse effects | Not available. |

13. Disposal considerations

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| 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 | Not available. |
| Hazardous waste code | Not available. |

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| Waste from residues / unused products | Dispose of in accordance with local regulations. 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 | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
 Immediate Hazard - Yes
 Delayed Hazard - Yes
 Fire Hazard - No
 Pressure Hazard - No
 Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations 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.

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 |
| 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)

16. Other information, including date of preparation or last revision

Issue date 12-06-2006
Revision date 04-17-2015
Version # 02
Further information Not available.

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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.