


SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME	CHLORAMPHENICOL, USP
PRODUCT CODE	0203
SUPPLIER	MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 661 Route 3, Unit C, Plattsburgh, NY, 12901 6641 N. Belt Line Road, Suite 130, Irving, TX, 75063 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020
EMERGENCY PHONE	CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670
RECOMMENDED USES	Manufacturing and Compounding
RESTRICTIONS ON USE	Not applicable

SECTION 2: HAZARDS IDENTIFICATION

GHS CLASSIFICATION	Acute Toxicity - Oral (Category 5) Carcinogenicity (Category 1A) Sensitization - Skin (Category 1) Sensitization - Respiratory (Category 1) Toxic to Reproduction (Category 1B) Specific Target Organ Toxicity - Repeated Exposure (Category 2) - (bone marrow, blood)
PICTOGRAM	
SIGNAL WORD	Danger
HAZARD STATEMENT(S)	May be harmful if swallowed. May cause cancer. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage fertility or the unborn child. Suspected of causing genetic defects. May cause damage to organs through prolonged or repeated exposure. Repeated exposure may cause skin dryness or cracking.
ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS	

PRECAUTIONARY STATEMENT(S)	Prevention	Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves, protective clothing, eye and face protection and hearing protection. Avoid breathing dust, fume, gas, mist, vapors, and spray. Contaminated work clothing should not be allowed out of the workplace. In case of inadequate ventilation wear respiratory protection.		
	Response	IF SWALLOWED: Get medical help IF EXPOSED OR CONCERNED: Get medical advice. IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse. IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms, get medical help immediately call a poison center or medical professional. Get medical help, if you feel unwell.		
	Storage	Store locked up.		
	Disposal	Dispose of contents and/or container in accordance with local regulations.		
HMIS CLASSIFICATION	Health Hazard	3	Flammability	1
	Reactivity	0	Personal Protection	G

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME	Acetamide, 2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]-, [R-(R*,R*)]-								
BOTANICAL NAME	Not applicable								
SYNONYM	Not applicable								
CHEMICAL FORMULA	C ₁₁ H ₁₂ Cl ₂ N ₂ O ₅								
CHEMICAL FAMILY	Phenethylamine derivative								
CAS NUMBER	56-75-7								
ALTERNATE CAS NUMBER	Not applicable								
MOLECULAR WEIGHT	323.13								
COMPOSITION	<table border="1"> <thead> <tr> <th>CHEMICAL NAME</th> <th>CAS NUMBER</th> <th>EC NUMBER</th> <th>% BY WEIGHT</th> </tr> </thead> <tbody> <tr> <td>CHLORAMPHENICOL</td> <td>56-75-7</td> <td>200-287-4</td> <td>100</td> </tr> </tbody> </table>	CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT	CHLORAMPHENICOL	56-75-7	200-287-4	100
CHEMICAL NAME	CAS NUMBER	EC NUMBER	% BY WEIGHT						
CHLORAMPHENICOL	56-75-7	200-287-4	100						

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT	Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.
IN CASE OF SKIN CONTACT	Wash with soap & water for 15 minutes. If irritation persists seek medical aid.
IF SWALLOWED	Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.
IF INHALED	Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician
MEDICAL ATTENTION AND SPECIAL TREATMENT	Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture.

Short term excursions, temperature excursions as experienced during shipping and warehousing, up to 40 °C are acceptable

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: CHLORAMPHENICOL CAS #: 56-75-7

	Country	Limit value-8 hours		Limit value-Short Term		IDLH	REL	Advisory	Notes
		ppm	mg/m ³	ppm	mg/m ³				
OSHA	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
ACGIH	USA	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
NIOSH	USA	N/L	N/L	N/L	N/L	N/L	N/L	8:12:08 chloramphenicols	IARC Group 2A carcinogen; NTP:Reasonably Anticipated To Be Human Carcinogen; FDA Pregnancy Category C
WEEL	USA	N/L	0.5	N/L	N/L	N/L	N/L	N/A	N/A
HSIS	Australia	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
HSE	UK	N/L	N/L	N/L	N/L	N/L	N/L	N/A	N/A
GESTIS	Latvia	N/L	1	N/L	N/L	N/L	N/L	N/A	N/A

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

 Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³
PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

 USP: ELV: Industrial use: TWA: 0.5 mg/m³
SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

Fine, white to grayish-white or yellowish-white, needle-like crystals or elongated plates.

SOLUBILITY

Slightly soluble in water; freely soluble in alcohol, in propylene glycol, in acetone, and in ethyl acetate.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)	1.14	LOWER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available	MELTING/FREEZING POINT	(149 - 153) ^{°C} , (300.2-307.4) ^{°F} or (150.5 - 151.5) ^{°C} , (302.9-304.7) ^{°F}
PARTICLE CHARACTERISTICS	Not available	OXIDIZING PROPERTY	Not available	pH	4.5 - 7.5 (saturated solution)
RELATIVE DENSITY (WATER = 1)	Not available	SPECIFIC GRAVITY	Not available	UPPER FLAMMABLE/ EXPLOSIVE LIMIT(S)	Not available
VAPOR DENSITY (AIR = 1)	Not available	VAPOR PRESSURE	< 0.0000001 kPa (25 ^{°C})	VISCOSITY	Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY	Not established
CHEMICAL STABILITY	Stable under recommended storage conditions
INCOMPATIBLE MATERIALS	Strong oxidants, acids, acid chlorides, acid anhydrides
HAZARDOUS DECOMPOSITION PRODUCTS	Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chlorides and other gases may occur
HAZARDOUS POLYMERIZATION	Will not occur
POSSIBILITY OF HAZARDOUS REACTION	Not established
CONDITIONS TO AVOID	Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY	Oral: Rat: LD50: (mg/kg): 2500 Dermal: Rabbit LD50: (mg/kg): Not available Inhalation: Rat: LC50: (mg/L/4hr): Not available
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	May cause sensitization by inhalation.
SKIN SENSITIZATION	Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals. May cause sensitization by skin contact.

GERM CELL MUTAGENICITY

Laboratory experiments have shown mutagenic effects.
 Genotoxicity in vitro - rat - Liver- DNA damage
 Genotoxicity in vivo - mouse - Intraperitoneal- Cytogenetic analysis
 Suspected of causing genetic defects. Chloramphenicol induced chromosome aberrations in bone marrow cells of mice but not rats treated in vivo. It induced chromosomal aberrations in plants and in meiotic cells of male mice, sister chromatid exchanges in Syrian hamsters, gene mutations in mouse lymphoma cells, and petite mutations in haploid yeast. Chloramphenicol did not induce sister chromatid exchanges or chromosomal aberrations in human cells, DNA damage in hamster cells, or sex-linked recessive lethal mutations in *Drosophila*. In most studies, it was also not mutagenic to and did not cause DNA damage in *S. typhimurium* or *E. coli* and did not cause DNA damage in bacteria.

CARCINOGENICITY

OSHA CHLORAMPHENICOL is listed.
NTP CHLORAMPHENICOL is listed.
IARC CHLORAMPHENICOL is listed in group 2a (probably carcinogenic to humans).
California Proposition 65 This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

ADDITIONAL CARCINOGENICITY INFORMATION

May cause cancer. There is limited evidence for the carcinogenicity of chloramphenicol in humans. There is inadequate evidence for the carcinogenicity of chloramphenicol in experimental animals.

REPRODUCTIVE TOXICITY

Species: Rat; Dose: 23 GM/KG; Route of Application: Oral; Exposure Time: (1-21D PREG)
 Result: Possible risk of congenital malformation in the fetus.
 Species: Rat; Dose: 2500 MG/KG; Route of Application: Oral; Exposure Time: (9D PREG)
 Result: Effects on Embryo or Fetus: Fetotoxicity (except death, e.g., stunted fetus). Effects on Embryo or Fetus: Other effects to embryo. Specific Developmental Abnormalities: Homeostasis
 Species: Rat; Dose: 2500 MG/KG; Route of Application: Oral; Exposure Time: (11D PREG)
 Result: Specific Developmental Abnormalities: Central nervous system.
 Species: Rat; Dose: 2 GM/KG; Route of Application: Oral; Exposure Time: (8D PREG)
 Result: Effects on Embryo or Fetus: Fetal death.

May damage fertility or the unborn child. Maternal exposure to chloramphenicol may cause toxicity or bone marrow depression in newborns. The offspring of pregnant rats given chloramphenicol at doses of 2000 mg/kg experienced abdominal wall defects or umbilical hernias, with rib fusion. Increased incidences of foreleg, hindleg, and 5th sternebra malformations were observed in the fetuses of pregnant rats treated with 1000 mg/kg or 2000 mg/kg orally and pregnant mice treated with 1000 mg/kg orally. Pregnant rabbits also had offspring which displayed malformation of the foreleg when administered 500 mg/kg of chloramphenicol during pregnancy. Chloramphenicol injected into chick eggs at doses of 0.5 mg resulted in beak, eye, and leg malformations.

Chloramphenicol is excreted in breast milk in concentrations up to 25 ug per mL.

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 through prolonged or repeated exposure.

ASPIRATION HAZARDS

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

SIGNS AND SYMPTOMS OF EXPOSURE
ROUTES OF EXPOSURE:

Ingestion; Skin; Nose

EARLY ONSET SYMPTOMS RELATED TO EXPOSURE:

Bitter taste. Unusual bleeding or Bruising. Diarrhea. Nausea or Vomiting. Swelling of the abdomen. Pale skin. Sore throat. Fever or Chills. Severe headache. Depression. Unusual tiredness or Weakness. Vomiting. Dizziness. Shivering or Hypothermia

DELAYED HEALTH EFFECT FROM EXPOSURE:

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. Blood disorders. Impaired kidney function.

POTENTIAL HEALTH EFFECTS

Inhalation	May be harmful if inhaled. May cause respiratory tract irritation. May cause an allergic reaction.
Ingestion	May be harmful if swallowed.
Skin	May be harmful if absorbed through skin. May cause skin irritation. May cause an allergic reaction.
Eyes	May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION
ECOTOXICITY

EC50: 48 Hr: Crustacea: Shrimp (*Penaeus stylirostris*): (mg/L): > 0.05
 EC50: 48 Hr: Crustacea: *Daphnia magna*: (mg/L): > 0.05
 LC50: 96 Hr: Fish: (mg/L): Not available
 EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Not available

BIOACCUMULATIVE POTENTIAL

LogPow: 1.14

An estimated BCF of <1 suggests the potential for bioconcentration in aquatic organisms is low.

MOBILITY IN SOIL

Water solubility: 2500 mg/L (25°C)

If released to soil, chloramphenicol is expected to have high mobility based upon an estimated Koc of 99. Volatilization from moist soil surfaces is not expected to be an important fate process based upon an estimated Henry's Law constant of 2.3×10^{-18} atm-cu m/mole. If released into water, chloramphenicol is not expected to adsorb to suspended solids and sediment based upon the estimated Koc. Half-lives in marine and freshwater sediment of 2.4 to 18.4 days and <12 days, respectively, indicate that biodegradation may occur in the environment.

OTHER ADVERSE EFFECTS

Not available

This product is not intended to be released into the environment

SECTION 13: DISPOSAL CONSIDERATIONS
DISPOSAL METHODS

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.

SECTION 14: TRANSPORT INFORMATION
UN PROPER SHIPPING NAME

Not dangerous good

UN NUMBER

Not applicable

CLASS

Not applicable

PACKING GROUP

Not applicable

AUSTRALIA
HAZCHEM

Not applicable

EU
TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL 73/78 AND THE IBC CODE

Not listed

ENVIRONMENTAL HAZARDS

Not available

SPECIAL SHIPPING INFORMATION

Not applicable

SECTION 15: REGULATORY INFORMATION
UNITED STATES REGULATIONS

Chemical Name & CAS	CERCLA 40 CFR Part 302.4	SARA (Title III) 40 CFR Part 372.65	EPA 40 CFR Part 355		Pennsylvania	Right-to-know		California Prop 65
			Appendix A	Appendix B		New Jersey	Massachusetts	
CHLORAMPHENICOL 56-75-7	N/L	N/L	N/L	N/L	X	N/L	X	N/L

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

Chemical Name & CAS	Poisons and Therapeutic Goods	Therapeutic Goods Act	Code of Practices - Illicit Drug Precursors	Poisons Standard	Work Health and Safety Regulations	Inventory of Industrial Chemicals
CHLORAMPHENICOL 56-75-7	N/L	Listed as Schedule 4	N/L	Listed	N/L	Listed

N/L = Not Listed

EU REGULATIONS

Chemical Name & CAS	REACH ANNEX XVII	REACH ANNEX XIV	EC 1005/2009	EC 850/2004	EC 1107/2009	PIC - Prior Informed Consent Regulation	EC 2012/18
CHLORAMPHENICOL 56-75-7	N/L	N/L	N/L	N/L	N/L	N/L	N/L

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

SUBJECT TO INTERNATIONAL AGREEMENT

Not applicable

SECTION 16: OTHER INFORMATION
REFERENCES

Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** - American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** - Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** - Chemical Abstract Service; **CERCLA** - Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** - Effective Concentration, 50%; **EPA** - Environmental Protection Agency; **GHS** - Global Harmonized System; **HMIS** - Hazardous Materials Information System; **HSE** - Health and Safety Executive; **HSIS** - Hazardous Substances Information System; **IARC** - International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** - Ready Biodegradability Model; **ISS** - Istituto Superiore Sanità; **LC50** - Lethal Concentration, 50%; **LD50** - Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** - National Institute for Occupational Safety and Health; **NTP** - National Toxicology Program; **OSHA PEL** - Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** - Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** - Superfund Amendments and Reauthorization Act; **STEL** - Short Term Exposure Limit; **TLV** - Threshold Limit Value; **TWA** - Time Weighted Average; **WHMIS** - Workplace Hazardous Materials Information System

LAST REVISION

04/2024

SUPERSEDES

12/2022

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA[®] shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.