

COLCHICINE

GHS Safety Data Sheet

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

COLCHICINE

OTHER NAMES

C22-H25-N-O6, "N-(5, 6, 7, 9-tetrahydro-1, 2, 3, 10-tetramethoxy-9-oxobenzo(alpha)-, heptalen-7-yl)acetamide, "N-acetyl trimethylcolchicinic acid methylether", "benzo(a)heptalen-9(5H)-one, 7-acetamido-6, 7-dihydro-1, 2, 3, 10-tetramethoxy-", colchicin, 7-alpha-H-colchicine, "Colchineos Colchisol Colcin Colsaloid Condylon NSC 757", "alkaloid plant hormone", "acute gout treatment"

PROPER SHIPPING NAME

ALKALOIDS, SOLID, N.O.S. or ALKALOID SALTS, SOLID, N.O.S.(contains colchicine)

PRODUCT USE

Alkaloid obtained from the corm and seeds of the meadow saffron, *Colchicum autumnale* (Liliaceae) and other *Colchicum* spp. Used to induce chromosome doubling in plants; for the relief of pain in acute gout; for treatment of Familial Mediterranean Fever; antineoplastic; laboratory reagent. As used in the treatment of acute gout, colchicine is considered to act against the inflammatory response to the urate crystal; it possesses no analgesic properties nor does it reduce the concentrations of uric acid or effect the rate of uric acid excretion.

SUPPLIER

Company: S D FINE- CHEM LIMITED

Address:

315- 317, T.V.Ind.Estate,

248, Worli Road,

Mumbai- 400030, India

www.sdfine.com

Telephone: 91- 22 24959898/99

Fax: 91- 22 2493 7232

Email: technical@sdfine.com

Section 2 - HAZARDS IDENTIFICATION

GHS Classification

Acute Toxicity Category 2

Acute Toxicity Category 2

Reproductive Toxicity Category 1B



EMERGENCY OVERVIEW

HAZARD

DANGER

Determined by using GHS criteria

H300 Fatal if swallowed.

H330 Fatal if inhaled.

H360 May damage fertility or the unborn child.

PRECAUTIONARY STATEMENTS

Prevention

Code	Phrase
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Section 2 - HAZARDS IDENTIFICATION

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P260	Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash ... thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well- ventilated area.
P281	Use personal protective equipment as required.
P284	Wear respiratory protection.
Response Code	Phrase
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER or doctor/physician.
P320	Specific treatment is urgent (see MSDS).
P330	Rinse mouth.
Storage Code	Phrase
P403+P233	Store in a well- ventilated place. Keep container tightly closed.
P405	Store locked up.
Disposal Code	Phrase
P501	Dispose of contents/container to ...

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
colchicine	64-86-8	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

- IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.
- Urgent hospital treatment is likely to be needed.
- In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.

EYE

- If this product comes in contact with the eyes:
- Immediately hold eyelids apart and flush the eye continuously with running water.
- Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
- Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
- Transport to hospital or doctor without delay.

SKIN

- If skin contact occurs:
- Immediately remove all contaminated clothing, including footwear.
- Flush skin and hair with running water (and soap if available).
- Seek medical attention in event of irritation.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.

NOTES TO PHYSICIAN

- for poisons (where specific treatment regime is absent):

BASIC TREATMENT

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Section 4 - FIRST AID MEASURES

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.

In acute poisoning the stomach should be emptied by aspiration and lavage.

A purgative, such as sodium sulfate 30 g in 250 ml water, should be given.

Demulcent drinks may be given freely. Respiration may require assistance.

The circulation should be maintained and fluid and electrolyte imbalance corrected.

Morphine sulfate, 10 mg intramuscularly, may be given to relieve severe abdominal cramps; atropine has also been given [Martindale].

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.
- Use fire fighting procedures suitable for surrounding area.

FIRE/EXPLOSION HAZARD

- Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).
- Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.
- In the same way as gases and vapours, dusts in the form of a cloud are only ignitable over a range of concentrations; in principle, the concepts of lower explosive limit (LEL) and upper explosive limit (UEL) are applicable to dust clouds but only the LEL is of practical use; - this is because of the inherent difficulty of achieving homogeneous dust clouds at high temperatures (for dusts the LEL is often called the "Minimum Explosible Concentration", MEC).

Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

FIRE INCOMPATIBILITY

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up waste regularly and abnormal spills immediately.
- Avoid breathing dust and contact with skin and eyes.
- Wear protective clothing, gloves, safety glasses and dust respirator.
- Use dry clean up procedures and avoid generating dust.

MAJOR SPILLS

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Prevent, by any means available, spillage from entering drains or water course.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

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COLCHICINE

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.
- Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)
- Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.
- Establish good housekeeping practices.
- Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.

SUITABLE CONTAINER

- Glass container is suitable for laboratory quantities.
- Packaging as recommended by manufacturer.
- Check that containers are clearly labelled.
- Tamper-proof containers.
- Polyethylene or polypropylene containers.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure. <</>.

All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

STORAGE INCOMPATIBILITY

- Avoid strong acids, acid chlorides, acid anhydrides and chloroformates.
- Protect from light.
- Avoid reaction with oxidising agents.

STORAGE REQUIREMENTS

- Store in original containers.
 - Keep containers securely sealed.
 - Store in a cool, dry, well-ventilated area.
 - Store away from incompatible materials and foodstuff containers.
- Store in secure poison area. Refrigerate.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- colchicine:

CAS:64- 86- 8

MATERIAL DATA

COLCHICINE:

■ Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

■ NOTE E: Substances with specific effects on human health that are classified as carcinogenic, mutagenic and/ or toxic for reproduction in categories 1 or 2 are ascribed Note E if they are classified as very toxic (T+), toxic (T) or harmful (Xn). For these substances the risk phrases R20 ,R21, R22, R23, R24,R25, R26, R27, R28, R39, R68, R48 and R65 and all combinations of these risk phrases shall be proceeded by the word "Also".

R45-23: May cause cancer. Also toxic by inhalation

This note applies only to certain complex oil-derived substances in Annex I.

PERSONAL PROTECTION



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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

RESPIRATOR

•Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

EYE

- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent].

HANDS/FEET

■ The selection of the suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:.

- Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Change gloves frequently and when contaminated, punctured or torn.

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.

ENGINEERING CONTROLS

■ For potent pharmacological agents:

Powders

To prevent contamination and overexposure, no open handling of powder should be allowed.

- Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
- In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).

Unless written procedures, specific to the workplace are available, the following is intended as a guide:

- For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets*; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems; Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*.
- HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.
- The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated. Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. When handling: Quantities of up to 25 grams, an approved respirator with HEPA filters or cartridges should be considered; Quantities of 25 grams to 1 kilogram, a half-face negative pressure, full negative pressure, or powered helmet-type air purifying respirator should be considered. Quantities in excess of 1 kilogram, a full face negative pressure, helmet-type air purifying, or supplied air respirator should be considered.

Written procedures, specific to a particular work-place, may replace these recommendations

* For Class II Biological Safety Cabinets, Types B2 or B3 should be considered.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Pale yellow to greenish-yellow odourless or almost odourless crystals or amorphous scales or powder with a hay-like odour when dampened and warmed, and a very bitter taste. Soluble in water, alcohol and chloroform. Darkens on exposure to light.

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Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Mixes with water.

State	Divided solid	Molecular Weight	399.48
Melting Range (°C)	142- 150	Viscosity	Not Applicable
Boiling Range (°C)	Not available.	Solubility in water (g/L)	Miscible
Flash Point (°C)	Not available	pH (1% solution)	5.9 (0.5% soln.)
Decomposition Temp (°C)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°C)	Not available.	Vapour Pressure (kPa)	Not applicable.
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available.
Lower Explosive Limit (%)	Not available.	Relative Vapour Density (air=1)	14.0
Volatile Component (%vol)	Not applicable	Evaporation Rate	Not applicable

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
 - Product is considered stable.
 - Hazardous polymerisation will not occur.
- For incompatible materials - refer to Section 7 - Handling and Storage.*

Section 11 - TOXICOLOGICAL INFORMATION

Health hazard summary table:

Acute toxicity	Acute Tox. (inhal) 2
	Acute Tox. (oral) 2
Skin corrosion/irritation	Not applicable
Serious eye damage/irritation	Not applicable
Respiratory or skin sensitization	Not applicable
Germ cell mutagenicity	Not applicable
Carcinogenicity	Not applicable
Reproductive toxicity	Repr. 1B
STOT- single exposure	Not applicable
STOT- repeated exposure	Not applicable
Aspiration hazard	Not applicable

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Severely toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 5 gram may be fatal or may produce serious damage to the health of the individual.

EYE

■ There is evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation.
Severe inflammation may be expected with pain.

SKIN

■ The material is not thought to be a skin irritant (as classified by EC Directives using animal models).
Abrasive damage however, may result from prolonged exposures.
■ Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ Inhalation of dusts, generated by the material, during the course of normal handling, may produce severely toxic effects; these may be fatal.
■ The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models).
Nevertheless inhalation of dusts, or fumes, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur

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Section 11 - TOXICOLOGICAL INFORMATION

further disability if excessive concentrations of particulate are inhaled.

If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.

CHRONIC HEALTH EFFECTS

■ Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung. Prime symptom is breathlessness; lung shadows show on X-ray.

Colchicine is readily absorbed from the gastro-intestinal tract. Steatorrhoea (fatty stools) and a histiocytic lymphoma in the jejunum (part of small intestine) developed in a 53 year old man after taking 0.5 mg daily for 3 years, as a treatment for gout.

Fatal agranulocytosis and thrombocytopenia, with bone marrow hypoplasia, occurred in a patient who had taken colchicine prophylactically in the recommended doses. Obstructive jaundice could have contributed to the toxicity of the drug. [Martindale]

May cause congenital malformation in the fetus.

In histological studies colchine has been shown to bind specifically with tubulin thus interfering with microtubule organisation and as a result might be an effector in cell division.

TOXICITY AND IRRITATION

■ The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

Section 12 - ECOLOGICAL INFORMATION

This material and its container must be disposed of as hazardous waste.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
colchicine	HIGH	No Data Available	LOW	MED

Section 13 - DISPOSAL CONSIDERATIONS

- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.

- Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction.
- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.
- Where in doubt contact the responsible authority.
- Recycle wherever possible.
- Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
- Dispose of by: burial in a land-fill specifically licenced to accept chemical and / or pharmaceutical wastes or Incineration in a licenced apparatus (after admixture with suitable combustible material)
- Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14 - TRANSPORTATION INFORMATION



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Section 14 - TRANSPORTATION INFORMATION

Labels Required: TOXIC

HAZCHEM:

2X

Land Transport UNDG:

Class or division:	6.1	Subsidiary risk:	None
UN No.:	1544	UN packing group:	I
Shipping Name:ALKALOIDS, SOLID, N.O.S. or ALKALOID SALTS, SOLID, N.O.S. (contains colchicine)			

Air Transport IATA:

ICAO/IATA Class:	6.1	ICAO/IATA Subrisk:	None
UN/ID Number:	1544	Packing Group:	I
Special provisions:	A3		
Cargo Only			
Packing Instructions:	673	Maximum Qty/Pack:	50 kg
Passenger and Cargo			
Packing Instructions:	666	Maximum Qty/Pack:	5 kg
Passenger and Cargo			
Limited Quantity			
Packing Instructions:	Forbidden	Maximum Qty/Pack:	Forbidden

Shipping name:ALKALOIDS, SOLID, N.O.S. or ALKALOID SALTS, SOLID, N.O.S.(contains colchicine)

Maritime Transport IMDG:

IMDG Class:	6.1	IMDG Subrisk:	None
UN Number:	1544	Packing Group:	I
EMS Number:	F- A, S- A	Special provisions:	43 274
Limited Quantities:	0		

Shipping name:ALKALOIDS, SOLID, N.O.S. or ALKALOID SALTS, SOLID, N.O.S.(contains colchicine)

Section 15 - REGULATORY INFORMATION

REGULATIONS

colchicine (CAS: 64-86-8) is found on the following regulatory lists;

"Acros Transport Information","India Hazardous Wastes (Management, Handling and Transboundary Movement) Rules - Schedule 2: List of Wastes Constituents with Concentration Limits","India Manufacture, Storage and Import of Hazardous Chemical Rules - Schedule 1: List of Hazardous and Toxic Chemicals","International Chemical Secretariat (ChemSec) SIN List (*Substitute It Now!)", "Sigma-AldrichTransport Information"

Section 16 - OTHER INFORMATION

- Classification of the preparation and its individual components has drawn on official and authoritative sources using available literature references.

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

The above information is believed to be accurate and represent the best information currently available to us, but does not represent any warranty expressed or implied of the properties of the product. User should make their own investigation to determine the suitability of the information for their particular purpose.

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