

5- IODOURACIL

GHS Safety Data Sheet

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

5- IODOURACIL

OTHER NAMES

C4-H3-I-N2-O2, "uracil, 5-iodo-"

PRODUCT USE

■ Intermediate.

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 4

Acute Toxicity Category 4

Acute Toxicity Category 4

Eye Irritation Category 2A

Germ Cell Mutagen Category 1B

Skin Corrosion/Irritation Category 2

STOT - SE Category 3



EMERGENCY OVERVIEW

HAZARD

DANGER

Determined by using GHS criteria

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H340	May cause genetic defects.

PRECAUTIONARY STATEMENTS

Prevention

Code

P201

P202

Phrase

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood.

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5- IODOURACIL

P261	Avoid breathing 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.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
Response Code	Phrase
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P330	Rinse mouth.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362	Take off contaminated clothing and wash before re- use.
P363	Wash contaminated clothing before reuse.
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	%
5- iodouracil	696-07-1	>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:
- Wash out immediately with fresh 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.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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.

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Section 4 - FIRST AID MEASURES

NOTES TO PHYSICIAN

- Treat symptomatically.

For employees potentially exposed to antineoplastic and/ or cytotoxic agents on a regular basis, a preplacement physical examination and history (noting risk factors) is recommended. Periodic follow-up examinations should also be undertaken and should be overseen by a physician familiar with the toxic effects of the substance and full details of the nature of work undertaken by the employee.

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Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- Foam.
- Dry chemical powder.
- BCF (where regulations permit).
- Carbon dioxide.

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use water delivered as a fine spray to control fire and cool adjacent 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), hydrogen iodide, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive 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

- It is recommended that areas handling final finished product have cytotoxic spill kits available.

Spill kits should include:

- impermeable body covering,
- shoe covers,
- latex and utility latex gloves,
- goggles.

To avoid accidental exposure due to waste handling of cytotoxics:

- Place waste residue in a segregated sealed plastic container.
- Used syringes, needles and sharps should not be crushed, clipped, recapped, but placed directly into an approved sharps container.
- Dispose of any cleanup materials and waste residue according to all applicable laws and regulations e.g, secure chemical landfill disposal.
- 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.

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Section 6 - ACCIDENTAL RELEASE MEASURES

All personnel likely to be involved in an antineoplastic (cytotoxic) spill must receive practical training in:

- the correct procedures for handling cytotoxic drugs or waste in order to prevent and minimise the risk of spills
- the location of the spill kit in the area
- the arrangements for medical treatment of any affected personnel
- the procedure for containment of the spill, and decontamination of personnel and the environment, including the different procedures for major and minor spills.

MAJOR SPILLS

- Moderate hazard.
 - CAUTION: Advise personnel in area.
 - Alert Emergency Services and tell them location and nature of hazard.
 - Control personal contact by wearing protective clothing.
 - Prevent, by any means available, spillage from entering drains or water courses.
- Personal Protective Equipment advice is contained in Section 8 of the MSDS.**

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Australian Standard (AS2639) and the National Institute of Health (USA) recommends that the preparation of injectable antineoplastic drugs should be performed in a Class II laminar flow biological safety cabinet and that personnel preparing drugs of this class should wear appropriate personal protective gear. Emphasise controls on containment.
- 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.
- Polyethylene or polypropylene container.
- Check all containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidising agents.

STORAGE REQUIREMENTS

- Antineoplastics (cytotoxics):
 - should be clearly identifiable to all personnel involved in their handling
 - should be stored in impervious break-resistant containers
 - should be stored in separate, clearly marked storage areas to minimise the risk of breakage, and to limit contamination in the event of leakage.
- Spill kits should be available in storage areas.
- Store in original containers.
 - Keep containers securely sealed.
 - Store in a cool, dry, well-ventilated area.
 - Store away from incompatible materials and foodstuff containers.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

- 5-iodouracil:

CAS:696- 07- 1

MATERIAL DATA

5- IODOURACIL:

- It is the goal of the ACGIH (and other Agencies) to recommend TLVs (or their equivalent) for all substances for which there is evidence of health effects at airborne concentrations encountered in the workplace.
- At this time no TLV has been established, even though this material may produce adverse health effects (as evidenced in animal experiments or clinical experience).

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NOTE: The ACGIH occupational exposure standard for Particles Not Otherwise Specified (P.N.O.S) does NOT apply. Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations.

CEL TWA: 0.001 mg/m³

(CEL=Chemwatch Exposure Limit).

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

■ NOTE:

- The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

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.

Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.

- polychloroprene
- nitrile rubber
- butyl rubber
- fluorocarbon

OTHER

- When handling antineoplastic materials, it is recommended that a disposable work-uniform (such as Tyvek or closed front surgical-type gown with knit cuffs) is worn.
- Potentially contaminated bodily fluids should be handled in accordance with local standards or codes of practice (appendix 10 of 'Cytotoxic Drugs and Related Waste' - Workcover New South Wales, HSE Information Sheet MISC615, OSHA Technical Manual (OTM) Section VI: Chapter 2).
- 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.

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Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

- 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

White powder; does not mix well with water.

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	237.99
Melting Range (°C)	274- 276 (decomp)	Viscosity	Not Applicable
Boiling Range (°C)	Not applicable	Solubility in water (g/L)	Partly miscible
Flash Point (°C)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°C)	274	pH (as supplied)	Not applicable
Autoignition Temp (°C)	Not available	Vapour Pressure (kPa)	Negligible
Upper Explosive Limit (%)	Not available.	Specific Gravity (water=1)	Not available
Lower Explosive Limit (%)	Not available	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	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. (dermal) 4 Acute Tox. (inhal) 4 Acute Tox. (oral) 4
Skin corrosion/irritation	Skin Irrit. 2
Serious eye damage/irritation	Eye Irrit. 2A
Respiratory or skin sensitization	Not applicable
Germ cell mutagenicity	Muta. 1B
Carcinogenicity	Not applicable
Reproductive toxicity	Not applicable

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Section 11 - TOXICOLOGICAL INFORMATION

STOT- single exposure
STOT- repeated exposure
Aspiration hazard

STOT SE 3
Not applicable
Not applicable

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.

■ The killing action of antineoplastic drugs used for cancer chemotherapy is not selective for cancerous cells alone but affect all dividing cells.

Acute side effects include loss of appetite, nausea and vomiting, allergic reaction (skin rash, itch, redness, low blood pressure, unwellness and anaphylactic shock) and local irritation.

EYE

■ This material can cause eye irritation and damage in some persons.

SKIN

■ Skin contact with the material may be harmful; systemic effects may result following absorption.

■ This material can cause inflammation of the skin on contact in some persons.

■ The material may accentuate any pre-existing dermatitis condition.

■ 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 be harmful.

■ The material can cause respiratory irritation in some persons.

The body's response to such irritation can cause further lung damage.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur 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

■ Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems.

Based on experiments and other information, there is ample evidence to presume that exposure to this material can cause genetic defects that can be inherited.

There has been some concern that this material can cause cancer or mutations but there is not enough data to make an assessment.

Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

Based on laboratory and animal testing, exposure to the material may result in irreversible effects and mutations in humans.

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.

Anti-cancer drugs used for chemotherapy can depress the bone marrow with reduction in the number of white blood cells and platelets and bleeding. Susceptibility to infections and bleeding is increased, which can be life- threatening. Digestive system effects may include inflammation of the mouth cavity, mouth ulcers, oesophagus inflammation, abdominal pain and bleeds, diarrhoea, bowel ulcers and perforation. Reversible hair loss can result and wound healing may be delayed. Long-term effects on the gonads may cause periods to stop and inhibit sperm production. Most anti-cancer drugs can potentially cause mutations and birth defects, and coupled with the effects of the suppression of the immune system, may also cause cancer.

Iodine and iodides, may give rise to local allergic reactions such as hives, rupture of skin blood vessels, pain in joints or diseases of the lymph nodes.

Iodine and iodides cause goitre and diminished as well as increased activity of the thyroid gland. A toxic syndrome resulting from chronic iodide overdose and from repeated administration of small amounts of iodine is characterised by excessive saliva production, head cold, sneezing, conjunctivitis, headache, fever, laryngitis, inflammation of the bronchi and mouth cavity, inflamed parotid gland, and various skin rashes. Swelling and inflammation of the throat, irritated and swollen eyes and lung swelling may also occur. Swelling of the glottis, necessitating a tracheotomy has been reported. Use of iodides in pregnancy can cause foetal death, severe goitre, hypothyroidism and the cretinoid appearance of the newborn.

TOXICITY AND IRRITATION

■ Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound.

No significant acute toxicological data identified in literature search.

NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.

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Section 11 - TOXICOLOGICAL INFORMATION

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient

Persistence:
Water/Soil
HIGH

Persistence: Air

No Data
Available

Bioaccumulation

LOW

Mobility

HIGH

5- iodouracil

Section 13 - DISPOSAL CONSIDERATIONS

■ 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.
- Antineoplastic (cytotoxic) wastes must be packed directly, ready for incineration, into colour-coded, secure, labelled, leak-proof containers sufficiently robust to withstand handling without breaking, bursting or leaking.
- Containers of special design are available for particular needs (such as disposal of sharps) and should be used.
- Once filled and closed, such containers must never be re-opened.
- Immediate containers must bear a nationally accepted symbol or device depicting cytotoxic substances and be labelled with the words: CYTOTOXIC WASTE - INCINERATE in a style of lettering approved by the national/ state authority.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

Section 15 - REGULATORY INFORMATION

REGULATIONS

5-iodouracil (CAS: 696-07-1) is found on the following regulatory lists;

"FisherTransport Information","India Hazardous Wastes (Management, Handling and Transboundary Movement) Rules - Schedule 2: List of Wastes Constituents with Concentration Limits","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.

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Section 16 - OTHER INFORMATION

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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