Colcemid

Leica Biosystems Amsterdam

Chemwatch Hazard Alert Code: **0**

Version No: **1.2**
Safety Data Sheet (Conforms to Regulations (EC) No 453/2010)

Issue Date: **05/22/2015**
Print Date: **05/23/2015**
Initial Date: **05/21/2015**
L.REACH.NLD.EN.RISK

SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1.Product Identifier

Product name	Colcemid
Synonyms	KBI-90051
Other means of identification	Not Available

1.2.Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Use according to manufacturer's directions.
Uses advised against	Not Applicable

1.3.Details of the manufacturer/importer

Registered company name	Leica Biosystems Amsterdam
Address	Vlierweg 20 Amsterdam Netherlands
Telephone	0031-20 6919181
Fax	0031-20 6963531
Website	www.leicabiosystems.com
Email	info.amsterdam@leicabiosystems.com

1.4.Emergency telephone number

Association / Organisation	Leica Biosystems Amsterdam
Emergency telephone numbers	0031-20 6919181
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

2.1.Classification of the substance or mixture

DSD classification	In case of mixtures, classification has been prepared by following DPD (Directive 1999/45/EC) and CLP Regulation (EC) No 1272/2008 regulations
DPD classification [1]	*R40(3)?* — *Limited evidence of a carcinogenic effect*.* **LIMITED EVIDENCE*
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI*
Classification according to regulation (EC) No 1272/2008 [CLP] [1]	Not Applicable

2.2. Label elements

CLP label elements	Not Applicable

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SIGNAL WORD	NOT APPLICABLE

Hazard statement(s)

Not Applicable

**LIMITED EVIDENCE*

Precautionary statement(s) Prevention

Precautionary statement(s) Response

Precautionary statement(s) Storage

Precautionary statement(s) Disposal

2.3. Other hazards

REACh - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1.CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classification according to directive 67/548/EEC [DSD]	Classification according to regulation (EC) No 1272/2008 [CLP]
1.477-30-5 2.207-514-6 3.Not Available 4.Not Available	10 ug/ml	demecolcine	R25R23?R21?R40(3)? [1]	Acute Toxicity (Oral) Category 3, Acute Toxicity (Inhalation) Category 4*; H301, H332* [1]
1.7732-18-5 2.231-791-2 3.Not Available 4.Not Available	90-100	water	Not Applicable	Not Applicable

Legend:	*1. Classified by Chemwatch; 2. Classification drawn from EC Directive 67/548/EEC - Annex I; 3. Classification drawn from EC Directive 1272/2008 - Annex VI 4. Classification drawn from C&L*

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 FIRST AID MEASURES

4.1. Description of first aid measures

General	▸ Immediately give a glass of water. ▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. ▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary. If this product comes in contact with eyes: ▸ Wash out immediately with water. ▸ If irritation continues, seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. If skin or hair contact occurs: ▸ Flush skin and hair with running water (and soap if available). ▸ Seek medical attention in event of irritation.
Eye Contact	If this product comes in contact with eyes: ▸ Wash out immediately with water. ▸ If irritation continues, seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: ▸ Flush skin and hair with running water (and soap if available). ▸ Seek medical attention in event of irritation.
Inhalation	▸ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary.
Ingestion	▸ Immediately give a glass of water. ▸ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

	See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

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

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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.

Following administration of antineoplastics, control of nausea and vomiting may be attempted by giving phenothiazines such as perphenazine, prochlorperazine, promethazine or thiethylperazine. In bone-marrow depression, transfusion of blood or platelets reduces the risk of life-threatening haemorrhage. Granulocyte transfusions and injection of antibiotics may be necessary to combat infection in the neutropenic patient. Hyperuricaemia is avoided by the addition of allopurinol to treatment schedules and measures such as alkalisation of the urine and hydration may be adopted. MARTINDALE: The Extra Pharmacopoeia, 28th Edition.

SECTION 5 FIREFIGHTING MEASURES

5.1. Extinguishing media

	▸ There is no restriction on the type of extinguisher which may be used. ▸ Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.

5.3. Advice for firefighters

Fire Fighting	▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves in the event of a fire. ▸ Prevent, by any means available, spillage from entering drains or water courses. ▸ Use fire fighting procedures suitable for surrounding area. ▸ **DO NOT** approach containers suspected to be hot. ▸ Cool fire exposed containers with water spray from a protected location. ▸ If safe to do so, remove containers from path of fire. ▸ Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	▸ Non combustible. ▸ Not considered a significant fire risk, however containers may burn.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

	See section 8

6.2. Environmental precautions

	See section 12

6.3. Methods and material for containment and cleaning up

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, ▸ approved respirator (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent), see Section 8, ▸ disposable dust pan and scoop, ▸ absorbent towels, ▸ spill control pillows, ▸ disposable sponges, ▸ sharps container, ▸ disposable garbage bag and ▸ hazardous waste label Where spills are treated with loose absorbents, such as vermiculite, ensure dust exposure is strictly avoided. 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. All personnel likely to involved in a 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 ▸ the procedure for waste disposal according to the nature and extent of the spill ▸ Clean up all spills immediately. ▸ Avoid breathing vapours and contact with skin and eyes. ▸ Control personal contact with the substance, by using protective equipment. ▸ Contain and absorb spill with sand, earth, inert material or vermiculite. ▸ Wipe up. ▸ Place in a suitable, labelled container for waste disposal.
Major Spills	Not Applicable

6.4. Reference to other sections

Continued...

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

SECTION 7 HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe 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. ▸ Limit all unnecessary personal contact. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ Avoid contact with incompatible materials. ▸ When handling, **DO NOT** eat, drink or smoke. ▸ Keep containers securely sealed when not in use. ▸ Avoid physical damage to containers. ▸ Always wash hands with soap and water after handling. ▸ Work clothes should be laundered separately. ▸ Use good occupational work practice. ▸ Observe manufacturer's storage and handling recommendations contained within this MSDS. ▸ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Fire and explosion protection	See section 5
Other information	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.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	▸ Polyethylene or polypropylene container. ▸ Packing as recommended by manufacturer. ▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	Avoid contamination of water, foodstuffs, feed or seed.

PACKAGE MATERIAL INCOMPATIBILITIES

Not Available

7.3. Specific end use(s)

See section 1.2

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1. Control parameters

DERIVED NO EFFECT LEVEL (DNEL)

Not Available

PREDICTED NO EFFECT LEVEL (PNEC)

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Colcemid	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
demecolcine	Not Available	Not Available
water	Not Available	Not Available

MATERIAL DATA

CEL TWA: 0.001 mg/m3
(CEL=Chemwatch Exposure Limit)

8.2. Exposure controls

8.2.1. Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk.

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	Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure. General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Type of Contaminant:	Air Speed:
solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)
aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)
grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood - local control only

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Personal protection	
Eye and face protection	▸ 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 lenses 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]
Skin protection	See Hand protection below
Hands/feet protection	The selection of 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: ▸ frequency and duration of contact, ▸ chemical resistance of glove material, ▸ glove thickness and ▸ dexterity Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). ▸ When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. ▸ When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. ▸ Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use. ▸ Contaminated gloves should be replaced. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. ▸ 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. ▸ Wash hands immediately after removing gloves. ▸ Protective shoe covers. [AS/NZS 2210] ▸ Head covering.
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities.
Thermal hazards	Not Available

Respiratory protection

Continued...

Not Available

8.2.3. Environmental exposure controls

See section 12

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Not Available

Physical state	Liquid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available
pH (as supplied)	Not Available	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Available
Flash point (°C)	Not Available	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Not Available	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Available	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	Not Available	**Volatile Component (%vol)**	Not Available
Vapour pressure (kPa)	Not Available	**Gas group**	Not Available
Solubility in water (g/L)	Immiscible	**pH as a solution (1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

9.2. Other information

	Not Available

SECTION 10 STABILITY AND REACTIVITY

10.1.Reactivity	See section 7.2
10.2.Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
10.3. Possibility of hazardous reactions	See section 7.2
10.4. Conditions to avoid	See section 7.2
10.5. Incompatible materials	See section 7.2
10.6. Hazardous decomposition products	See section 5.3

SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Inhaled	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product
Ingestion	The material has **NOT** been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern. Antineoplastic action is dependent on cytotoxic action which is not selective for malignant cells alone but may affect all rapidly dividing cells. The spectrum of effects seen with these agents is therefore similar although differences do arise. Acute adverse effects commonly produced by these agents include anorexia, nausea and vomiting (often central in origin and occurring minutes or hours after administration), allergic reaction (skin rashes, pruritus, erythema, hypotension, malaise, and anaphylaxis) and local irritant effects. Hyperuricaemia and acute renal failure (due to uric acid nephropathy) may result from the lysis of large numbers of cells and breakdown of nucleoproteins.
Skin Contact	The liquid may be miscible with fats or oils and may degrease the skin, producing a skin reaction described as non-allergic contact dermatitis. The material is unlikely to produce an irritant dermatitis as described in EC Directives .
Eye	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

Continued...

Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course. Delayed or long-term effects may result from the action of antineoplastic agents on rapidly dividing normal cells in the bone marrow, lymphoreticular tissue, gastrointestinal mucosa, skin, gonads and foetus. The most common of these is bone-marrow depression with leucopenia, anaemia, thrombocytopenia and bleeding. Immunosuppressant effects involve both antibody and cell-mediated immunity and may increase susceptibility to infection and increase the risk of haemorrhage, both potentially life-threatening. GI effects may include stomatitis, mouth ulcers, oesophagitis, abdominal pain, haemorrhage, diarrhoea and intestinal ulceration and perforation. Reversible baldness (alopecia) may result from the action of theses drugs on active hair follicles. Wound healing may be delayed. Long-term effects on the gonads may result in amenorrhoea and the inhibition of spermatogenesis. Most antineoplastics are potentially mutagenic or teratogenic and coupled with the effects of prolonged immunosuppression may also be carcinogenic.

Colcemid	**TOXICITY**	**IRRITATION**
	Not Available	Not Available

demecolcine	**TOXICITY**	**IRRITATION**
	Oral (mouse) LD50: 25.53 mg/kg[2]	Not Available

water	**TOXICITY**	**IRRITATION**
	Oral (rat) LD50: >90000 mg/kg[2]	Not Available

Legend:	*1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's msds. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*

DEMECOLCINE	Somnolence, muscle weakness, diarrhoea, effects of fertility, foetotoxicity, foetolethality, specific developmental abnormalities (central nervous system, eye, ear, body wall) recorded.
Colcemid & WATER	No significant acute toxicological data identified in literature search.

Acute Toxicity	⊘	**Carcinogenicity**	⊘
Skin Irritation/Corrosion	⊘	**Reproductivity**	⊘
Serious Eye Damage/Irritation	⊘	**STOT - Single Exposure**	⊘
Respiratory or Skin sensitisation	⊘	**STOT - Repeated Exposure**	⊘
Mutagenicity	⊘	**Aspiration Hazard**	⊘

Legend: ✔ *– Data required to make classification available*
✘ *– Data available but does not fill the criteria for classification*
⊘ *– Data Not Available to make classification*

CMR STATUS

Not Applicable

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

NOT AVAILABLE

Ingredient	Endpoint	Test Duration	Effect	Value	Species	BCF
demecolcine	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available
water	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
demecolcine	HIGH	HIGH
water	LOW	LOW

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
demecolcine	LOW (LogKOW = 1.37)
water	LOW (LogKOW = -1.38)

12.4. Mobility in soil

Ingredient	Mobility
demecolcine	LOW (KOC = 3430)

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water	LOW (KOC = 14.3)

12.5.Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT and vPvB Criteria fulfilled?	Not Available	Not Available	Not Available

12.6. Other adverse effects

No data available

SECTION 13 DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product / Packaging disposal	Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: ▸ Reduction ▸ Reuse ▸ Recycling ▸ Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. ▸ **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. ▸ Where policies and procedures permit the merging of cytotoxic wastes with medical waste in an outer container used for medical waste, cytotoxic waste must first be placed in identifiable colour-coded/ labelled cytotoxic containers prior to merging. ▸ Management procedures must ensure that merged medical and cytotoxic waste is subjected to the incineration requirements appropriate for the total destruction of the cytotoxic waste. **WASTE STORAGE OF CYTOTOXIC WASTES** For the storage of cytotoxic waste, segregated or merged with medical waste, provide: ▸ special storage areas with adequate lighting. ▸ waste security and restriction of access to authorised persons. ▸ storage areas designed to facilitate easy routine cleaning and maintenance to hygienic standards, or post-spill decontamination. ▸ storage of cytotoxic waste in standard, identifying bins or other appropriate containers. **COLLECTION OF CYTOTOXIC WASTES** ▸ Procedures for the collection of cytotoxic wastes, which are compatible with existing operational needs, and which protect workers, other people and the environment, must be developed. ▸ Waste must be removed from the site by contractors whose workers have been instructed in the protective methods to be used against the hazards involved, and who comply with the safe work practices established by internal and/or national/ state policies. Contractors must instruct, train and direct their personnel in the safe and legal handling of cytotoxic wastes. Contractor's personnel should observe the operating procedures of the waste-generator. ▸ Transport of cytotoxic wastes, through the community, must comply with the appropriate national/ state codes. **DESTRUCTION OF CYTOTOXIC WASTES** ▸ Destruction of cytotoxic wastes should be carried out in multi-chambered incinerators, licenced for this purpose, operating at 1100 deg. C. or more, with a residence time of at least 1 second. ▸ Operators must be trained in handling procedures and hazards involved with handling the waste. ▸ Waste which arrives at the incinerator inappropriately packaged should **NOT** be returned to the waste generator. An authorised representative of the waste generator must attend the incinerator site to rectify the situation.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 TRANSPORT INFORMATION

Labels Required

Marine Pollutant	NO

Land transport (Not Applicable): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.2. Packing group	Not Applicable
14.3. UN proper shipping name	Not Applicable
14.4. Environmental hazard	No relevant data
14.5. Transport hazard class(es)	Class: Not Applicable Subrisk: Not Applicable

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Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.2. Packing group	Not Applicable
14.3. UN proper shipping name	Not Applicable
14.4. Environmental hazard	No relevant data
14.5. Transport hazard class(es)	ICAO/IATA Class: Not Applicable ICAO / IATA Subrisk: Not Applicable ERG Code: Not Applicable
14.6. Special precautions for user	Special provisions: Not Applicable Cargo Only Packing Instructions: Not Applicable Cargo Only Maximum Qty / Pack: Not Applicable Passenger and Cargo Packing Instructions: Not Applicable Passenger and Cargo Maximum Qty / Pack: Not Applicable Passenger and Cargo Limited Quantity Packing Instructions: Not Applicable Passenger and Cargo Limited Maximum Qty / Pack: Not Applicable

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.2. Packing group	Not Applicable
14.3. UN proper shipping name	Not Applicable
14.4. Environmental hazard	Not Applicable
14.5. Transport hazard class(es)	IMDG Class: Not Applicable IMDG Subrisk: Not Applicable
14.6. Special precautions for user	EMS Number: Not Applicable Special provisions: Not Applicable Limited Quantities: Not Applicable

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable
14.2. Packing group	Not Applicable
14.3. UN proper shipping name	Not Applicable
14.4. Environmental hazard	No relevant data
14.5. Transport hazard class(es)	Not Applicable: Not Applicable
14.6. Special precautions for user	Classification code: Not Applicable Limited quantity: Not Applicable Equipment required: Not Applicable Fire cones number: Not Applicable

Transport in bulk according to Annex II of MARPOL 73 / 78 and the IBC code

Not Applicable

SECTION 15 REGULATORY INFORMATION

15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture

demecolcine(477-30-5) is found on the following regulatory lists	"European Customs Inventory of Chemical Substances ECICS (English)","European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)"

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water(7732-18-5) is found on the following regulatory lists	"European Customs Inventory of Chemical Substances ECICS (English)","European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)","EU REACH Regulation (EC) No 1907/2006 - Annex IV - Exemptions from the Obligation to Register in Accordance with Article 2(7)(a) (English)"

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No 453/2010, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and their amendments as well as the following British legislation: - The Control of Substances Hazardous to Health Regulations (COSHH) 2002 - COSHH Essentials - The Management of Health and Safety at Work Regulations 1999

15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

National Inventory	Status
Australia - AICS	N (demecolcine)
Canada - DSL	N (demecolcine)
China - IECSC	N (demecolcine)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (demecolcine; water)
Korea - KECI	N (demecolcine)
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	N (demecolcine)
Legend:	*Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

SECTION 16 OTHER INFORMATION

Full text Risk and Hazard codes

H301	Toxic if swallowed
H332*	H332*

R21?	Skin contact may produce health damage*.
R23?	Inhalation may produce serious health damage*.
R25	Toxic if swallowed.

Other information

DSD / DPD label elements

Not Applicable

Relevant risk statements are found in section 2.1

Indication(s) of danger	Not Applicable

SAFETY ADVICE

S56	Dispose of this material and its container at hazardous or special waste collection point.

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net

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. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices