

# Clomicalm 80

## Virbac (Australia) Pty Limited

Chemwatch: 5457-18  
Version No: 2.1.1.1  
Safety Data Sheet according to WHS and ADG requirements

Chemwatch Hazard Alert Code: 2

Issue Date: 04/03/2021  
Print Date: 04/03/2021  
L.GHS.AUS.EN

### SECTION 1 Identification of the substance / mixture and of the company / undertaking

#### Product Identifier

Product name	Clomicalm 80
Proper shipping name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains clomipramine hydrochloride)
Chemical formula	Not Applicable
Other means of identification	Not Available

#### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Veterinary product.
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#### Details of the supplier of the safety data sheet

Registered company name	Virbac (Australia) Pty Limited
Address	361 Horsley Road Milperra NSW 2214 Australia
Telephone	1800 242 100
Fax	+61 2 9772 9773
Website	<a href="http://au.virbac.com">au.virbac.com</a>
Email	<a href="mailto:au_customerservice@virbac.com.au">au_customerservice@virbac.com.au</a>

#### Emergency telephone number

Association / Organisation	Poisons Information Centre
Emergency telephone numbers	13 11 26
Other emergency telephone numbers	Not Available

### SECTION 2 Hazards identification

#### Classification of the substance or mixture

**HAZARDOUS CHEMICAL. DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.**

Poisons Schedule	S4
Classification [1]	Specific target organ toxicity - single exposure Category 3 (narcotic effects), Germ cell mutagenicity Category 2, Reproductive Toxicity Category 2, Chronic Aquatic Hazard Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### Label elements

Hazard pictogram(s)	
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Signal word	Warning
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#### Hazard statement(s)

H336	May cause drowsiness or dizziness.
H341	Suspected of causing genetic defects.
H361d	Suspected of damaging the unborn child.
H411	Toxic to aquatic life with long lasting effects.

#### Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P261	Avoid breathing dust/fumes.

P273	Avoid release to the environment.
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#### Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/attention.
P312	Call a POISON CENTER/doctor/... if you feel unwell.
P391	Collect spillage.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

#### Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

#### Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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### SECTION 3 Composition / information on ingredients

#### Substances

See section below for composition of Mixtures

#### Mixtures

CAS No	%[weight]	Name
17321-77-6	23	<u>clomipramine hydrochloride</u>

### SECTION 4 First aid measures

#### Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with fresh running water.</li> <li>▶ 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.</li> <li>▶ Seek medical attention without delay; if pain persists or recurs seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately remove all contaminated clothing, including footwear.</li> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
Inhalation	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
Ingestion	<ul style="list-style-type: none"> <li>▶ For advice, contact a Poisons Information Centre or a doctor at once.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ <b>If swallowed do NOT induce vomiting.</b></li> <li>▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>▶ Observe the patient carefully.</li> <li>▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>▶ Transport to hospital or doctor without delay.</li> </ul>

#### Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5 Firefighting measures

#### Extinguishing media

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

#### Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
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#### Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
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<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>‡ Non combustible.</li> <li>‡ Not considered a significant fire risk, however containers may burn.</li> </ul>
<b>HAZCHEM</b>	2Z

## SECTION 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

<b>Minor Spills</b>	<p>Environmental hazard - contain spillage.</p> <ul style="list-style-type: none"> <li>‡ Clean up waste regularly and abnormal spills immediately.</li> <li>‡ Avoid breathing dust and contact with skin and eyes.</li> <li>‡ Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>‡ Use dry clean up procedures and avoid generating dust.</li> <li>‡ Vacuum up or sweep up. <b>NOTE:</b> Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).</li> <li>‡ Dampen with water to prevent dusting before sweeping.</li> <li>‡ Place in suitable containers for disposal.</li> </ul>
<b>Major Spills</b>	<p>Environmental hazard - contain spillage. Moderate hazard.</p> <ul style="list-style-type: none"> <li>‡ <b>CAUTION:</b> Advise personnel in area.</li> <li>‡ Alert Emergency Services and tell them location and nature of hazard.</li> <li>‡ Control personal contact by wearing protective clothing.</li> <li>‡ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>‡ Recover product wherever possible.</li> <li>‡ <b>IF DRY:</b> Use dry clean up procedures and avoid generating dust. Collect residues and place in sealed plastic bags or other containers for disposal. <b>IF WET:</b> Vacuum/shovel up and place in labelled containers for disposal.</li> <li>‡ <b>ALWAYS:</b> Wash area down with large amounts of water and prevent runoff into drains.</li> <li>‡ If contamination of drains or waterways occurs, advise Emergency Services.</li> </ul>

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

## SECTION 7 Handling and storage

### Precautions for safe handling

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>‡ Avoid all personal contact, including inhalation.</li> <li>‡ Wear protective clothing when risk of exposure occurs.</li> <li>‡ Use in a well-ventilated area.</li> <li>‡ Prevent concentration in hollows and sumps.</li> <li>‡ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>‡ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>‡ Avoid contact with incompatible materials.</li> <li>‡ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>‡ Keep containers securely sealed when not in use.</li> <li>‡ Avoid physical damage to containers.</li> <li>‡ Always wash hands with soap and water after handling.</li> <li>‡ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>‡ Use good occupational work practice.</li> <li>‡ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>‡ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>‡ Store in original containers.</li> <li>‡ Keep containers securely sealed.</li> <li>‡ Store in a cool, dry area protected from environmental extremes.</li> <li>‡ Store away from incompatible materials and foodstuff containers.</li> <li>‡ Protect containers against physical damage and check regularly for leaks.</li> <li>‡ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul> <p>For major quantities:</p> <ul style="list-style-type: none"> <li>‡ Consider storage in banded areas - ensure storage areas are isolated from sources of community water (including stormwater, ground water, lakes and streams).</li> <li>‡ Ensure that accidental discharge to air or water is the subject of a contingency disaster management plan; this may require consultation with local authorities.</li> </ul>

### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>‡ Glass container is suitable for laboratory quantities</li> <li>‡ Polyethylene or polypropylene container.</li> <li>‡ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>‡ Avoid reaction with oxidising agents</li> </ul>

## SECTION 8 Exposure controls / personal protection

### Control parameters

Occupational Exposure Limits (OEL)

**INGREDIENT DATA**

Not Available

**Emergency Limits**

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Clomicalm 80	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
clomipramine hydrochloride	Not Available	Not Available

**Occupational Exposure Banding**

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
clomipramine hydrochloride	E	≤ 0.01 mg/m <sup>3</sup>

**Notes:** Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

**MATERIAL DATA**

**Exposure controls**


<b>Appropriate engineering controls</b>	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation.									
	HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.									
	Barrier protection or laminar flow cabinets should be considered for laboratory scale handling.									
	A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.									
	When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology.									
	Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.									
	Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required.									
	Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. 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.									
	<table border="1" style="width: 100%;"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, etc. evaporating from tank (in still air)</td> <td>0.25-0.5 m/s (50-100 f/min.)</td> </tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min.)</td> </tr> </tbody> </table>	Type of Contaminant:	Air Speed:	solvent, vapours, 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 (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)	direct spray, 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.)	
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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 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 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.

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.

The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of:

- 10; high efficiency particulate (HEPA) filters or cartridges
- 10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator.
- 25-50; a full face-piece negative pressure respirator with HEPA filters
- 50-100; tight-fitting, full face-piece HEPA PAPR
- 100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.

<p><b>Personal protection</b></p>	
<p><b>Eye and face protection</b></p>	<p>When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> <li>▶ Chemical goggles.</li> <li>▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes.</li> <li>▶ 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]</li> </ul>
<p><b>Skin protection</b></p>	<p>See Hand protection below</p>
<p><b>Hands/feet protection</b></p>	<p>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.</p> <p>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.</p> <p>Personal hygiene is a key element of effective hand care. 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.</p> <p>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</p> <ul style="list-style-type: none"> <li>· frequency and duration of contact,</li> <li>· chemical resistance of glove material,</li> <li>· glove thickness and</li> <li>· dexterity</li> </ul> <p>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</p> <ul style="list-style-type: none"> <li>· 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.</li> <li>· 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.</li> <li>· Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.</li> <li>· Contaminated gloves should be replaced.</li> </ul> <p>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> <li>· Excellent when breakthrough time &gt; 480 min</li> <li>· Good when breakthrough time &gt; 20 min</li> <li>· Fair when breakthrough time &lt; 20 min</li> <li>· Poor when glove material degrades</li> </ul> <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers' technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> <li>· Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.</li> <li>· Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential</li> </ul> <p>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.</p> <ul style="list-style-type: none"> <li>▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.</li> <li>▶ Double gloving should be considered.</li> <li>▶ PVC gloves.</li> <li>▶ Change gloves frequently and when contaminated, punctured or torn.</li> <li>▶ Wash hands immediately after removing gloves.</li> <li>▶ Protective shoe covers. [AS/NZS 2210]</li> <li>▶ Head covering.</li> </ul> <p>Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.</p> <ul style="list-style-type: none"> <li>▶ polychloroprene.</li> <li>▶ nitrile rubber.</li> <li>▶ butyl rubber.</li> <li>▶ fluoroacoutchouc.</li> <li>▶ polyvinyl chloride.</li> </ul> <p>Gloves should be examined for wear and/ or degradation constantly.</p>
<p><b>Body protection</b></p>	<p>See Other protection below</p>
<p><b>Other protection</b></p>	<ul style="list-style-type: none"> <li>▶ For quantities up to 500 grams a laboratory coat may be suitable.</li> <li>▶ 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.</li> <li>▶ For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</li> <li>▶ For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.</li> <li>▶ Eye wash unit.</li> <li>▶ Ensure there is ready access to an emergency shower.</li> <li>▶ For Emergencies: Vinyl suit</li> </ul>

### Respiratory protection

- ▶ Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- ▶ The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and

likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).

- ▶ Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- ▶ Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- ▶ Use approved positive flow mask if significant quantities of dust becomes airborne.
- ▶ Try to avoid creating dust conditions.

## SECTION 9 Physical and chemical properties

### Information on basic physical and chemical properties

<b>Appearance</b>	Brown to grey coloured tablet with meaty odour; soluble in water.		
<b>Physical state</b>	Manufactured	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Available	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Applicable
<b>Initial boiling point and boiling range (°C)</b>	Not Applicable	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Miscible	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available

## SECTION 10 Stability and reactivity

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

## SECTION 11 Toxicological information

### Information on toxicological effects

<b>Inhaled</b>	<p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.</p> <p>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.</p> <p>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.</p>
<b>Ingestion</b>	Accidental ingestion of the material may be damaging to the health of the individual.
<b>Skin Contact</b>	<p>Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.</p> <p><b>PHOTOSENSITISER:</b> Certain individuals working with this substance may show an abnormally heightened or allergic reaction of the skin to the influence of sunlight. This results in sensitivity to sun, which may be severe, unless protective covering and 15+SPF sunblock cream are used. Responses may vary from sunburn-like responses to edematous, vesiculated lesions or bullae.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds 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.</p>

<b>Eye</b>	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.	
<b>Chronic</b>	<p>Strong evidence exists that the substance may cause irreversible but non-lethal mutagenic effects following a single exposure.</p> <p>Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, generally on the basis that results in appropriate animal studies provide strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.</p> <p>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. A prime symptom is breathlessness. Lung shadows show on X-ray.</p> <p>Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.</p>	
<b>Clomicalm 80</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>clomipramine hydrochloride</b>	<b>TOXICITY</b> Oral(Mammal) LD50; 383 mg/kg <sup>[2]</sup>	<b>IRRITATION</b> Not Available
<b>Legend:</b>	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

<b>CLOMIPRAMINE HYDROCHLORIDE</b>	Convulsions, increased pulse rate, cyanosis, foetolethality, effects on newborn recorded.		
<b>Acute Toxicity</b>	✗	<b>Carcinogenicity</b>	✗
<b>Skin Irritation/Corrosion</b>	✗	<b>Reproductivity</b>	✓
<b>Serious Eye Damage/Irritation</b>	✗	<b>STOT - Single Exposure</b>	✓
<b>Respiratory or Skin sensitisation</b>	✗	<b>STOT - Repeated Exposure</b>	✗
<b>Mutagenicity</b>	✓	<b>Aspiration Hazard</b>	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
✓ – Data available to make classification

## SECTION 12 Ecological information

### Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
<b>Clomicalm 80</b>	Not Available	Not Available	Not Available	Not Available	Not Available
<b>clomipramine hydrochloride</b>	EC50	48	Crustacea	-1.79-2.91mg/L	4
	NOEC	4	Not Available	1.82676-mg/L	4
<b>Legend:</b>	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.  
**DO NOT discharge into sewer or waterways.**

### Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

### Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

### Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

## SECTION 13 Disposal considerations



### Waste treatment methods

<b>Product / Packaging disposal</b>	► Containers may still present a chemical hazard/ danger when empty.
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	<ul style="list-style-type: none"> <li>▶ Return to supplier for reuse/ recycling if possible.</li> <li>Otherwise: <ul style="list-style-type: none"> <li>▶ 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.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>▶ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> <li>▶ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Management Authority for disposal.</li> <li>▶ Bury residue in an authorised landfill.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul> </li> </ul>
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**SECTION 14 Transport information**

**Labels Required**

	
<b>Marine Pollutant</b>	
<b>HAZCHEM</b>	2Z

**Land transport (ADG)**

<b>UN number</b>	3077	
<b>UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains clomipramine hydrochloride)	
<b>Transport hazard class(es)</b>	Class	9
	Subrisk	Not Applicable
<b>Packing group</b>	III	
<b>Environmental hazard</b>	Environmentally hazardous	
<b>Special precautions for user</b>	Special provisions	274 331 335 375 AU01
	Limited quantity	5 kg

Environmentally Hazardous Substances meeting the descriptions of UN 3077 or UN 3082 are not subject to this Code when transported by road or rail in;  
(a) packagings;  
(b) IBCs; or  
(c) any other receptacle not exceeding 500 kg(L).  
- Australian Special Provisions (SP AU01) - ADG Code 7th Ed.

**Air transport (ICAO-IATA / DGR)**

<b>UN number</b>	3077	
<b>UN proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s. * (contains clomipramine hydrochloride)	
<b>Transport hazard class(es)</b>	ICAO/IATA Class	9
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	9L
<b>Packing group</b>	III	
<b>Environmental hazard</b>	Environmentally hazardous	
<b>Special precautions for user</b>	Special provisions	A97 A158 A179 A197 A215
	Cargo Only Packing Instructions	956
	Cargo Only Maximum Qty / Pack	400 kg
	Passenger and Cargo Packing Instructions	956
	Passenger and Cargo Maximum Qty / Pack	400 kg
	Passenger and Cargo Limited Quantity Packing Instructions	Y956
	Passenger and Cargo Limited Maximum Qty / Pack	30 kg G

**Sea transport (IMDG-Code / GGVSee)**

<b>UN number</b>	3077
<b>UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains clomipramine hydrochloride)



<b>Transport hazard class(es)</b>	IMDG Class	9
	IMDG Subrisk	Not Applicable
<b>Packing group</b>	III	
<b>Environmental hazard</b>	Marine Pollutant	
<b>Special precautions for user</b>	EMS Number	F-A , S-F
	Special provisions	274 335 966 967 969
	Limited Quantities	5 kg

**Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

**Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code**

Product name	Group
clomipramine hydrochloride	Not Available

**Transport in bulk in accordance with the ICG Code**

Product name	Ship Type
clomipramine hydrochloride	Not Available

**SECTION 15 Regulatory information**

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

clomipramine hydrochloride is found on the following regulatory lists

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

**National Inventory Status**

National Inventory	Status
Australia - AIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (clomipramine hydrochloride)
China - IECSC	No (clomipramine hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (clomipramine hydrochloride)
Korea - KECI	No (clomipramine hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (clomipramine hydrochloride)
USA - TSCA	No (clomipramine hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	No (clomipramine hydrochloride)
Russia - ARIPS	No (clomipramine hydrochloride)
<b>Legend:</b>	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)

**SECTION 16 Other information**

<b>Revision Date</b>	04/03/2021
<b>Initial Date</b>	04/03/2021

**Other information**

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.

The 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.

**Definitions and abbreviations**

PC—TWA: Permissible Concentration-Time Weighted Average  
PC—STEL: Permissible Concentration-Short Term Exposure Limit  
IARC: International Agency for Research on Cancer  
ACGIH: American Conference of Governmental Industrial Hygienists  
STEL: Short Term Exposure Limit  
TEEL: Temporary Emergency Exposure Limit.  
IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor  
NOAEL :No Observed Adverse Effect Level  
LOAEL: Lowest Observed Adverse Effect Level  
TLV: Threshold Limit Value  
LOD: Limit Of Detection  
OTV: Odour Threshold Value  
BCF: BioConcentration Factors  
BEI: Biological Exposure Index

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