

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

### 1.1. Product identifier

Trade name or designation of the mixture	Clomicalm 80
Registration number	A007762
Synonyms	CGA310816 TAB (80) * A-9572 A1
Item Code	CA4940

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

Identified uses	Veterinary Product
Uses advised against	None known.

### 1.3. Details of the supplier of the safety data sheet

#### National Supplier

Company name	Virbac New Zealand Limited
Address	26 - 30 Maui St, Pukete, Hamilton 3200, New Zealand
Telephone	0800 VIRBAC (0800 847 222)
Website	nz.virbac.com

1.4 Emergency telephone number	National Poison Centre: 0800 POISON (0800 764 766)
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## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

#### Classification according to Regulation (EC) No 1272/2008 as amended

##### Health hazards

Reproductive toxicity (fertility)	Category 2	H361f - Suspected of damaging fertility.
Specific target organ toxicity - single exposure	Category 3 narcotic effects	H336 - May cause drowsiness or dizziness.

##### Environmental hazards

Hazardous to the aquatic environment, long-term aquatic hazard	Category 2	H411 - Toxic to aquatic life with long lasting effects.
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Hazard summary	Exposure to powder or dusts may be irritating to eyes, nose and throat. Possible reproductive hazard. Dangerous for the environment if discharged into watercourses.
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### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

Contains: Clomipramine Hydrochloride

#### Hazard pictograms



Signal word: Warning

#### Hazard statements

H336	May cause drowsiness or dizziness.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.

#### Precautionary statements

##### Prevention

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.

P261 Avoid breathing dust.  
P271 Use only outdoors or in a well-ventilated area.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.

#### Response

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P308 + P313 IF exposed or concerned: Get medical advice/attention.

#### Storage

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

#### Disposal

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

**Supplemental label information** 14 % of the mixture consists of component(s) of unknown acute oral toxicity. 99,5 % of the mixture consists of component(s) of unknown acute inhalation toxicity.

**2.3. Other hazards** None known.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	Index No.	Notes
Clomipramine Hydrochloride	23	17321-77-6 241-344-3	-	-	
<b>Classification:</b>	Acute Tox. 4;H302, STOT SE 3;H336, Repr. 2;H361, Repr. 2;H361f, Aquatic Chronic 1;H410				

**Composition comments** The full text for all H-statements is displayed in section 16. Remaining components of this product are non-hazardous and/or are present at concentrations below reportable levels.

## SECTION 4: First aid measures

**General information** If you feel unwell, seek medical advice (show the label where possible).

### 4.1. Description of first aid measures

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.  
**Skin contact** Wash off with soap and water. Get medical attention if irritation develops and persists.  
**Eye contact** Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention or advice.  
**Ingestion** Rinse mouth. Get medical attention if symptoms occur.

**4.2. Most important symptoms and effects, both acute and delayed** May cause reproductive effects. May cause drowsiness and dizziness.

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

## SECTION 5: Firefighting measures

**General fire hazards** Not available.

### 5.1. Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).  
**Unsuitable extinguishing media** Do not use water jet as an extinguisher, as this will spread the fire.

**5.2. Special hazards arising from the substance or mixture** During fire, gases hazardous to health may be formed.

### 5.3. Advice for firefighters

**Special protective equipment for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.  
**Special fire fighting procedures** Use water spray to cool unopened containers.

**Specific methods** Use standard firefighting procedures and consider the hazards of other involved materials.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**For non-emergency personnel** Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained.

**For emergency responders** Keep unnecessary personnel away.

**6.2. Environmental precautions** Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground. Inform appropriate managerial or supervisory personnel of all environmental releases.

**6.3. Methods and material for containment and cleaning up** Stop the flow of material, if this is without risk. Collect dust using a vacuum cleaner equipped with HEPA filter.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

**6.4. Reference to other sections** Not available.

## SECTION 7: Handling and storage

**7.1. Precautions for safe handling** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact with eyes, skin, and clothing. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

**7.2. Conditions for safe storage, including any incompatibilities** Storage temperature: between 2 °C and 30 °C. Store in original tightly closed container. Store in a well-ventilated place.

**7.3. Specific end use(s)** Veterinary Pharmaceutical.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

**Occupational exposure limits** No exposure limits noted for ingredient(s).

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Recommended monitoring procedures** Novartis Internal Exposure Limit (NPIEL): 0.111 mg/m<sup>3</sup> 8 hour TWA (Clomipramine hydrochloride)

**Derived no effect levels (DNELs)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

### 8.2. Exposure controls

**Appropriate engineering controls** Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

### Individual protection measures, such as personal protective equipment

**General information** Not available.

**Eye/face protection** Wear safety glasses with side shields (or goggles). Safety glasses with side-shields conforming to EN 166.

#### Skin protection

- **Hand protection** Wear appropriate chemical resistant gloves. Protective gloves complying with EN 374.

- **Other** Wear suitable protective clothing.

**Respiratory protection** In case of inadequate ventilation use suitable respirator.

**Thermal hazards** Not available.

**Hygiene measures** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**Environmental exposure controls** Inform appropriate managerial or supervisory personnel of all environmental releases.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>	Tablet.
<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Colour</b>	Brown to grey.
<b>Odour</b>	Meaty.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Miscible.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidising properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	No hazardous decomposition products are known.

## SECTION 11: Toxicological information

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

### 11.1. Information on toxicological effects

**Acute toxicity** Not known.

<b>Components</b>	<b>Species</b>	<b>Test Results</b>
Clomipramine Hydrochloride (CAS 17321-77-6)		
<b>Acute</b>		
<b>Oral</b>		
LD50	Mouse	630 - 920 mg/kg (as salt)
	Rat	750 - 1450 mg/kg (as salt)

Components	Species	Test Results
<b>Other</b> LD50	Rat	17 mg/kg -Intravenous
<b>Skin corrosion/irritation</b>	Rabbit: No skin irritation. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Serious eye damage/eye irritation</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Respiratory sensitisation</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Skin sensitisation</b>	Due to partial or complete lack of data the classification is not possible.	
<b>Germ cell mutagenicity</b>	In vitro and in vivo tests did not show mutagenic effects. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Carcinogenicity</b>	No effects identified in animal studies. (Active ingredient(s)) Based on available data, the classification criteria are not met.	
<b>Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended)</b>		
Not listed.		
<b>Reproductive toxicity</b>	Suspected of damaging fertility. (Active ingredient(s))	
<b>Specific target organ toxicity - single exposure</b>	May cause drowsiness and dizziness. (active ingredient)	
<b>Specific target organ toxicity - repeated exposure</b>	No significant target organ toxicity reported. (active ingredient) Based on available data, the classification criteria are not met.	
<b>Aspiration hazard</b>	Not applicable.	
<b>Mixture versus substance information</b>	No information available.	
<b>Other information</b>	Not available.	

## SECTION 12: Ecological information

**12.1. Toxicity** Toxic to aquatic life with long lasting effects.

Components	Species	Test Results
Clomipramine Hydrochloride (CAS 17321-77-6)		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	LC0	Zebra danio (Danio rerio) 0,32 mg/l
	LC50	Zebra danio (Danio rerio) 0,43 mg/l
	LD100	Zebra danio (Danio rerio) 0,58 mg/l

**12.2. Persistence and degradability** The product is not readily biodegradable.

### 12.3. Bioaccumulative potential

#### Partition coefficient n-octanol/water (log Kow)

Clomipramine Hydrochloride 2,1 (at 23 °C)

**Bioconcentration factor (BCF)** Not available.

**12.4. Mobility in soil** No data available.

**12.5. Results of PBT and vPvB assessment** No Chemical Safety Assessment has been carried out.

**12.6. Other adverse effects** Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

**Disposal methods/information** Dispose of contents/container in accordance with local/regional/national/international regulations.

## SECTION 14: Transport information

**General information** Effective January 1, 2015 by Special Provision, UN3077 and UN3082 when packaged in inner packages of 5L / 5 KG or less are not subject to the dangerous goods regulations.

### ADR

**14.1. UN number** UN3077

**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Clomipramine Hydrochloride)

**14.3. Transport hazard class(es)**

Class	9
Subsidiary risk	-
Label(s)	9
Hazard No. (ADR)	90
Tunnel restriction code	E

**14.4. Packing group** III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Not available.**RID****14.1. UN number** UN3077**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Clomipramine Hydrochloride)**14.3. Transport hazard class(es)**

Class	9
Subsidiary risk	-
Label(s)	9

**14.4. Packing group** III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Not available.**ADN****14.1. UN number** UN3077**14.2. UN proper shipping name** Environmentally Hazardous Solid, N.o.s. (Clomipramine Hydrochloride)**14.3. Transport hazard class(es)**

Class	9
Subsidiary risk	-
Label(s)	9

**14.4. Packing group** III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Not available.**IATA****14.1. UN number** UN3077**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Clomipramine Hydrochloride)**14.3. Transport hazard class(es)**

Class	9
Subsidiary risk	-

**14.4. Packing group** III**14.5. Environmental hazards** Yes**ERG Code** 9L**14.6. Special precautions for user** Not available.**Other information****Passenger and cargo aircraft** Allowed with restrictions.**Cargo aircraft only** Allowed with restrictions.**IMDG****14.1. UN number** UN3077**14.2. UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Clomipramine Hydrochloride)**14.3. Transport hazard class(es)**

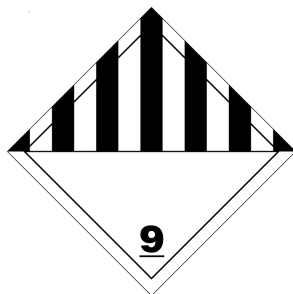
Class	9
Subsidiary risk	-

**14.4. Packing group** III**14.5. Environmental hazards****Marine pollutant** Yes**EmS** F-A, S-F**14.6. Special precautions for user** Not available.

**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

**ADN; ADR; IATA; IMDG; RID**



**Marine pollutant**



## **SECTION 15: Regulatory information**

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

#### **EU regulations**

**Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended**

Not listed.

**Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended**

Not listed.

**Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended**

Not listed.

**Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA**

Not listed.

#### **Authorisations**

**Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**

Not listed.

#### **Restrictions on use**

**Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

#### **Other EU regulations**

**Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended**

Not listed.

#### **Other regulations**

The product is classified and labelled in accordance with EC directives or respective national laws.

#### **National regulations**

Follow national regulation for work with chemical agents.

### **15.2. Chemical safety assessment**

No Chemical Safety Assessment has been carried out.

## **SECTION 16: Other information**

#### **List of abbreviations**

Not available.

#### **References**

Not available.

**Information on evaluation method leading to the classification of mixture**

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

**Full text of any H-statements not written out in full under Sections 2 to 15**

May form combustible dust concentrations in air.  
H302 Harmful if swallowed.  
H336 May cause drowsiness or dizziness.  
H361 Suspected of damaging fertility.  
H361f Suspected of damaging fertility.  
H410 Very toxic to aquatic life with long lasting effects.

**Revision information**

None.

**Disclaimer**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional product information see [nz.virbac.com](http://nz.virbac.com)