

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

1.1. Product identifier

Trade name or designation of the mixture	Clomicalm 20
Registration number	A007761
Synonyms	A-9571 A1 * CGA310816 TAB (20)
Item Code	CA4935

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.
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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.

2.2. Label elements

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

Contains: Clomipramine Hydrochloride

Hazard pictograms



Signal word

Warning

Hazard statements

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.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Response

P308 + P313

IF exposed or concerned: Get medical advice/attention.

Storage

Not available.

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. 98,5 % 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	11	17321-77-6 241-344-3	-	-	
Classification:	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.

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 (CO2).

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 ³ 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	Safety glasses with side-shields conforming to EN 166.
Skin protection	
- Hand protection	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

Appearance	Tablet.
Physical state	Solid.
Form	Powder.
Colour	Brown to grey.
Odour	Meaty.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.

Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Miscible.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

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

SECTION 11: Toxicological information

General information Not available.

11.1. Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
Clomipramine Hydrochloride (CAS 17321-77-6)		
Acute		
Oral		
LD50	Mouse	630 - 920 mg/kg (as salt)
	Rat	750 - 1450 mg/kg (as salt)
Other		
LD50	Rat	17 mg/kg -Intravenous

Skin corrosion/irritation Rabbit: No skin irritation. (Active ingredient(s))
Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Due to partial or complete lack of data the classification is not possible.

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation Due to partial or complete lack of data the classification is not possible.

Germ cell mutagenicity In vitro and in vivo tests did not show mutagenic effects. (Active ingredient(s))
Based on available data, the classification criteria are not met.

Carcinogenicity No effects identified in animal studies. (Active ingredient(s))
Based on available data, the classification criteria are not met.

Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended)

Not listed.

Reproductive toxicity	Suspected of damaging fertility. (Active ingredient(s))
Specific target organ toxicity - single exposure	May cause drowsiness and dizziness. (active ingredient) Based on available data, the classification criteria are not met.
Specific target organ toxicity - repeated exposure	No significant target organ toxicity reported. (active ingredient) Based on available data, the classification criteria are not met.
Aspiration hazard	Not applicable.
Mixture versus substance information	No information available.
Other information	Not available.

SECTION 12: Ecological information

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

Components	Species	Test Results
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Clomipramine Hydrochloride (CAS 17321-77-6)

Aquatic

Acute

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 K_{ow})

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)**

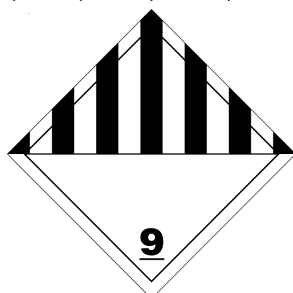
Class 9
 Subsidiary risk -
 Label(s) 9

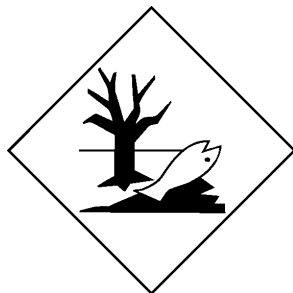
14.4. Packing group III**14.5. Environmental hazards** Yes**14.6. Special precautions for user** Not available.**IATA****14.1. UN number** UN3077**14.2. UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Clomipramine Hydrochloride)**14.3. Transport hazard class(es)**

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**



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

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