

SECTION 1 - IDENTIFICATION OF THE MATERIAL AND SUPPLIER

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Chemical nature: Clomipramine hydrochloride plus other ingredients.

Trade Name: **CLOMICALM® 20 Tablets for Dogs**

APVMA Code: 50184

Product Use: For the treatment of anxieties and stereotypes (obsessive-compulsive disorders) such as lick dermatitis in dogs weighing between 5 and 20 kg.
FOR ANIMAL TREATMENT ONLY.

Creation Date: **October, 2013**

This version issued: **October, 2013** and is valid for 5 years from this date.

SECTION 2 - HAZARDS IDENTIFICATION**STATEMENT OF HAZARDOUS NATURE**

This product is classified as: Xn, Harmful. N, Dangerous to the environment. Hazardous according to the criteria of SWA.

Not a Dangerous Good according to the Australian Dangerous Goods (ADG) Code.

Risk Phrases: R22, R50/53. Harmful if swallowed. Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment.

Safety Phrases: S20, S22, S24, S36, S61. When using, do not eat or drink. Do not breathe dust. Avoid contact with skin. Wear suitable protective clothing. Avoid release to the environment. Refer to special instructions/Safety Data Sheets.

SUSMP Classification: S4

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated

**GHS Signal word: WARNING****HAZARD STATEMENT:**

H302: Harmful if swallowed.

H410: Very toxic to aquatic life with long lasting effects.

PREVENTION

P102: Keep out of reach of children.

P264: Wash contacted areas thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

RESPONSE

P353: Rinse skin or shower with water.

P301+P312: IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P332+P313: If skin irritation occurs: Get medical advice.

P337+P313: If eye irritation persists: Get medical advice.

P391: Collect spillage.

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

STORAGE

P402: Store in a dry place.

P411+P235: Store at temperatures not exceeding 30°C. Keep cool.

DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

Emergency Overview

Description & Colour: Solid, brown-grey oval/oblong tablet.

Odour: Aromatic, like meat (artificial flavour).

SAFETY DATA SHEET

Issued by: Novartis Animal Health Australasia Pty Ltd.

Phone: 02 9805 3555 (office hours)

Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)

Major Health Hazards: Harmful if swallowed. This is a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

Potential Health Effects

INHALATION:

Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

Long Term Exposure: No data for health effects associated with long term inhalation.

SKIN CONTACT:

Short Term Exposure: Available data indicates that this product is not harmful. It should present no hazards in normal use. However product may be mildly irritating, but is unlikely to cause anything more than mild discomfort which should disappear once contact ceases.

Long Term Exposure: No data for health effects associated with long term skin exposure.

EYE CONTACT:

Short Term Exposure: This product may be mildly irritating to eyes, but is unlikely to cause anything more than mild discomfort which should disappear once product is removed.

Long Term Exposure: No data for health effects associated with long term eye exposure.

INGESTION:

Short Term Exposure: Significant oral exposure is considered to be unlikely. Available data shows that this product is harmful, but symptoms are not available. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.

Long Term Exposure: No data for health effects associated with long term ingestion.

CARCINOGEN STATUS:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Clomipramine hydrochloride	17321-77-6	20mg/tab	not set	not set
Other non hazardous ingredients	secret	to 100%	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

SECTION 4 - FIRST AID MEASURES

GENERAL INFORMATION:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Inhalation: First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Skin Contact: Gently brush away excess particles. Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

Eye Contact: Quickly and gently brush particles from eyes. No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

Ingestion: If swallowed, do NOT induce vomiting. Wash mouth with water and contact a Poisons Information Centre, or call a doctor.

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SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Hazards: The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: Not combustible. Use extinguishing media suited to burning materials.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Combustible solid.

Upper Flammability Limit: No data.

Lower Flammability Limit: No data.

Autoignition temperature: No data.

Flammability Class: No data.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, clean up, rinsing to sewer and put empty container in garbage. Although no special protective clothing is normally necessary because of occasional minor contact with this product, it is good practice to wear impermeable gloves when handling chemical products. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

SECTION 7 - HANDLING AND STORAGE

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Store packages of this product in a cool place. Keep containers dry and away from water. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits **TWA (mg/m³)** **STEL (mg/m³)**

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that dusts are minimised.

Eye Protection: Eye protection is not normally necessary when this product is being used. However, if in doubt, wear suitable protective glasses or goggles.

Skin Protection: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when skin contact is likely.

Protective Material Types: We suggest that protective clothing be made from the following materials: cotton, rubber, PVC.

Respirator: If there is a significant chance that dusts are likely to build up in the area where this product is being used, we recommend that you use a suitable Dust Mask.

Safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

SAFETY DATA SHEET

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES:

Description & colour:	Solid, brown-grey oval/oblong tablet.
Odour:	Aromatic, like meat (artificial flavour).
Boiling Point:	No specific data. Expected to decompose before boiling.
Freezing/Melting Point:	191-194°C.
Volatiles:	No specific data. Expected to be low at 100°C.
Vapour Pressure:	Negligible at normal ambient temperatures.
Vapour Density:	Not applicable.
Specific Gravity:	No data.
Water Solubility:	Some, but not all ingredients are soluble.
pH:	No data.
Volatility:	Negligible at normal ambient temperatures.
Odour Threshold:	No data.
Evaporation Rate:	Not applicable.
Coeff Oil/water Distribution:	No data
Viscosity:	Not applicable.
Autoignition temp:	No data.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity:	This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.
Conditions to Avoid:	This product should be kept in a cool place, preferably below 30°C. Containers should be kept dry. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.
Incompatibilities:	strong oxidising agents.
Fire Decomposition:	Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. May form hydrogen chloride gas, other compounds of chlorine. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.
Polymerisation:	This product will not undergo polymerisation reactions.

SECTION 11 - TOXICOLOGICAL INFORMATION

LOCAL EFFECTS:

Target Organs: There is no data to hand indicating any particular target organs.

Classification of Hazardous Ingredients

Ingredient	Risk Phrases
No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.	
LD ₅₀ Oral, Rat 750-1450mg/kg	
Chronic Toxicity:	Clomipramine hydrochloride has been extensively tested on laboratory mammals and did not show reproductive, mutagenic, carcinogenic or teratogenic effects.
12-month rat study, Daily clomipramine	
12.5 mg/kg	No adverse effects
25 mg/kg	Reduced bodyweight gain
50 mg/kg	Larger reduction in bodyweight gain. Increased liver and ovarian weights
125 mg/kg	Severe reduction in bodyweight gain. Testicular atrophy and calcification. Increased liver, kidney and ovarian weights. High mortality rate.
12-month dog study, Daily clomipramine	
12.5 mg/kg	No adverse effects
100 mg/kg	Vomiting, dilation of pupils, sedation or muscular weakness, tremors and convulsions. High mortality rate.

SECTION 12 - ECOLOGICAL INFORMATION

Very toxic to aquatic organisms, may cause long-term adverse effects to the aquatic environment. Clomipramine is not readily biodegradable.

Fish: LC₅₀ zebra fish (Brachydanio rerio): 10.3mg/L

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SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of empty, used containers by wrapping in paper and putting in garbage.

SECTION 14 - TRANSPORT INFORMATION

ADG Code: This product is not classified as a Dangerous Good. No special transport conditions are necessary unless required by other regulations.

SECTION 15 - REGULATORY INFORMATION

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

The following ingredient: Clomipramine hydrochloride, is mentioned in the SUSMP.

SECTION 16 - OTHER INFORMATION

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number
Contact Point:	Regulator Affairs Manager – Animal Health Division – 02 9805 3555

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD INFORMATION OF THE PRODUCT AND HOW TO SAFELY HANDLE AND USE THE PRODUCT IN THE WORKPLACE. EACH USER MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)

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