



Product Name: CLOMICALM[®] 5 Tablets for Dogs and Cats

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Date of issue: November 2008

MATERIAL SAFETY DATA SHEET

Section 1 - Identification of Chemical Product and Company

COMPANY DETAILS:

Novartis Animal Health Australasia Pty Limited
A.C.N. 076 745 198
54 Waterloo Road
North Ryde NSW 2113

Phone: (02) 9805 3555
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Product Name: CLOMICALM[®] 5 Tablets for Dogs and Cats
Active Ingredients: Clomipramine hydrochloride
Ciba-Geigy Code : CGA 310816
Product Use: For the treatment of stereotypic behaviours (obsessive-compulsive disorders) and as an aid in the treatment of anxiety disorders, in dogs weighing between 1.25 and 5 kg. As an aid in the treatment of urine spraying in desexed and female cats weighing 3 kg or more.
Revision Date: November 2008

Section 2 Hazards Identification

Hazard classification: Hazardous Substance
Non-Dangerous Goods
Risk Phrases: R22 Harmful if swallowed.
R50/53 Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.
Safety Phrases: None
SUSDP Classification: 4
UN Number: None Allocated

Section 3 Composition / Information on Ingredients

Ingredients	CAS No.	Content (mg/tablet)
Clomipramine hydrochloride	[17321-77-6]	5
other ingredients determined not to be hazardous		up to 120

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

Section 4 First Aid Measures

Label regulated First Aid Statement: If poisoning occurs contact a Doctor or **Poisons Information Centre (Phone 131126)**.
Scheduled poisons : Product is an S₄ scheduled poison. Poisons Information Centres in each State capital city can provide additional assistance for scheduled poisons (Phone 131126).
Inhalation: Inhalation is extremely unlikely as CLOMICALM is in tablet form.
Skin Contact: Remove contaminated clothing and thoroughly wash the affected parts of the body with soap and water.
Eye contact: If product gets in eyes, rinse eyes with clean water for several minutes. If irritation persists seek medical assistance.
Swallowed: If poisoning occurs, contact a Doctor or Poisons Information Centre

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Advice to doctor: (Phone: 131126).
There is no specific antidote. Treat symptomatically.
Poisoning symptoms include: Severe hypotension, cardiac arrhythmia, athetoid and choreiform movements.

Section 5 Fire Fighting Measures

Fire and explosion hazards: This product is not flammable and there is no risk of an explosion from the product or active constituent under normal circumstances if it is involved in a fire.

Extinguishing Media: This product is combustible. Extinguish warehouse and factory fires using dry powder, foam, carbon dioxide (CO₂) or water spray (do not use water jet).

Fire Fighting: Combustion products are toxic and/or irritant. When fighting fires use a self contained breathing apparatus. Wear personal protective equipment. Do not allow fire-water to enter drains or seeping into the ground.

Section 6 Accidental Release Measures

Accidental Release: Minor spills do not normally need any special cleanup measures and due to the nature of the product large spills are unlikely to occur.

Section 7 Handling and Storage

Safe Handling: Avoid contact with skin, eyes and clothing.

Storage: Keep out of reach of children. Store below 30°C in a dry place. Store unused product in the original closed container.

Section 8 Exposure Controls / Personal Protection

Exposure Limits: No specific exposure standards have been set for this material.

Eye Protection: No specific measures are required for this product.

Skin protection: No specific measures are required for this product.

General advice: After use and before eating, drinking or smoking, wash hands thoroughly with soap and water.

Section 9 - Physical and Chemical Properties

Physical State: Solid, oval/oblong tablet

Colour: Brown-grey

Odour: Aromatic, like meat (artificial flavour)

Flammability: Non-flammable

Section 10 - Stability and Reactivity

Chemical Stability: Product is stable under normal conditions.

Section 11 - Toxicological Information

Acute Toxicity :

Oral: Harmful. Tests on rats indicate a single dose of the active ingredient is slightly harmful.
LD₅₀ = 750-1450 mg/kg

Local Effects: Irritation - (Based on studies with Rabbits)

Skin: Non-irritant

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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

25 mg/kg

50 mg/kg

125 mg/kg

No adverse effects

Reduced bodyweight gain

Larger reduction in bodyweight gain. Increased liver and ovarian weights

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

100 mg/kg

No adverse effects

Vomiting, dilation of pupils, sedation or muscular weakness, tremors and convulsions. High mortality rate.

Section 12 - Ecological Information

Ecological data for *Clomipramine hydrochloride*

Species	LC ₅₀ mg/L
Zebra fish (96 hrs)	10.3

Biodegradability: Not readily degradable

Section 13 - Disposal Considerations

After intended use: Dispose of empty, used containers by wrapping in paper and putting in garbage.

Section 14 - Transport Information

UN Number: None allocated

UN proper shipping name: None allocated

Class & Subsidiary Risk : None allocated

Packaging Group: None allocated

HAZCHEM Code: None allocated

Section 15 - Regulatory Information

Australia: Product first registered for use in Australia on the 7th January 1999 by the Australian Pesticides and Veterinary medicines Authority

Section 16 - Other Information

This MSDS 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

AICS: Australian Inventory of Chemical Substances

CAS Number: Chemical Abstracts Service Registry Number

Hazchem Number: Emergency action code of numbers and letters that provide information to emergency services especially fire-fighters

IARC International Agency for Research on Cancer

NOHSC National Occupational Health and Safety Commission

NOS Not otherwise specified

NTP National Toxicology Program (USA)



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R-Phrase

STEL

SUSDP

TWA

UN Number

Risk Phrase

Short-term Exposure Limit

Standard for the Uniform Scheduling of Drugs & Poisons

Time Weighted Average

United Nations Number

Note:

This product is a registered veterinary chemical and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Federal health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

This Material Safety Data Sheet 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 should read this MSDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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