

SAFETY DATA SHEET

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Section 1 - Identification of The Material and Supplier

Issued by: Intervet Australia Pty Limited
(trading as MSD Animal Health)
91-105 Harpin Street
Bendigo East, Vic 3550, AUSTRALIA
Company ABN: 79 008 467 034

Tel: 1 800 033 461 (Business hours)
Fax: 1 800 817 414

Chemical nature: The active ingredient, FLURALANER (synonym Carbamoyl Benzamide Phenyl Isoxazoline or CBPI), belongs to a novel anti-parasitic class of Isoxazoline-substituted benzamide derivatives. It is presented in a suitable tableting blend of ingredients. The finished product (trade name, BRAVECTO®) are for animal treatment only.

Trade Name: BRAVECTO® Fluralaner Chewable Tablets for Dogs

Other Names: This SDS is intended for a range of similar products suited to dogs of various sizes.

APVMA Code: 68873 (BRAVECTO® 1400 mg Fluralaner Chewable Tablets for Very Large Dogs)
68870 (BRAVECTO® 1000 mg Fluralaner Chewable Tablets for Large Dogs)
68871 (BRAVECTO® 500 mg Fluralaner Chewable Tablets for Medium Sized Dogs)
68872 (BRAVECTO® 250 mg Fluralaner Chewable Tablets for Small Dogs)
68867 (BRAVECTO® 112.5 mg Chewable Tablets for Very Small Dogs)

Recommended Use: Treatment and prevention of flea (*Ctenocephalides felis*) infestations; treatment and control of paralysis tick (*Ixodes holocyclus*) and brown dog tick (*Rhipicephalus sanguineus*) in dogs.

Creation Date: December, 2016

This version issued: December, 2016 and is valid for 5 years from this date.

Poisons Information Centre: Phone 13 1126 from anywhere in Australia

Section 2 - Hazards Identification

Statement of Hazardous Nature:

This product is classified as: Not classified as hazardous according to the criteria of SWA.
Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

SUSMP Classification: S5

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

UN Number: None allocated

GHS Signal word: NONE. Not hazardous.

Hazardous to aquatic environment Short term/Acute Category 1

HAZARD STATEMENT:

H400: Very toxic to aquatic life.

PREVENTION

P102: Keep out of reach of children.

P273: Avoid release to the environment.

P281: Use personal protective equipment as required.

RESPONSE

P352: Wash with plenty of soap and water.

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

P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

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STORAGE

P410: Protect from sunlight.
P402+P404: Store in a dry place. Store in a closed container.

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

Physical Description & Colour: Round light to dark brown tablet; may have some marbling and/or specks.

Odour: No data re odour.

Major Health Hazards: no significant risk factors have been found for this product.

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc, %	TWA (mg/m ³)	STEL (mg/m ³)
Fluralaner	864731-61-3	136g/kg	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 11 26 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 product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

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 are likely to be irritating if inhaled.

Extinguishing Media: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

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.

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Autoignition temperature: No data.
Flammability Class: Combustible solid.

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. Protect this product from light. 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 such as protective glasses or goggles is recommended when this product is being used.

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: There is no specific recommendation for any particular protective material type.

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.

Section 9 - Physical and Chemical Properties

Physical Description & Colour: Round light to dark brown tablet; may have some marbling and/or specks.

Odour: No data re odour.

Boiling Point: Not applicable.

Freezing/Melting Point: Decomposes before melting.

Volatiles: No specific data. Expected to be low at 100°C.

Vapour Pressure: Negligible at normal ambient temperatures.

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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: Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

Incompatibilities: strong acids, strong bases, oxidising agents.

Fire Decomposition: Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. 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: In single dose dermal toxicity testing in rats, local effects observed in some animals included erythema, scaling and scabs.

Target Organs: The liver is the main elimination organ of Fluralaner and a sensitive target for effects. These changes are considered to be reversible.

Classification of Hazardous Ingredients

Ingredient

Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

Studies in laboratory animals demonstrate that Fluralaner has low acute toxicity by oral and dermal routes (oral rat LD₅₀ >2000 mg/kg bw; dermal rat LD₅₀ >2000 mg/kg bw). In the case of an accidental ingestion of the maximum administered single dose, comparison with the oral LD₅₀ values indicate a margin of exposure of ~ 4-fold (2000 mg/kg bw (LD₅₀) / 560 mg/kg bw exposure).

Fluralaner was not sensitizing to guinea pig skin.

Subchronic / Chronic Toxicity: In a 90 day study of Fluralaner in rats, the NOAEL was established orally at the highest dose of 400 mg/kg/body weight/day. In a 90 day study in rats, the NOAEL was established dermally at the highest dose of 500 mg/kg/body weight/day. The liver is the main elimination organ of Fluralaner and a sensitive target for effects as reflected by increased liver enzyme activity in blood plasma with decreased lipid and protein concentration, increased organ weight and increased hepatocellular fatty change as the main functional endpoints in rats. In the absence of any indicator of liver injury (Kupffer cell proliferation, necrosis, apoptosis, fibrosis, other degenerative changes, etc.) these changes are considered to represent reversible metabolic effects and hence are of non-adverse character.

Reproductive / Developmental Toxicity: In prenatal development toxicity studies of Fluralaner in rats (embryogenesis pilot and pivotal) the final NOEL was 100 mg/kg/body weight/day in maternal and foetal organisms. No

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teratogenicity were recorded at up to the limit dose of 1000 mg/kg/body weight/day, and nor were any effects seen on embryo or foetus below maternal toxic dose levels.

Mutagenicity / Genotoxicity: Fluralaner was negative in a bacterial reverse mutation (Ames) study, a mouse lymphoma in vitro study, a chromosome aberration in vitro study, and a mouse erythrocyte micronucleus in vivo study.

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. In addition product is unlikely to cause any discomfort in normal use.

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

Eye Contact:

Short Term Exposure: This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.

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. However, this product may be mildly irritating to mucous membranes but is unlikely to cause anything more than mild 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 12 - Ecological Information

This product is very toxic to aquatic life.

AQUATIC ECOTOXICITY: Fluralaner:

96-hr LC₅₀ (Common carp): 2 mg/L

48-hr EC₅₀ (*Daphnia magna*): 0.0001 - 0.01 mg/L

72-hr EC₅₀ (*P. subcapitata*): >10 mg/L

PERSISTENCE AND DEGRADABILITY:

Biodegradation Results: No data available.

Aerobic Biodegradation(soil) Results: Fluralaner: DT₅₀: 60 days

Hydrolysis Rate Results: Hydrolysis Half-life: Fluralaner: >1 year (25°C) at pH 4, 7, and 9.

BIOACCUMULATIVE POTENTIAL:

Partition Coefficient (log Pow) Results: Fluralaner: 4.5

MOBILITY IN SOIL:

Soil Adsorption/Desorption Results: log Koc: Fluralaner: 4190 - 6255

PBT and vPvB ASSESSMENT:

This substance has not been assessed.

ENVIRONMENTAL FATE AND EFFECTS: No data available.

OTHER INGREDIENT ENVIRONMENTAL DATA: Fluralaner: Bioconcentration Factor (BCF): 27.

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Section 13 - Disposal Considerations

Disposal: 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.

Section 14 - Transport Information

UN Number: This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. 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: Fluralaner, 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

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

OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

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" (Feb 2016)

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