

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Pexion 100 mg and 400 mg Tablets for Dogs
Product code:	A010986 (100 mg), A010987 (400 mg)
Recommended use:	Imepitoin is an antiepileptic agent for use as an aid in the treatment of idiopathic epilepsy in dogs.
Company details:	Boehringer Ingelheim Animal Health New Zealand Limited
Address:	Level 3, Boehringer Ingelheim Building 2 Osterley Way Manukau City Auckland 2104 New Zealand
Telephone number:	Phone: +64 9 263 1400
Emergency telephone number:	Boehringer Ingelheim Freephone: 0800 800 822 National Poisons Centre : 0800 764 766 (0800 POISON) Fire Service, Ambulance : Dial 111
Date of issue:	17 May 2018
Date of review:	7 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization:	Solid
	Active constituent:
	100 mg tablet contains 100 mg imepitoin.
	400 mg tablet contains 400 mg imepitoin.

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Imepitoin	188116-07-6	~70%
Ingredients determined not to be hazardous	N/A	Balance

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications:	6.1E, 6.8B, 6.9A
Priority and secondary identifiers:	WARNING
Risk and safety phrases:	6.1E Substance that is acutely toxic 6.8B Substance that is suspected to be a human reproductive or developmental toxicant. 6.9A Substance that is suspected to be a target organ toxicant.
	Hazard Statement(s) H303 May be harmful if swallowed. H361F Suspected of damaging fertility. H372 Causes damage to organs through prolonged or repeated exposure.
	Precautionary statement – Prevention P102 Keep out of reach of children. P103 Read label before use. P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P281 Use personal protective equipment as required.

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Precautionary statement – Response

P101 If medical advice is needed, have product container or label at hand.

P312 Call a POISON CENTRE or doctor/physician if you feel unwell.

P314 Get medical advice/attention if you feel unwell.

P308+P313 IF exposed or concerned: Get medical advice/attention.

Precautionary statement – Storage

P405 Store locked up.

Precautionary statement – Disposal

P501 In the case of a substance that is in compliance with a HSNO approval other than a Part 6A (Group Standards) approval, a label must provide a description of one or more appropriate and achievable methods for the disposal of a substance in accordance with the Hazardous Substances (Disposal) Regulations 2001. This may also include any method of disposal that must be avoided. See Section 13 for disposal details.

SECTION 4: FIRST AID MEASURES

Necessary first aid measures:

For advice, contact the National Poisons Centre on 0800 POISON (0800 764 766), or a doctor immediately.

Ingestion: If swallowed, seek medical attention. Do NOT induce vomiting. Wash out mouth thoroughly with water.

Eyes: If in eyes, hold eyelids apart and flush the eyes continuously with running water. Remove contact lenses. Continue flushing for several minutes until all contaminants are washed out completely. If symptoms develop, seek medical attention.

Skin: Wash affected area thoroughly with soap and water. If symptoms develop, seek medical attention.

Inhalation: No special precautions required. However, if inhaled, remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms persist, seek medical attention.

Workplace facilities:

No special facilities required.

Required instructions:

Observe good work practices and avoid skin contact. Wash hands and exposed skin before meals and after use. Do not eat or drink while using. Launder protective clothing separately from other clothing, and before each reuse.

Notes for medical personnel:

Treat symptomatically.

SECTION 5: FIRE FIGHTING MEASURES

Type of hazard:

This product will burn if exposed to fire.

Fire hazard properties:

Under fire conditions this product may emit toxic and/or irritating fumes and gases.

Extinguishing media and methods:

Use appropriate fire extinguisher for surrounding environment.

Hazchem code:

N/A

Recommended protective clothing:

Fire fighters should wear Self-Contained Breathing Apparatus operated in positive pressure mode and full protective clothing to prevent exposure to vapours or fumes. Water spray may be used to cool down heat-exposed containers.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:

For minor spills: Avoid inhalation of dust/fumes, and skin or eye contact. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, and then transfer material to a suitable labelled container for subsequent recycling or disposal.

In the event of a major spill: Increase ventilation. Evacuate all unprotected personnel. Wear sufficient respiratory protection and

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full protective clothing to prevent exposure. Sweep up material avoiding dust generation or dampen spilled material with water to avoid airborne dust, and then transfer material to a suitable labelled container for subsequent recycling or disposal. Dispose of waste according to the applicable local and national regulations. If contamination of sewers or waterways occurs inform the local water and waste management authorities in accordance with local regulations.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Used as directed on label or package insert. Avoid inhalation of dust, and skin or eye contact. Use only in a well ventilated area. Keep containers sealed when not in use. Prevent the buildup of dust in the work atmosphere. Maintain high standards of personal hygiene, i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities.

Approved handlers:

Avoid exposure. Do not handle until all safety precautions have been read and understood. It is recommended that pregnant or breastfeeding women should not handle this product unless adequate exposure protection can be assured at all times. Female personnel planning pregnancy should be made aware of the potential risks.

Conditions for safe storage:

Not required

Store in a cool, dry, well-ventilated area, out of direct sunlight and moisture. Store in suitable, labelled containers. Keep containers tightly closed. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.

Store site requirements:

Store below 30 °C.

SECTION 8: EXPOSURE CONTROL/PERSONAL PROTECTION

Workplace exposure standards:

No exposure standards have been established for the mixture. However, over- exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels.

Application in the workplace:

Prevent exposure by using engineering controls, personal protective equipment and work practices that prevent skin contact.

Engineering controls:

Industrial application: This substance is hazardous and should be used with a local exhaust ventilation system, drawing solid/dust away from workers' breathing zone. A flameproof exhaust ventilation system is required. If the engineering controls are not sufficient to maintain concentrations of particulates below the exposure standards, suitable respiratory protection must be worn.

Personal protection:

Respiratory Protection

Industrial application: If engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable dust/particulate filter should be used.¹

Eye Protection

Industrial application: Safety glasses with side shields or chemical goggles should be worn. Final choice of appropriate eye/face protection will vary according to individual circumstances.²

Hand Protection

Wear gloves of impervious material. Final choice of appropriate gloves will vary according to individual circumstances i.e. methods of handling or according to risk assessments undertaken.³

Body Protection

Suitable protective workwear, e.g. cotton overalls buttoned at neck and wrist is recommended. Chemical resistant apron is recommended where large quantities are handled.

Other Information

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References:

No exposure standards have been established for this material. However, over-exposure to some chemicals may result in enhancement of pre-existing adverse medical conditions and/or allergic reactions and should be kept to the least possible levels. The exposure limits for particulates not otherwise classified are as follows: Particulates TWA 10 mg/m³ (inhalable) TWA 3 mg/m³ (respirable)
TWA (Time Weighted Average): The average airborne concentration of a particular substance when calculated over a normal eight- hour working day, for a five-day week.

1. Reference should be made to Australian/New Zealand Standards AS/NZS 1715, Selection, Use and Maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices, in order to make any necessary changes for individual circumstances.
2. Eye protection devices should conform with Australian/New Zealand Standard AS/NZS 1337 - Eye Protectors for Industrial Applications.
3. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Specify product data:

Formulation type: Solid

Appearance: White high density polyethylene screw-necked bottle with polypropylene child-resistant closure containing 100 or 250 tablets.

Specific gravity: Not available

Boiling Point: Not available

Vapour Pressure: Not available

Solubility in Water: Not available

Flammability: Non-flammable

SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:

Stable under normal conditions of use and storage.

Conditions to avoid:

Extremes of temperature and direct sunlight.

Material to avoid:

Not available.

Hazardous decomposition products:

Under fire conditions this product may emit toxic and/or irritating fumes including carbon oxides and nitrogen oxides.

Hazardous polymerization:

Not available.

Specific data:

N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data and interpretation:

Toxicology Information

Ingestion

Ingestion of this product may irritate the gastric tract causing nausea and vomiting. May be harmful if swallowed.

Inhalation

Inhalation of product dusts may cause irritation of the nose, throat and respiratory system.

Skin

May be irritating to skin. The symptoms may include redness, itching and swelling.

Eye

May be irritating to eyes. The symptoms may include redness, itching and tearing.

Respiratory sensitisation

Not expected to be a respiratory sensitiser.

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<p>Skin Sensitisation Not expected to be a skin sensitiser.</p> <p>Germ cell mutagenicity Not considered to be a mutagenic hazard.</p> <p>Carcinogenicity Not considered to be a carcinogenic hazard.</p> <p>Reproductive Toxicity Suspected of damaging fertility. Classified as a suspected human reproductive toxicant.</p> <p>STOT-single exposure Not expected to cause toxicity to a specific target organ.</p> <p>STOT-repeated exposure Not expected to cause toxicity to a specific target organ.</p> <p>Aspiration Hazard Not expected to be an aspiration hazard.</p> <p>Other Imepitoin causes damage to organs through prolonged or repeated exposure.</p>

SECTION 12: ENVIRONMENTAL INFORMATION

<p>Potential environmental interactions:</p> <p>Data organisation :</p> <p>Environmental risk and safety phrases:</p>	<p>No ecological data available for this product.</p> <p>Persistence and degradability Not available</p> <p>Mobility Not available</p> <p>Bioaccumulative Potential Not available</p> <p>Other Adverse Effects Not available</p> <p>Prevent this material entering waterways, drains and sewers.</p>
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SECTION 13: DISPOSAL CONSIDERATIONS

<p>Disposal information :</p>	<p>The disposal of the spilled or waste material and container must be done in accordance with applicable local and national regulations.</p> <p><u>Product Disposal:</u> Product wastes are controlled wastes and should be disposed of in accordance with all applicable local and national regulations. The product should be rendered non-hazardous before being sent to a licensed landfill facility. In this specific case, the product is a combustible substance and therefore can be sent to an approved high temperature incineration plant for disposal. Personal protective clothing and equipment as specified in Section 8 of this SDS must be worn during handling and disposal of this product. The ventilation requirements as specified in the same section must also be followed, and the precautions given in Section 7 of this SDS regarding handling must also be followed. Do not dispose into the sewerage system. Do not discharge into drains or watercourses or dispose where ground or surface waters may be affected. In New Zealand, the disposal agency or contractor must comply with the New Zealand Hazardous Substances (Disposal) Regulations 2001. Further details regarding disposal can be obtained on the EPA New Zealand website under specific group standards.</p> <p><u>Container Disposal:</u> The container or packaging must be cleaned and rendered incapable</p>
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	<p>of holding any substance. It can then be disposed of in a manner consistent with that of the substance it contained. In this instance the packaging can be disposed through a commercial waste collection service.</p> <p>Alternatively, the container or packaging can be recycled if the hazardous residues have been thoroughly cleaned or rendered non-hazardous.</p> <p>In New Zealand, the packaging (that may or may not hold any residual substance) that is lawfully disposed of by householders or other consumers through a public or commercial waste collection service is a means of compliance with regulations.</p>
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SECTION 14: TRANSPORT INFORMATION

Relevant information:	Not classified as dangerous for rail, road, air or sea transport.
Other requirements:	N/A

SECTION 15: REGULATORY INFORMATION

Regulatory status:	Registered pursuant to the ACVM Act 1997, No. A010986 (100 mg) and A010987 (400 mg). See www.foodsafety.govt.nz for registration conditions
	Restricted Veterinary Medicine For use only under the authority or prescription of a veterinarian.
	Approved pursuant to the HSNO Act, Approval Code HSR100757. See www.epa.govt.nz for approval conditions
HSNO and ACVM controls:	Refer to Section 3

SECTION 16: OTHER INFORMATION

Additional information:	For product information visit the Boehringer Ingelheim website www.boehringer-ingelheim.co.nz
	While the information set forth is believed to be accurate as of the date hereof, BOEHRINGER INGELHEIM makes no warranty with respect hereto and disclaims all liability from reliance thereon.