

SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND SUPPLIER

Product name:	Buscopan Compositum
Product code:	A003483
Recommended use:	Spasmodic and analgesic animal remedy for horses, cattle, calves, pigs, piglets and 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:	4 February 2020

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Liquid

Active Constituents :
 Hyoscine-N-Butylbromide 4 mg/mL
 Dipyrone 500 mg/mL

Product components:

<u>Name</u>	<u>CAS</u>	<u>Proportion</u>
Methanesulfonic acid, [(2,3-dihydro-1,5-dimethyl-3-oxo-2-phenyl-1H-pyrazol-4-yl)methylamino]-, sodium salt, monohydrate	5907-38-0	≤77%
Hyoscine Butylbromide	149-64-4	≤1%
Phenol	108-95-2	<1%
Ingredients determined not to be hazardous	N/A	Balance

SECTION 3: HAZARDS IDENTIFICATION

Hazard classifications: 6.3B, 6.8B

Priority and secondary identifiers: WARNING

Risk and safety phrases: 6.3B May cause mild skin irritation. Avoid skin contact.
 6.8B Substance that is suspected to be a human reproductive or developmental toxicant.

Hazard Statement(s)

H316 Causes mild skin irritation.
 H361 Suspected of damaging fertility or the unborn child.

Precautionary statement – Prevention

P103 Read label before use.
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P281 Use personal protective equipment as required.

Precautionary statement – Response

P308+P313 IF exposed or concerned: Get medical advice/attention.
 P332+P313 If skin irritation occurs: Get medical advice/attention.

Precautionary statement – Storage

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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: If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with soap and running water. Wash contaminated clothing before reuse, or discard. Seek medical attention.

Inhalation: Remove affected person from contaminated area to fresh air. Keep at rest until recovered. If symptoms develop, 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:

Non combustible

Fire hazard properties:

Under fire conditions this product may emit toxic and/or irritating fumes, smoke and gases including sulphur oxides, hydrogen bromide, carbon monoxide and carbon dioxide.

Extinguishing media and methods:

Use appropriate fire extinguisher for surrounding environment.

Hazchem code:

N/A

Recommended protective clothing:

Fire fighters should wear full protective clothing and self-contained breathing apparatus operated in positive pressure mode. Fight fire from safe location.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Emergency procedures:

Wear appropriate personal protective equipment and clothing.

For a small liquid spill: Wipe up or soak up using an inert non-combustible absorbent material. Collect the material and place into a suitable labelled container for disposal. If contamination of sewers or waterways occurs inform the local water and waste management authorities in accordance with local regulations.

For a large liquid spill: Increase ventilation. If possible contain the spill. Place inert absorbent material onto spillage. Collect the

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material and place into a suitable labelled container. Do not dilute material but contain. 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:

Use only in a well ventilated area. Prevent the buildup of mists or vapours in the work atmosphere. Avoid contact with clothing, skin or eyes and accidental injection. Use entire contents when first opened. Sterilise all injection apparatus before use. Avoid the use of strong disinfectants. If possible avoid injection during wet weather or dusty conditions. Maintain high standards of personal hygiene i.e. Washing hands prior to eating, drinking, smoking or using toilet facilities. 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.

Approved handlers:

Not required.

Conditions for safe storage:

Store in a cool, dry, well-ventilated area. Protect from light. Store in suitable, labelled containers. Keep containers closed when not in use. Store away from incompatible materials. Ensure that storage conditions comply with applicable local and national regulations.

Store site requirements:

Store below 30 °C. Protect from light. Avoid freezing.

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:

None required, when used as intended. However, if there is risk of airborne exposure, use with good general ventilation. If mists or vapours are produced, local exhaust ventilation should be used.

Personal protection:

Respiratory Protection

None required, when used as intended. However, if engineering controls are not effective in controlling airborne exposure then an approved respirator with a replaceable vapor/mist filter should be used. Refer to relevant regulations for further information concerning respiratory protective requirements.¹

Eye Protection

Safety glasses with side shields, chemical goggles or full-face shield as appropriate should be used. Final choice of appropriate eye/face protection will vary according to individual circumstances. Eye protection devices should conform to relevant regulations.²

Hand Protection

None required, when used as intended. However, where exposure to the contents is likely wear gloves of impervious material such as Nitrile rubber, Layer thickness: 0.43 mm Resistance (permeability):

Level 6 (480 min).

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Final choice of appropriate gloves will vary according to individual circumstances, i.e. methods of handling or according to risk assessments undertaken. Occupational protective gloves should conform to relevant regulations.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.

References:

1. Reference should be made to Australian 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 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:	<u>Formulation type:</u> Liquid <u>Appearance:</u> 100 mL bottle, solution for injection <u>Specific gravity:</u> Not available <u>Boiling Point:</u> Not available <u>Vapour Pressure:</u> Not available <u>Solubility in Water:</u> Miscible in all proportions <u>Flammability:</u> Non-combustible <u>Auto-ignition temperature:</u> Does not ignite
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SECTION 10: STABILITY AND REACTIVITY

Stability of the substance:	Stable under normal conditions of use and storage. Reacts with incompatible materials.
Conditions to avoid:	Extreme temperatures and direct sunlight.
Materials to avoid:	Strong oxidizing agents.
Hazardous decomposition products:	Under fire conditions this product may emit toxic and/or irritating fumes, smoke and gases including sulphur oxides, hydrogen bromide, carbon monoxide and carbon dioxide.
Specific data:	N/A

SECTION 11: TOXICOLOGICAL INFORMATION

Data:	Toxicology Information Toxicity data for material given below. Acute Toxicity - Oral Hyoscine Butylbromide, LD50(rat -male/female): 1640 mg/kg Metamizol Sodium Monohydrate, LD50 (rat): 3000 mg/kg rat Ingestion Ingestion unlikely due to form of the product. Ingestion of this product may irritate the gastric tract causing nausea and vomiting or other systemic effects. Inhalation Not a likely source of exposure. Inhalation of product vapour may cause irritation of the nose, throat and respiratory system.
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Skin

Causes a mild skin irritation. Skin contact will cause redness, itching and swelling. Repeated exposure may cause skin dryness and cracking and may lead to dermatitis.

Eye

Unlikely due to form of product. May be irritating to eyes. The symptoms may include redness, itching and tearing.

Respiratory sensitisation

Not expected to be a respiratory sensitiser.

Germ cell mutagenicity

Not considered to be a mutagenic hazard.

Hyoscine Butylbromide

Genetic toxicity in vitro - Ames-test Salmonella typhimurium
Result: negative Method: OECD Guideline 471 Assessment of teratogenicity

Did not show teratogenic effects in animal experiments

Carcinogenicity

Not considered to be a carcinogenic hazard. Phenol is listed as a Group 2B: Possibly carcinogenic to humans according to International Agency for Research on Cancer (IARC). Hyoscine Butylbromide did not show carcinogenic effects in animal experiments.

Reproductive toxicity

Suspected of damaging fertility or the unborn child. Classified as a suspected human reproductive or developmental toxicant. Hyoscine Butylbromide experiments have shown no reproductive toxicity effects on laboratory animals.

STOT-single exposure

Not expected to cause toxicity to a specific target organ.

STOT-repeated exposure

Not expected to cause toxicity to a specific target organ.

Aspiration Hazard

Not expected to be an aspiration hazard.

SECTION 12: ENVIRONMENTAL INFORMATION

Potential environmental interactions:

N/A

Data organisation :

Persistence and degradability

Hyoscine Butylbromide

Biological degradation: Not easily biodegradable (by OECD criteria).
20% Exposition time: 28 d Method: OECD 301E Guideline

Metamizol Sodium Monohydrate

Biological degradation: 20 - 50% Exposition time: 11 d

Bioaccumulative Potential

Metamizol Sodium Monohydrate

No bioaccumulation is to be expected ($\log P(o/w) < 1$).

Environmental Protection

Do not discharge this material into waterways, drains and sewers.

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Acute Toxicity - Fish

Hyoscine Butylbromide LC50 (golden orfe): 2000 mg/L/48h
Metamizol Sodium Monohydrate
LC50 (golden orfe): > 500 mg/L/48h
LC50 (golden orfe): > 500 mg/L/96h

Acute Toxicity - Daphnia

Hyoscine Butylbromide
NOEC (*Daphnia magna*): 32 mg/L/21 d

Acute Toxicity - Algae

Hyoscine Butylbromide
NOEC (green algae): 80 mg/L/72h
Algae, Growth Inhibition Test

Acute Toxicity - Bacteria

Hyoscine Butylbromide EC50 (*Pseudomonas putida*): 21.0 g/L/16h
Method: DIN 38412 Part 8
EC50 (activated sludge) > 1000 mg/L
Method: OECD Guideline 209
Metamizol Sodium Monohydrate
EC50 (*Pseudomonas putida*) > 1000 mg/L

Environmental risk and safety phrases:

Do not discharge this material into waterways, drains and sewers

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal information :

Preferably dispose of the product by use. The disposal of the spilled or waste material must be done in accordance with applicable local and national regulations.

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. A003483
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

Classified as Hazardous according to the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, New Zealand.
Group Standard: Veterinary Medicine (Limited Pack Size, Finished Dose) Group Standard 2012

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.