

Safety Data Sheet

According to Australian Work Health and Safety Regulations 2021 and the GHS Revision 7

Initial preparation date: 02.20.2019

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Revision date: 05.01.2024

BACTICORTORTEN-B LOTION, ANTIBIOTIC LOTION WITH ANTI-INFLAMMATORY, ANAESTHETIC & BITTERANT

SECTION 1: Identification

Product identifier

Product name: BACTICORTORTEN-B LOTION, ANTIBIOTIC LOTION WITH ANTI-INFLAMMATORY, ANAESTHETIC & BITTERANT

Synonyms: BACTICORTEN-B LOTION

Recommended use of the product and restriction on use

Relevant identified uses: VETERINARY USE: For the treatment of skin infections caused by neomycin sensitive bacteria and pruritis and dermatoses responsive to corticosteroid therapy in dogs, cats and horses.

Uses advised against: Not for human use.

Reasons why uses advised against: Veterinary product.

Manufacturer or supplier details

Supplier:

Australia

Dechra Veterinary Products (Australia) Pty Ltd

2 Cal Close

Somersby, NSW 2250

1300 015 825

info.au@dechra.com

<http://www.dechra.com.au/>

Emergency telephone number:

Australia

Poisons Information Centre

13 11 26 (24 hours, 7 days a week)

SECTION 2: Hazard(s) identification

Classification in accordance with Australian Work Health and Safety Regulations and the GHS Revision 7:

Respiratory sensitization, category 1

Reproductive toxicity, category 1A

Label elements

Hazard pictograms:



Signal Word: Danger

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Hazard statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

H360 May damage fertility or the unborn child

Precautionary statements:

P102 Keep out of reach of children

P201 Obtain special instructions before use

P202 Do not handle until all safety precautions have been read and understood

P261 Avoid breathing dust, fumes, gas, mist, vapours or spray

P280 Wear protective gloves, protective clothing and eye protection

P284 In case of inadequate ventilation wear respiratory protection

P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor

P308+P313 If exposed or concerned: Get medical advice and attention

P405 Store locked up

P501 Dispose of contents and container in accordance with local, regional, national, and international regulations

Hazards not otherwise classified:

None

SECTION 3: Composition and information on ingredients

Identification	Name	Weight %
CAS number: 57-55-6	PROPYLENE GLYCOL	15-25
CAS number: 8012-95-1	PARAFFIN LIQUID	3-8
CAS number: 73-78-9	LIGNOCAINE HYDROCHLORIDE	1-2
CAS number: 1405-10-3	NEOMYCIN SULFATE	<1
CAS number: 50-23-7	HYDROCORTISONE	<1

Additional Information:

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with the Australian Work Health and Safety Regulations 2021.

SECTION 4: First aid measures

Description of first aid measures

General notes:

Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

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If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If exposed, seek medical advice/attention.

After skin contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

After eye contact:

Rinse eyes with plenty of water for several minutes. Remove contact lenses if present and easy to do so. Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

After swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

Most important symptoms and effects, both acute and delayed

Acute symptoms and effects:

Inhalation exposure may cause allergy, asthma symptoms or breathing difficulties. Symptoms may include cough, chronic phlegm, shortness of breath, wheezing and chest tightness. Symptoms may be delayed.

Delayed symptoms and effects:

Long term exposure to hydrocortisone may affect fertility and the unborn child. Symptoms include, but are not limited to: menstrual problems, altered sexual behavior/fertility, pregnancy outcome, intrauterine growth retardation, pre-term birth, birth defects and postnatal death.

Immediate medical attention and special treatment

Specific treatment:

Not determined or not applicable.

Notes for the doctor:

Treat symptomatically.

SECTION 5: Fire fighting measures

Extinguishing media

Suitable extinguishing media:

Water mist/fog, carbon dioxide, dry chemical or alcohol resistant foam.

Unsuitable extinguishing media:

Do not use water jet.

Specific hazards during fire-fighting:

Thermal decomposition may produce irritating/toxic fumes/gases.

Special protective equipment for firefighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full-face piece operated in positive pressure mode.

Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts.

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Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

Environmental precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

Methods and material for containment and cleaning up:

Do not touch damaged containers or spilled material unless wearing appropriate personal protective clothing. Stop leak if you can do it without risk. Contain and collect spillage and place in suitable container for future disposal. Dispose of in accordance with all applicable regulations (see Section 13).

Reference to other sections:

For personal protective equipment see Section 8. For disposal see Section 13.

SECTION 7: Handling and storage precautions

Precautions for safe handling:

Do not allow pregnant women to use or handle this product. Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

Conditions for safe storage, including any incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Keep away from food and beverages. Protect from freezing and physical damage. Store away from heat, open flames and other sources of ignition. Keep container tightly sealed. Store away from incompatible materials (See Section 10). Storage Temperature: Store below 30 °C (room temperature). Container Type: HDPE tube with flip top cap.

SECTION 8: Exposure controls and personal protection

Only those substances with limit values have been included below.

Occupational Exposure limit values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
Australia	PARAFFIN LIQUID	8012-95-1	TWA: 5 mg/m ³
	PROPYLENE GLYCOL	57-55-6	8-Hour TWA: 10 mg/m ³ (particulates only)
	PROPYLENE GLYCOL	57-55-6	8-Hour TWA: 474 mg/m ³ ([150 ppm] total vapour and particulates)

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Biological limit values:

No biological exposure limits noted for the ingredient(s).

Information on monitoring procedures:

Not determined or not applicable.

Appropriate engineering controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

Personal protection equipment

Eye and face protection:

Safety glasses or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

Skin and body protection:

Chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing. Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

Respiratory protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

General hygienic measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Liquid (lotion)
Colour	White
Odour	Slight
pH	2.5 - 4.0
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.

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Relative density	0.96 - 1.02
Relative vapor density	Not determined or not available.
Density	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Particle characteristics	Not determined or not available.
Solubilities	Soluble in water.

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Chemical stability:

Stable under recommended handling and storage conditions.

Possibility of hazardous reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

Conditions to avoid:

Extreme heat, open flames, hot surfaces, sparks, ignition sources and incompatible materials.

Incompatible materials:

Strong acids and oxidizing agents

Hazardous decomposition products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Hazard information

Acute toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Route	Result
NEOMYCIN SULFATE	oral	LD50 Mouse: > 5000 mg/kg
LIGNOCAINE HYDROCHLORIDE	Oral ATE	LD50 Rat: 500 mg/kg
PARAFFIN LIQUID	oral	LD50 Rat: >5000 mg/kg
	dermal	LD50 Rabbit: >2000 mg/kg
PROPYLENE GLYCOL	oral	LD50 Rat: 22,000 mg/kg
	dermal	LD50 Rabbit: >2000 mg/kg
	inhalation	LC50 Rabbit: > 44.9 mg/L (4hr [vapour])

Skin corrosion/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

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No data available.

Substance data:

Name	Result
LIGNOCAINE HYDROCHLORIDE	Causes skin irritation.

Serious eye damage/irritation

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data:

Name	Result
LIGNOCAINE HYDROCHLORIDE	Causes serious eye irritation.

Respiratory or skin sensitization

Assessment:

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Product data:

No data available.

Substance data:

Name	Result
NEOMYCIN SULFATE	May cause an allergic skin reaction.
	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
LIGNOCAINE HYDROCHLORIDE	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carcinogenicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data: No data available.

International Agency for Research on Cancer (IARC): None of the ingredients are listed.

National Toxicology Program (NTP): None of the ingredients are listed.

Germ cell mutagenicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data: No data available.

Reproductive toxicity

Assessment:

May damage fertility or the unborn child.

Product data:

No data available.

Substance data:

Name	Result
HYDROCORTISONE	May damage fertility or the unborn child.

Specific target organ toxicity (single exposure)

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Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data:

Name	Result
LIGNOCAINE HYDROCHLORIDE	May cause respiratory irritation.

Specific target organ toxicity (repeated exposure)

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data:

Name	Result
HYDROCORTISONE	May cause damage to organs (adrenal glands, bone marrow, lymphoreticular tissue) through prolonged or repeated exposure.

Aspiration toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data:

No data available.

Substance data:

Name	Result
PARAFFIN LIQUID	Maybe fatal if swallowed and enters airways.

Information on likely routes of exposure:

Inhalation; Ingestion; Skin contact; Eye contact

Symptoms related to the physical, chemical and toxicological characteristics:

Refer to Section 4 of this SDS.

Other information:

No data available.

SECTION 12: Ecological information

Acute (short-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

Product data: No data available.

Substance data:

Name	Result
HYDROCORTISONE	Aquatic Invertebrates EC50 Daphnia magna: > 100 mg/L (48 hr [mobility])
PROPYLENE GLYCOL	Fish LC50 Oncorhynchus mykiss: 51,600 mg/L (96 hr)
	Aquatic Plants EC50 Raphidocelis subcapitata: 19000 mg/L (96 hr [growth rate])
	Aquatic Invertebrates EC50 Daphnia magna: 43,500 mg/L (48 hr [Immobilisation])

Chronic (long-term) toxicity

Assessment: Based on available data, the classification criteria are not met.

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Product data: No data available.

Substance data:

Name	Result
PROPYLENE GLYCOL	Aquatic Invertebrates NOEC Ceriodaphnia sp.: 13020 mg/L (7 d [reproduction])

Persistence and degradability

Product data: No data available.

Substance data:

Name	Result
HYDROCORTISONE	The substance is readily biodegradable. 96% degradation in water, measured by CO ₂ evolution, after 22 days.
PARAFFIN LIQUID	Standard biodegradability studies are not applicable to petroleum UVCB substances.
PROPYLENE GLYCOL	The substance is readily biodegradable. 81.7% degradation in water, measured by CO ₂ evolution, after 28 days.

Bioaccumulative potential

Product data: No data available.

Substance data:

Name	Result
PARAFFIN LIQUID	The substance has the potential to bioaccumulate (BCF: ≥ 500 , QSAR substance data).
PROPYLENE GLYCOL	The substance is not expected to bioaccumulate (BCF: 0.09).

Mobility in soil

Product data: No data available.

Substance data:

Name	Result
HYDROCORTISONE	The substance is mobile, therefore, there is low potential for adsorption to soil and sediment (Log K _{oc} : 1.61).
PARAFFIN LIQUID	The substance is slightly mobile, therefore, adsorption to soil and sediment is expected (log K _{oc} : >3, QSAR substance data).
PROPYLENE GLYCOL	The substance is highly mobile, therefore, adsorption to soil is not expected (calculated K _{oc} : 2.9).

Results of PBT and vPvB assessment

Product data:

PBT assessment: This product does not contain any substances that are assessed to be a PBT.

vPvB assessment: This product does not contain any substances that are assessed to be a vPvB.

Substance data:

PBT assessment:

PARAFFIN LIQUID	Standard PBT studies are not applicable to petroleum UVCB substances.
PROPYLENE GLYCOL	The substance is not PBT.

vPvB assessment:

PARAFFIN LIQUID	Standard vPvB studies are not applicable to petroleum UVCB substances.
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PROPYLENE GLYCOL	The substance is not vPvB.
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Other adverse effects: No data available.

SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

Contaminated packages:

Not determined or not applicable.

SECTION 14: Transport information

Australian Dangerous Goods (ADG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Maritime Dangerous Goods (IMDG)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN number	Not regulated
UN proper shipping name	Not regulated
UN transport hazard class(es)	None
Packing group	None
Environmental hazards	None
Special precautions for user	None

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Bulk Name	None
Ship type	None

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Pollution category	None
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SECTION 15: Regulatory information

Australia regulations

Australian Inventory of Chemical Substances (AICS):

1405-10-3	NEOMYCIN SULFATE	Not Listed
50-23-7	HYDROCORTISONE	Listed
73-78-9	LIGNOCAINE HYDROCHLORIDE	Not Listed
8012-95-1	PARAFFIN LIQUID	Listed
57-55-6	PROPYLENE GLYCOL	Listed

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP): Poison schedule: S4.

Additional information:

APVMA No 48412

SECTION 16: Other information

Abbreviations and Acronyms: None

Disclaimer:

This SDS was authored in accordance with the Australian Work Health and Safety Regulations 2021 and the GHS Revision 7 and supplemented by the Australian Code of Practice on the Preparation of Safety Data Sheets for Hazardous Chemicals. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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Revision Notes:

Revision Date	Notes
2024-05-01	Version 2; Supersedes Version 1 (02.20.2019)

End of Safety Data Sheet