

Safety Data Sheet

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

Initial preparation date: 01.08.2024

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FORTHYRON (200 µg, 400 µg) flavoured tablets

SECTION 1: Identification

Product identifier

Product name: FORTHYRON (200 µg, 400 µg) flavoured tablets

Synonyms: FORTHYRON

Recommended use of the product and restriction on use

Relevant identified uses: VETERINARY USE; For the treatment of hypothyroidism in dogs.

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:

Skin irritation, category 2

Eye irritation, category 2A

Specific target organ toxicity - single exposure, category 3, respiratory tract irritation

Label elements

Hazard pictograms:



Signal Word: Warning

Hazard statements:

H315 Causes skin irritation

H319 Causes serious eye irritation

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H335 May cause respiratory irritation

Precautionary statements:

P280 Wear protective gloves

P271 Use only outdoors or in a well-ventilated area

P264 Wash hands thoroughly after handling.

P261 Avoid breathing dust.

P302+P352 IF ON SKIN: Wash with plenty of soap and water

P362 Take off contaminated clothing and wash before reuse

P321 Specific treatment (see Sections 4-8 of this SDS and any supplemental information on the product label).

P332+P313 If skin irritation occurs: Get medical advice and attention.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337+P313 If eye irritation persists: Get medical advice or attention.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P312 Call a POISON CENTER if you feel unwell

P403+P233 Store in a well-ventilated place. Keep container tightly closed

P405 Store locked up

P501 Dispose of contents and container in accordance with local regulations.

Hazards not otherwise classified:

None

SECTION 3: Composition and information on ingredients

Identification	Name	Weight %
CAS number: 7789-77-7	Calcium hydrogen phosphate dihydrate	>70
CAS number: 9004-34-6	Microcrystalline cellulose	5-10
CAS number: 8013-01-2	Natural meat flavour	<10
CAS number: 9063-38-1	Sodium starch glycolate	<5
CAS number: 557-04-0	Magnesium stearate	<5
CAS number: 55-03-8	Levothyroxine sodium	<0.2

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:

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Show this Safety Data Sheet to the doctor in attendance.

After inhalation:

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 experiencing respiratory symptoms, 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 gently flowing lukewarm water for 15 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:

Skin contact may result in redness, pain, burning and inflammation.

Eye contact may result in irritation, redness, pain, inflammation, itching, burning and tearing.

Inhalation may have adverse effects on the respiratory tract. Symptoms may include cough, breathing difficulties, sore throat and inflammation of the mucous membrane lining the respiratory tract.

Delayed symptoms and effects:

Effects are dependent on exposure (dose, concentration, contact time).

Immediate medical attention and special treatment

Specific treatment:

If respiratory symptoms persist, seek medical attention.

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:

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Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. 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 handle this product if you are pregnant, think you are pregnant or if you are breast feeding. Do not handle this product if you have a known sensitivity to bromide. 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). Sensitive to light. Do not store above 25°C. Return any divided tablet to the opened blister and use within 4 days.

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	Microcrystalline cellulose	9004-34-6	8-Hour TWA: 10 mg/m ³
	Magnesium stearate	557-04-0	TWA: 10 mg/m ³ (No Asbestos and <1% Crystalline silica inhalable dust (as Stearates))
	Natural meat flavour	8013-01-2	8-Hour TWA: 10 mg/m ³ (Inhalable dust [nuisance dusts])

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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	Solid
Colour	Off-white
Odour	Not determined or not available.
pH	4.1 - 4.7
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.
Relative density	Not determined or not available.
Relative vapor density	Not determined or not available.

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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	Partly 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 bases.

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
Microcrystalline cellulose	dermal	LD50 Rabbit: > 2000 mg/kg
	inhalation	LC50 Rat: > 5.8 mg/L (4 hr [dust/mist])
	oral	LD50 Rat: > 5000 mg/kg
Magnesium stearate	dermal	LD50 Rat: >2000 mg/kg

Skin corrosion/irritation

Assessment:

Causes skin irritation.

Product data:

No data available.

Substance data:

Name	Result
Calcium hydrogen phosphate dihydrate	Causes skin irritation.

Serious eye damage/irritation

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Assessment:

Causes serious eye irritation.

Product data:

No data available.

Substance data:

Name	Result
Calcium hydrogen phosphate dihydrate	Causes serious eye irritation.

Respiratory or skin sensitization

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

Product data:

No data available.

Substance data: No data available.

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

Product data:

No data available.

Substance data:

Name	Result
Levothyroxine sodium	Suspected of damaging fertility or the unborn child.

Specific target organ toxicity (single exposure)

Assessment:

May cause respiratory irritation.

Product data:

No data available.

Substance data:

Name	Result
Calcium hydrogen phosphate dihydrate	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.

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Substance data:

Name	Result
Levothyroxine sodium	Causes damage to organs (thyroid, gastrointestinal tract, cardiovascular system, kidneys) 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: No data available.

Information on likely routes of exposure:

Inhalation, skin and eye contact.

Symptoms related to the physical, chemical and toxicological characteristics:

See 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: No data available.

Chronic (long-term) toxicity

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

Product data: No data available.

Substance data: No data available.

Persistence and degradability

Product data: No data available.

Substance data: No data available.

Bioaccumulative potential

Product data: No data available.

Substance data: No data available.

Mobility in soil

Product data: No data available.

Substance data: No data available.

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: 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.

Other adverse effects: No data available.

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SECTION 13: Disposal considerations

Disposal methods:

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory entities

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
Pollution category	None

SECTION 15: Regulatory information

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Australia regulations

Australian Inventory of Chemical Substances (AICS):

55-03-8	Levothyroxine sodium	Not Listed
7789-77-7	Calcium hydrogen phosphate dihydrate	Listed
9004-34-6	Microcrystalline cellulose	Listed
9063-38-1	Sodium starch glycolate	Listed
557-04-0	Magnesium stearate	Listed
8013-01-2	Natural meat flavour	Listed

Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP):

Classified as a Schedule (S4)

Additional information:

APVMA numbers: 92446 (200 µg), 92445 (400 µg).

ACVM Number: A011977 (Forthyron 200 µg); A011978 (Forthyron 400 µg)

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.

Initial preparation date: 01.08.2024

Revision Notes:

Revision Date	Notes
2024-01-08	Version 1

End of Safety Data Sheet