

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 1 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

SECTION 1: Identification

Product identifier

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

Synonyms: FORTHYRON

Additional information: None

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:

Dechra Veterinary Products NZ Limited

PO Box 1604,

Paraparaumu Beach, 5252

New Zealand

Phone: 0800 479 838

Email: info.nz@dechra.com

Website: <http://www.dechra.co.nz/>

Emergency telephone number:

National Poisons Centre, New Zealand

0800 764 766

SECTION 2: Hazards identification

Not Classified as a Dangerous Good according to NZS 5433:2012 Transport of Dangerous Goods on Land.

Classified in accordance with the Hazardous Substances (Hazard Classification) Notice 2020

HSNO Classification or Subclasses – Physical hazards: Not applicable

HSNO Classification or Subclasses – Health hazards:

| Class | GHS Category | HSNO Category |
|--|--------------|-------------------------------------|
| Eye irritation | Category 2 | 6.4A |
| Skin irritation | Category 2 | 6.3A |
| Reproductive toxicity | Category 2 | 6.8B |
| Specific target organ toxicity - single exposure, respiratory tract irritation | Category 3, | 6.9 (Respiratory tract irritant) |

HSNO Classification or Subclasses – Environmental hazards: Not applicable

GHS classification:

Skin irritation, category 2

Eye irritation, category 2

Reproductive toxicity, category 2

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

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 2 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

Label elements

Hazard pictogram(s):



Signal word: Warning

Hazard statements:

- H315 Causes skin irritation
- H319 Causes serious eye irritation
- H335 May cause respiratory irritation
- H361 Suspected of damaging 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
- 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
- P308+P313 If exposed or concerned: Get medical attention.
- 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/information on ingredients

Mixture:

| 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 |

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 3 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

| | | |
|-------------------------|----------------------|------|
| 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 under the provisions of sections 55 (7) of the HSNO Act.

SECTION 4: First-aid measures

For advice, contact a Poisons Information Center (e.g. phone Australia 131 126, New Zealand 0800 764 766) or a doctor.

Description of first aid measures

General notes:

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).

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

Immediate medical attention and special treatment:

Specific treatment:

If respiratory symptoms persist, seek medical attention.

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 4 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

Notes for the doctor:

Treat symptomatically.

Workplace Facilities:

No additional information.

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/vapours/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.

Hazchem or Emergency Action Code:

Not Applicable.

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, vapour, 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:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Avoid breathing mist/vapour/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.

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 5 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

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.

Safe packaging material

Suitable material:

Not determined or not applicable.

Unsuitable material:

Not determined or not applicable.

SECTION 8: Exposure controls and personal protection



Occupational Exposure limit values:

| Country (Legal Basis) | Substance | Identifier | Permissible concentration |
|-----------------------|----------------------------|------------|--|
| New Zealand | 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]) |

Biological limit value:

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 vapour, 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).

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 6 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

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

| | |
|---|----------------------------------|
| Appearance | Solid |
| Colour | Off-white |
| Odour threshold | 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. |
| Upper flammability/explosive limit | Not determined or not available. |
| Lower flammability/explosive limit | Not determined or not available. |
| Vapour pressure | Not determined or not available. |
| Vapour density | Not determined or not available. |
| Relative density | Not determined or not available. |
| Solubilities | Partly soluble in water |
| 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. |
| Dynamic viscosity | Not determined or not available. |
| Kinematic viscosity | Not determined or not available. |
| Particle characteristics | Not determined or not available. |

Other information

| | |
|---------|----------------------------------|
| Density | Not determined or not available. |
|---------|----------------------------------|

SECTION 10: Stability and reactivity

Reactivity:

Not reactive under recommended handling and storage conditions.

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 7 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

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, moisture 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: Toxicological 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:

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.

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 8 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

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.

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:

Suspected of damaging fertility or the unborn child.

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.

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.

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 9 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

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.

Hazard to the ozone layer

Product data: No data available.

Substance data: No data available.

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 entities

Contaminated packages:

Not determined or not applicable.

Disposal methods that should not be used:

No additional information.

SECTION 14: Transportation information

Road/Rail transport: (NZS 5433:1999)

| | |
|-------------------------------|---------------|
| 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 |

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 10 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

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

| | |
|-------------------------------|---------------|
| 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 |

Transport in bulk according to Annex II of MARPOL and the IBC Code: Not Applicable

SECTION 15: Regulatory information

New Zealand Inventory of Chemicals (NZIoC): All Ingredients are listed.

HSNO Classification or Subclasses:

| Class | GHS Category | HSNO Category |
|--|--------------|----------------------------------|
| Eye irritation | Category 2 | 6.4A |
| Skin irritation | Category 2 | 6.3A |
| Reproductive toxicity | Category 2 | 6.8B |
| Specific target organ toxicity - single exposure, respiratory tract irritation | Category 3 | 6.9 (Respiratory tract irritant) |

| | |
|---|-----------------------|
| HSNO Group Standard Name: | HSNO Approval Number: |
| Veterinary Medicines (Limited Pack Size, Finished Dose) Group Standard 2020 | HSR100757 |

HSNO Controls: Not determined.

Approved handler test certificate: Not determined.

Tracking: Not determined.

Controlled substance license requirements: Not applicable.

Montreal Protocol (Ozone Depleting Substances): None of the ingredients are listed.

Stockholm Convention (Persistent Organic Pollutants): None of the ingredients are listed.

Rotterdam Convention (Prior Informed Consent): None of the ingredients are listed.

Basel Convention (Hazardous Waste): None of the ingredients are listed.

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

Safety Data Sheet

According to New Zealand, Hazardous Substances and New Organisms Act 1996 (HSNO Act) and Regulations, as amended.

Initial preparation date: 01.08.2024

Page 11 of 11

FORTHYRON (200 µg, 400 µg) flavoured tablets

SECTION 16: Other information

Abbreviations and Acronyms:

| | |
|---------------|---|
| ATE | Acute Toxicity Estimate |
| BCF | Bioconcentration Factor |
| CAS | Chemical Abstracts Service |
| EC50 | Effective Concentration of 50% |
| GHS | Globally Harmonized System |
| HSNO | Hazardous Substances and New Organisms |
| IARC | International Agency for Research on Cancer |
| IATA | International Air Transport Association |
| IBC | Intermediate Bulk Container |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Lethal Concentration 50% |
| LD50 | Lethal Dose 50% |
| MARPOL | International Convention for the Prevention of Pollution from Ships |
| NZIoC | New Zealand Inventory of Chemicals |
| TWA | Time Weighted Average |
| UN | United Nations |
| VOC | Volatile Organic Compounds |

Disclaimer:

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 |
|---------------|-----------|
| 01-08-2024 | Version 1 |

End of Safety Data Sheet