SAFETY DATA SHEET
Baycox 2,5%

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Baycox 2,5%

HSNO Approval Number : HSR002034
ACVM number : A005390

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet

Company
Bayer New Zealand Limited
3 Argus Place
0627 HILLCREST, AUCKLAND, NEW ZEALAND
NEW ZEALAND
Tel.: 0800 652 488
Fax: 0800 229 838
Mail: bhc-md-oeko@bayer.com

1.4 Emergency telephone number

In case of emergency: 0800 734 607 IXOM SH&E Shared services (24hr)

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

6.3: Skin irritation : Category B
6.4: Eye irritation : Category A
6.8: Toxic to Reproduction : Category B
6.9: Specific Target Organ Toxicity
9.2: Ecotoxic to soil environment : Category D

GHS label elements

Hazard pictograms :

Signal word : Warning
Hazard statements:
- H316 Causes mild skin irritation.
- H319 Causes serious eye irritation.
- H361 Suspected of damaging fertility or the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H423 Harmful to the soil environment.

Precautionary statements:
- Prevention:
  - P264 Wash skin thoroughly after handling.
  - P273 Avoid release to the environment.
  - P280 Wear protective gloves/eye protection/face protection.
- Response:
  - P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P332 + P313 IF skin irritation occurs: Get medical advice/attention.
  - P337 + P313 IF eye irritation persists: Get medical advice/attention.
  - P308 + P313 IF exposed or concerned: Get medical advice/attention.
- Storage:
  - P405 Store locked up.
- Disposal:
  - P501 Dispose of contents/container to an approved facility in accordance with local, regional, national and international regulations.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture
Substance name: Baycox 2,5%

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethanolamine</td>
<td>102-71-6</td>
<td>&gt;= 20 -&lt; 30</td>
</tr>
<tr>
<td>Toltrazuril</td>
<td>69004-03-1</td>
<td>&gt;= 1 -&lt; 2,5</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice:
- Take off all contaminated clothing immediately.
- You should call the National Poisons Centre if you feel that you may have been harmed or irritated by this product. The number is 0800 764 766 (0800 POISON) (24hr emergency service).
If inhaled: Remove to fresh air. Call a physician immediately.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. If skin reactions occur, contact a physician.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed: No information available.

Notes to physician: No information available.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: High volume water jet

Specific hazards during firefighting: Fire may cause evolution of:
- Hydrogen cyanide (hydrocyanic acid)
- Nitrogen oxides (NOx)
- Carbon oxides

Specific extinguishing methods: Prevent fire extinguishing water from contaminating surface water or the ground water system.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Use with adequate ventilation.

Environmental precautions: Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up: Suppress (knock down) gases/vapours/mists with a water spray jet. Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Place in closed containers. Label for proper disposal.
SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: No special protective measures against fire required.

Advice on safe handling: Industrial uses:
- Avoid formation of aerosol.
- Use with local exhaust ventilation.
- Avoid contact with skin, eyes and clothing.

Hygiene measures: Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

Conditions for safe storage: For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triethanolamine</td>
<td>102-71-6</td>
<td>WES-TWA</td>
<td>5 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Toltrazuril</td>
<td>69004-03-1</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Personal protective equipment

Respiratory protection: Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

Hand protection Material: Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear

Remarks: Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

Eye protection: Safety glasses

Protective measures: No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients. For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet. The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected. Wear suitable protective equipment.
SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Colour : colourless
Odour : weak
pH : 10 - 12
Concentration: 100 g/l
Solidification area : -50 - -10 °C
Flash point : ca. 180 °C
Density : 1,132 g/cm³ (20 °C)
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Explosive properties : No data available
Oxidizing properties : No data available
Impact sensitivity : No data available
Minimum ignition energy : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No data available
Chemical stability : No data available
Possibility of hazardous reactions : No data available
Conditions to avoid : Heat
Exposure to moisture
Incompatible materials : Oxidizing agents
Hazardous decomposition products : Hydrogen cyanide (hydrocyanic acid)
Nitrogen oxides (NOx)
Carbon oxides

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Product:
Acute oral toxicity: Acute toxicity estimate (ATE): > 5.000 mg/kg
Method: Calculation method

Components:

Triethanolamine:
Acute oral toxicity: LD50 (Rat): 7.200 mg/kg ca.
Method: BASF-Test
Assessment: No adverse effect has been observed in acute toxicity tests.

Acute dermal toxicity: LD50 (Rabbit): > 2.000 mg/kg
Method: OECD 402

Toltrazuril:
Acute oral toxicity: LD50 (Rat, female): 1.740 - 3.375 mg/kg

Acute dermal toxicity: LD50 (Rat, male): > 5.000 mg/kg

Skin corrosion/irritation

Components:

Triethanolamine:
Species: Rabbit
Method: OECD 404
Result: No skin irritation

Toltrazuril:
Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Components:

Triethanolamine:
Result: Irritating to eyes.
Assessment: Causes serious eye irritation.

Toltrazuril:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Components:

Triethanolamine:
Species: Guinea pig
Method: OECD 406
Result: Does not cause skin sensitisation.
Toltrazuril:
Species: Guinea pig
Method: OECD 406
Result: Does not cause skin sensitisation.

Chronic toxicity

Germ cell mutagenicity

Components:

Triethanolamine:
Genotoxicity in vitro: Remarks: Tests with bacteria and mammalian cells showed no evidence of genotoxic effects.

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: Ames test
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Result: negative

STOT - repeated exposure

Components:

Triethanolamine:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Experience with human exposure

Components:

Triethanolamine:
General Information: Avoid repeated exposure.
Liver disorders
Kidney disorders

Further information

Components:

Triethanolamine:
Remarks: Ingestion of large quantities:

Vomiting
Diarrhoea
Dizziness
Tiredness
Circulatory collapse
Unconsciousness
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Components:

Triethanolamine:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 11.800 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 450 - 1.000 mg/l
Exposure time: 96 h

Toxicity to algae : EC50 (Scenedesmus subspicatus): 512 mg/l
Method: DIN 38412
Remarks: Nominal concentration

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 16 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC50: > 1.000 mg/l
Exposure time: 3 h
Method: OECD 209
Remarks: Nominal concentration

EC50 (Pseudomonas putida): > 10.000 mg/l
Exposure time: 16 h

EC50 (Photobacterium phosphoreum): 525 mg/l
Exposure time: 0,5 h

Toxicity to terrestrial organisms : LC50 (Drosophila melanogaster (vinegar fly)): 49.950 mg/kg
Exposure time: 3 d

Ecotoxicology Assessment

Acute aquatic toxicity : slightly hazardous to water

Toltrazuril:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0,44 mg/l
Exposure time: 96 h
Test Type: Acute Fish toxicity

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 2 mg/l
Exposure time: 48 h
Method: OECD 202
Toxicity to algae: EC50 (Desmodesmus subspicatus (green algae)): > 0,39 mg/l
Exposure time: 72 h

Persistence and degradability

Components:

Triethanolamine:
Biodegradability: Result: rapidly biodegradable
Biodegradation: 90 - 100 %
Remarks: Readily biodegradable, according to appropriate OECD test.

Result: rapidly biodegradable
Biodegradation: 96 %
Method: OECD 301E

ThOD: 2.040 mg/g

Dissolved organic carbon (DOC): 90 - 100 %
Method: OECD 301E

Stability in water: Method: Expert judgement
Remarks: not hydrolyzed.

Toltrazuril:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 0,3 %
Exposure time: 28 d
Method: OECD 301F

Bioaccumulative potential

Components:

Triethanolamine:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 0,4
Exposure time: 42 d
Method: OECD 305
Remarks: Does not accumulate in organisms.

Partition coefficient: n-octanol/water: log Pow: -2,3 (25 °C)
Method: OECD 107

Toltrazuril:
Partition coefficient: n-octanol/water: log Pow: 4,18
Other adverse effects

Product:
Additional ecological information : Do not allow to enter surface waters or groundwater.

Components:

Triethanolamine:
Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).
Remarks: Expert judgement

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of as hazardous waste in compliance with local and national regulations.
Contaminated packaging : Contaminated, empty containers are to be treated in the same way as the contents.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
No statements available.

HSNO Approval Number
HSR002034

HSNO Controls
Certified handler certificate not required.
HSW tracking not required.
Refer to WORKSAFE user guide to the HSW regulations for further information.
The components of this product are reported in the following inventories:

NZIoC : On the inventory, or in compliance with the inventory

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IEC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Date format : dd.mm.yyyy

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release 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 or in any process, unless specified in the text.

NZ / EN