

SAFETY DATA SHEET

Dryclox Xtra



Version 1.1 Revision Date: 11.06.2018 SDS Number: 122000008234 Date of last issue: 30.11.2011
Date of first issue: 30.11.2011

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

1.1 Product identifier

Dryclox Xtra

HSNO Approval Number : HSR002346

ACVM number : A002346

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

6.5: Respiratory sensitisation : Category B

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H316 Causes mild skin irritation.
H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of

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the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Cloxacillina Benzatinica	23736-58-5	>= 10 -< 20
Binotal acid / ampicillin trihydrate	7177-48-2	>= 1 -< 10

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 : Clean mouth with water and drink afterwards plenty of water.
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : No information available.
No information available.
- Notes to physician : No information available.

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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 fire-fighting : Fire may cause evolution of:
Carbon monoxide (CO)
Carbon dioxide (CO₂)
- 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.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Use with adequate ventilation.
No special precautions required.
- 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.
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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.
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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin oils	8012-95-1	WES-TWA (Mist)	5 mg/m ³	NZ OEL
	Further information: Sampled by a method that does not collect vapour.			
		WES-STEL (Mist)	10 mg/m ³	NZ OEL
		TWA (Inhalable fraction)	5 mg/m ³	ACGIH
Aluminium stearate	637-12-7	WES-TWA	10 mg/m ³	NZ OEL
		TWA	10 mg/m ³	ACGIH
		TWA (Respirable fraction)	1 mg/m ³ (Aluminium)	ACGIH

Personal protective equipment

- Respiratory protection : In the case of vapour formation use a respirator with an approved filter.
- 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
- Decomposition temperature : No data available
- Explosive properties : No statements available.

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Oxidizing properties : No statements available.
Impact sensitivity : No data available

SECTION 10. STABILITY AND REACTIVITY

Chemical stability : No statements available.
Possibility of hazardous reac- : No data available
tions
Conditions to avoid : No data available
Incompatible materials : Oxidizing agents
Hazardous decomposition : Carbon monoxide (CO)
products : Carbon dioxide (CO₂)

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg
Acute inhalation toxicity : Assessment: No adverse effect has been observed in acute
toxicity tests.
Acute dermal toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg

Respiratory or skin sensitisation

Components:

Cloxacillina Benzatinica:

Result: May cause sensitisation by skin contact.

Result: May cause sensitisation by inhalation.

Binotal acid / ampicillin trihydrate:

Result: May cause sensitisation by inhalation.

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

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Chronic toxicity

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Binotal acid / ampicillin trihydrate:

Toxicity to microorganisms : > 10.000 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Product:

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

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.

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National Regulations

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

No statements available.

HSNO Approval Number

HSR002346

Not applicable

HSNO Controls

Approved handler certificate not required.

HSNO tracking not required.

Refer to EPA user guide to the HSNO control 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; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - 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; KECI - 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

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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
NZ OEL / WES-STEL : Workplace Exposure Standard - Short-Term Exposure Limit

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.

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