

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

 Version: 1.0
 Revision Date 12.12.2013

Print Date 17.12.2013

OSURNIA

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Substance No. : 000070003630
 NAH Substance Code : A-20114 B
 Trade name : OSURNIA
 Product name : FLORFENICOL 0.834MG/TERBINAFIN 0.834MG/BETAMETHASON ACETATE 0.083MG - GEL
 Active ingredient : AHC 2150176 A; Florfenicol
 : AHC 0597250 A; Terbinafine Base
 : AHC 2211860 A; Betamethasone Acetate

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

Use : Veterinary medicinal product

1.3 Details of the supplier of the safety data sheet

Company : Novartis Animal Health Inc.
 : Schwarzwaldallee 215
 : CH - 4058 Basel
 : Switzerland

 Telephone : +41616971111
 Contact person : Phone (office hours) +41 61 697 30 65
 E-mail address : msds.nah@novartis.com

1.4 Emergency telephone number

Emergency telephone number : **Phone (24 h) +41 61 696 33 33**
 Emergency information : concerning transport see emergency phone number in the shipping documents
 concerning storage see emergency phone number of local Novartis organization

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008.

classification not required The product is not subject of the Regulation (EC) No. 1272/2008.		
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Classification according to EU Directives 67/548/EEC or 1999/45/EC

classification not required The product is not subject of Directive 1999/45 EEC.	---
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2.2 Label elements

Labelling according to Regulation (EC) No. 1907/2006

Hazard pictograms : not required
 The product is not subject of the Regulation (EC) No. 1272/2008.

Labelling according to EC Directives 67/548/EEC or 1999/45/EC

Symbol(s) : not required
 The product is not subject of Directive 1999/45 EEC.

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OSURNIA

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous components

Identification	CAS-No.	Classification 67/548/EEC	Classification REGULATION (EC) No 1272/2008	Concentration (% w/w)
Florfenicol	73231-34-2, 76639-94-6	N R51/53, R62	Repro tox. Cat. 2 Aquatic Chronic 2 H361f H411	0.834
Terbinafine Base	91161-71-6	N R50/53	Aquatic Acute 1 Aquatic Chronic 1 H400 H410	0.834
Betamethasone Acetate	987-24-6	Xn R61, R48/20/21	Repro tox. Cat. 1B STOT RE 2 H360D H373	0.083
2,6-di-tert-butyl-p-cresol	128-37-0	Xn R22, R36/37/38	Acute Tox. 4 (oral) Skin irrit. 2 Eye irrit. Cat. 2 Aquatic Acute 1 Aquatic Chronic 1 H302 H315 H319 H400 H410	- < 0.10
Propylene carbonate	108-32-7	Xi R36	Eye irrit. Cat. 2 H319	> 50.00 - < 75.00
Glycerol formal	4740-78-7, 5464-28-8	Xi R63	Eye irrit. Cat. 2 Repro tox. Cat. 2 H319 H361	> 25.00 - < 50.00

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- Skin contact : Wash off with soap and water.
- Eye contact : Rinse immediately with plenty of water and seek medical advice.
- Ingestion : Rinse mouth with water. Drink water as a precaution.

4.2 Most important symptoms/effects, acute and delayed

- Poisoning Symptoms : No case of human poisoning is on record.
irritant effects

4.3 Indication of any immediate medical attention and special treatment needed

- Antidotes : No specific antidote is known! Apply symptomatic therapy.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

- Suitable extinguishing media : Dry powder, foam, carbon dioxide (CO₂) or water spray (do not use water jet).

5.2 Special hazards arising from the substance or mixture

- Hazardous decomposition products : Exposure to decomposition products may be a hazard to health.

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

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OSURNIA

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

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

6.3 Methods and materials for containment and cleaning up

Methods for cleaning up : Refer to protective measures listed in sections 7 and 8.
 Collect product in containers for safe disposal.
 Treat contaminated surfaces with water.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling advice : Handle in accordance with good industrial hygiene and safety practice.
 Avoid contact with skin, eyes and clothing.

Storage

Place of storage : Store in a refrigerator.

Storage temperature: : min. 2 °C - max. 8 °C
 Do not freeze.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters			
Identification	CAS-No.	Notes	Exposure limit(s)
Florfenicol	73231-34-2, 76639-94-6	Suspected of causing adverse effects on the reproductive system.	8 h TWA Novartis Internal Exposure Limit (NPIEL) 0.1mg/m ³
Terbinafine Base	91161-71-6		8 h TWA Novartis Internal Exposure Limit (NPIEL) 2 mg/m ³
2,6-di-tert-butyl-p-cresol	128-37-0	Inhalable dust/particles	8 h TWA Max. exposure level at working place (MAK SUVA (TLV)): 10 mg/m ³

8.2 Exposure controls

Protective measures : The use of technical measures should always have priority over the use of personal protective equipment.

Personal protective equipment

Open handling

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection : Gloves

Eye protection : If splashes are likely to occur, wear: Goggles

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place:
 Lab coat
 impervious clothing

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
 Wash hands before breaks and immediately after handling the product.
 Shower or bathe at the end of working.
 Thoroughly clean contaminated equipment with soap or soda solution.
 Thoroughly clean protective gear.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

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OSURNIA**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES****9.1 Information on basic physical and chemical properties**

Physical state	:	liquid
Form	:	clear gel
Colour	:	white - slightly yellowish
Density	:	1.2 g/ml
Flash point	:	> 90 °C Remarks: Derived from component with lowest flash point.

SECTION 10: STABILITY AND REACTIVITY**10.1 Reactivity**

Reactivity : Stable under recommended storage conditions.

10.2 Chemical stability

Chemical Stability : Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : None known.

10.4 Conditions to avoid

Conditions to avoid : Stable under recommended storage conditions.

10.5 Incompatible materials

Materials to avoid : no data available

10.6 Hazardous decomposition productsHazardous decomposition products : Stable under recommended storage conditions.
Type of listing: no data available**SECTION 11: TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects**

Acute oral toxicity	:	LD50 > 2,000 mg/kg Species: Rat Method: OECD Test Guideline 425 Remarks: Information given is based on tests on the mixture itself.
Acute dermal toxicity	:	> 2,020 mg/kg Species: Rat Method: OECD Test Guideline 402 Remarks: Information given is based on tests on the mixture itself.
Skin irritation	:	No skin irritation Species: rabbit Method: OECD Test Guideline 404 Remarks: Information given is based on tests on the mixture itself.
Eye irritation	:	moderately irritant Species: rabbit Method: OECD Test Guideline 405 Remarks: Information given is based on tests on the mixture itself.
Sensitisation	:	not sensitizing Species: Mouse Method: OECD Test Guideline 429 Remarks: Information given is based on tests on the mixture itself.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version: 1.0

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OSURNIA

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

- | | | |
|----------------------------|---|---|
| Toxicity to fish | : | LC50 > 900 mg/l
Species: <i>Oncorhynchus mykiss</i> (Rainbow trout)
Exposure time: 96 h
Remarks: Florfenicol |
| | : | NOEC > 900 mg/l
Species: <i>Oncorhynchus mykiss</i> (Rainbow trout)
Exposure time: 96 h
Remarks: Florfenicol |
| | : | NOEC 0.047 mg/l
Species: <i>Pimephales promelas</i> (Fathead minnow)
Exposure time: 32 d
Remarks: Terbinafine |
| Toxicity to daphnia | : | EC50 > 495 mg/l
Species: <i>Daphnia magna</i> (water flea)
Exposure time: 48 h
Remarks: Florfenicol |
| | : | NOEC 84.5 mg/l
Species: <i>Daphnia magna</i> (water flea)
Remarks: Florfenicol |
| | : | EC50 0.35 mg/l
Species: <i>Daphnia magna</i> (water flea)
Exposure time: 48 h
Remarks: Terbinafine |
| Toxicity to algae | : | EC50 3.83 mg/l
Species: Algae
Exposure time: 72 h
Remarks: Florfenicol |
| | : | NOEC 0.32 mg/l
Species: Algae
Exposure time: 72 h
Remarks: Florfenicol |
| | : | NOEC 0.00053 mg/l
Species: <i>Pseudokirchneriella subcapitata</i> (green algae)
Exposure time: 72 h
Remarks: Terbinafine |
| Toxicity to microorganisms | : | IC50 > 100 mg/l
Species: act.sewage sludge
Exposure time: 3 h
Remarks: Terbinafine |

12.2 Persistence and degradability

- | | | |
|------------------|---|--|
| Biodegradability | : | 4 %
not biodegradable
Test type: carbondioxide evolution
According to the results of tests of biodegradability this product is not readily biodegradable.
Remarks: Terbinafine |
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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

- Product : Collect product and dispose of in an incinerator approved for chemicals. Dispose of as special waste in compliance with local and national regulations. Spilled product cannot be used further and must be disposed of. If safe disposal is not possible, contact the manufacturer, the dealer or the local representative.
- Contaminated packaging : Dispose of empty containers in an incinerator approved for chemicals. In accordance with internal, local and national regulations.

SECTION 14: TRANSPORT INFORMATION

- Transport Condition : COOL: refrigerated transport at 2-8°C
Do not freeze.
- Land transport (ADR/RID)**
- UN number : FREE
- Class : Not classified as dangerous in the meaning of transport regulations.
- Sea transport (IMDG)**
- UN number : FREE
- Class : Not classified as dangerous in the meaning of transport regulations.
- Air transport (ICAO/IATA)**
- UN number : FREE
- Class : Not classified as dangerous in the meaning of transport regulations.
- Postal delivery - Switzerland : 1 allowed

SECTION 15: REGULATORY INFORMATION

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

National legislation

Weight limit (Switzerland - StFV) : 200,000 kg

Swiss Fire Prevention Code : F4

15.2 Chemical Safety Assessment

Assessment : not required

SECTION 16: OTHER INFORMATION

Full text of R-phrases referred to under sections 2 and 3

Full text of H-Statements referred to under sections 2 and 3.

R51/53	: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R62	: Possible risk of impaired fertility.
R50/53	: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61	: May cause harm to the unborn child.
R48/20/21	: Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.
R22	: Harmful if swallowed.
R36/37/38	: Irritating to eyes, respiratory system and skin.
R36	: Irritating to eyes.
R63	: Possible risk of harm to the unborn child.
H361f	: Suspected of damaging fertility.
H411	: Toxic to aquatic life with long lasting effects.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H360D	: May damage the unborn child.
H373	: May cause damage to organs through prolonged or repeated exposure.
H302	: Harmful if swallowed.
H315	: Causes skin irritation.
H319	: Causes serious eye irritation.
H400	: Very toxic to aquatic life.
H410	: Very toxic to aquatic life with long lasting effects.
H319	: Causes serious eye irritation.
H361	: Suspected of damaging fertility or the unborn child.

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Changes since the last version are highlighted in the margin. This version replaces all previous versions.

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.
