

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version: 1.0

Revision Date 09.12.2013

Print Date 17.12.2013

FLORVIO

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

1.1 Product identifiers

Substance No. : 000070003390
 NAH Substance Code : A 20130 A
 Trade name : FLORVIO
 FLORVIO 23 MG/ML SOL
 Type of preparation : Concentrate vet. use
 Active ingredient : AHC 2150176; Florfenicol

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

Use : Veterinary medicinal product
 Antibiotic

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.

Chronic aquatic toxicity Category 3	H412	
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Classification according to EU Directives 67/548/EEC or 1999/45/EC

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	R52/53
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2.2 Label elements

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

Hazard pictograms : not required
 Hazard statements : H412 Harmful to aquatic life with long lasting effects.
 Precautionary statements : P273 Avoid release to the environment.

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

Symbol(s) : not required
 R-phrases : R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 S-phrases : S60 This material and its container must be disposed of as hazardous waste.

Further information

The product is a veterinary product and is not subject of Directives 67/548/EEC or 1999/45/EC or to Regulation (EC) No. 1272/2008.
 Therefore the product does not need to be labeled according to the European directives and respective national laws.

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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
				2.30

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

- Skin contact : Wash off with soap and water.
- Eye contact : Rinse with plenty of water.
- Ingestion : Rinse mouth with water.

4.2 Most important symptoms/effects, acute and delayed

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

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.

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 : Cover up product with absorptive material such as sand, soil, diatomaceous earth, etc.
Pick up and transfer to properly labelled containers.
Treat contaminated surfaces with water.
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.

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.
People with known hypersensitivity to polyethylene glycols should avoid contact with the veterinary product.

Storage

- Storage temperature: : min. 2 °C - max. 25 °C
Do not freeze.

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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.	Novartis Internal Exposure Limit (NPIEL) 0.1 mg/m ³ 8 h TWA
Polyethylene glycol	25322-68-3	A health risk of teratogenic effects can be excluded, if there is compliance with the TLV.	Max. exposure level at working place (MAK SUVA (TLV)): 1,000 ppm

8.2 Exposure controls

- Protective measures**
- : The use of technical measures should always have priority over the use of personal protective equipment.
 - : In working with or around this substance precautionary measures should be taken according to workplace health risk assessments and local policies.
- Personal protective equipment**
- Open handling**
- Respiratory protection** : No personal respiratory protective equipment normally required.
- Hand protection** : Gloves
- Eye protection** : Safety glasses
- Hygiene measures** : Wash hands before breaks and immediately after handling the product.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- Physical state** : liquid
- Form** : solution
- Colour** : colourless
- Odour** : odourless
- Density** : 1.11 - 1.15 g/ml
- Flash point** : 220 °C
Test type: closed cup
Remarks: Polyethyleneglycol 300
- Autoignition temperature** : 305 °C
Remarks: Polyethyleneglycol 300

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** : Stable under recommended storage conditions.

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 products

- Hazardous decomposition products** : Stable under recommended storage conditions.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity	:	LD50 > 2,000 mg/kg
		Species: Rat Remarks: Florfenicol
	:	LD50 27,500 mg/kg
		Species: Rat Remarks: Polyethyleneglycol 300
Acute dermal toxicity	:	LD50 > 20,000 mg/kg
		Species: rabbit Remarks: Polyethyleneglycol 300
Eye irritation	:	Mild eye irritation
		Species: rabbit Remarks: Polyethyleneglycol 300
Mutagenicity (in vitro)	:	negative
		Remarks: Derived from the active ingredient(s)
Mutagenicity (in vivo)	:	negative
		Remarks: Derived from the active ingredient(s)
Repeated dose toxicity	:	NOEL: 1 mg/kg
		Species : Rat Remarks: Derived from the active ingredient(s)
Carcinogenicity	:	Did not show carcinogenic effects in animal experiments.
		Derived from the active ingredient(s)
Toxicity for reproduction	:	Adverse effects on the male reproductive system (rat).
		Derived from the active ingredient(s)
Developmental Toxicity	:	no potential for embryo- or fetotoxicity (rat)
		Derived from the active ingredient(s)
Further information	:	Did not show carcinogenic, teratogenic or mutagenic effects in animal experiments.
		Derived from the active ingredient(s)

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish	:	NOEC > 900 mg/l
		Species: Oncorhynchus mykiss (rainbow trout) Exposure time: 96 h Remarks: Florfenicol
	:	LC50 < 500 mg/l
		Species: Leuciscus idus (Golden orfe) Remarks: Polyethyleneglycol 300
Toxicity to daphnia	:	EC50 > 100 mg/l
		Species: Daphnia magna (water flea) Exposure time: 48 h Remarks: Florfenicol
Toxicity to algae	:	EC50 3.83 mg/l
		Species: Algae Exposure time: 72 h Remarks: Florfenicol

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	:	NOEC 0.32 mg/l
	:	Species: Algae
	:	Exposure time: 72 h
	:	Remarks: Florfenicol
12.2 Persistence and degradability		
Biodegradability	:	> 90 %
	:	readily biodegradable
	:	Test type: aerobic
	:	Exposure time: 28 d
	:	Remarks: Polyethyleneglycol 300

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product	:	Refer to protective measures listed in sections 7 and 8. Pick up and transfer to properly labelled containers. Dispose of in an incinerator approved for chemicals. In accordance with internal, local and national regulations.
Contaminated packaging	:	Dispose of empty containers in an incinerator approved for chemicals. In accordance with internal, local and national regulations. Check possibilities of recycling not contaminated packaging material.

SECTION 14: TRANSPORT INFORMATION

Transport Condition	:	TEMPCONTROL: Transport + intermediate storage between +2°C and +30°C Do not freeze.
Land transport (ADR/RID)		
UN number	:	FREE
Class	:	Not classified as dangerous good
Sea transport (IMDG)		
UN number	:	FREE
Class	:	Not classified as dangerous good
Air transport (ICAO/IATA)		
UN number	:	FREE
Class	:	Not classified as dangerous good
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		
Swiss Fire Prevention Code	:	F4 PN4

15.2 Chemical Safety Assessment

Assessment	:	not required
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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.
H361f	:	Suspected of damaging fertility.
H411	:	Toxic to aquatic life with long lasting effects.

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.