

**STELFONTA**[®]

Stelfonta[®]

Safety Data Sheet

according to the Model Work Health and Safety Regulations

QBiotics Document Number: SDS 06-AU QBiotics Version: 2

Date of issue: 16 September 2019 Revision date: 22 November 2019 Supersedes: 16 September 2019

SECTION 1: Identification : Product identifier and chemical identity

1.1. Product identifier

Product form : Mixture
Trade name : Stelfonta[®]

1.2. Other means of identification

Synonyms : Tigilanol Tiglate Injection, 1 mg/mL
EBC-46 Injection, 1 mg/mL

1.3. Recommended use of the chemical and restrictions on use

Recommended use : Stelfonta[®] is used for the treatment of solid tumors in veterinary applications only

1.4. Supplier's details

Supplier
QBiotics Group Limited
Suite 3A/165 Moggill Road
Taringa, Qld, 4068
Australia

Telephone: +61 7 3870 8933

1.5. Emergency phone number

Emergency number : +61 (0) 409 734 320 8 -5 PM. Australian Eastern Standard Time (AEST)

SECTION 2: Hazards identification

2.1. Classification of the hazardous chemical

Classification according to the model Work Health and Safety Regulations (WHS Regulations)

Not classified

2.2. Label elements

No labelling applicable

2.3. Other hazards

other hazards which do not result in classification : None under normal conditions.

SECTION 3: Composition/information on ingredients

Name	CAS-No.	%	Classification according to the model Work Health and Safety Regulations (WHS Regulations)
Water	7732-18-5	60	Not classified
Propane 1,2-diol	57-55-6	40	Not classified
12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tiglaen-3-one	943001-56-7	0.1 - 0.2	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Sodium acetate trihydrate	6131-90-4	< 0.1	Not classified
Acetic acid	64-19-7	< 0.1	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314
Other substances (not contributing to the classification of this product)		99.6 - 99.9	

Note: Also see section 16 for the full Hazard statements

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Unlikely route of exposure. Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.

First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Do NOT induce vomiting. Call a poison center or a doctor if you feel unwell.

4.2. Symptoms caused by exposure

Symptoms/effects after inhalation : None known.
Symptoms/effects after skin contact : May cause slight temporary irritation.
Symptoms/effects after eye contact : May cause slight temporary irritation.
Symptoms/effects after ingestion : Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician : Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None to our knowledge.

5.2. Special hazards arising from the substance or mixture

Fire hazard : The product is not flammable. Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases.
Explosion hazard : No direct explosion hazard.
General measures : Evacuate unnecessary personnel.

5.3. Special protective equipment and precautions for fire-fighters

Protective equipment for firefighters : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Hazchem Code : None assigned

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate unnecessary personnel.

6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. For bulk solution, notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : For bulk solution, the spill area should be treated with solutions of either dilute ammonium hydroxide or 0.1% sodium hydroxide in ethanol or sodium carbonate/detergent based agents such as Pyroneg. Apply the treated area with an inert material such as dry sand or suitable chemical absorbent. Collect all waste in suitable and labelled containers and dispose according to local legislation. Prevent runoff from entering water courses, sewers and basements.

Any unused medicinal product or waste materials derived from such medicinal products should be disposed of in accordance with local requirements. For bulk solution, dispose of materials or solid residues at an authorized site.

SECTION 7: Handling and storage, including how the chemical may be safely used

7.1. Precautions for safe handling

Precautions for safe handling : Avoid contact with skin and eyes. Personal protective equipment consisting of disposable impervious gloves and protective eye glasses should be worn when handling the product during medical treatment.
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep cool. Protect from sunlight. Store at temperatures not exceeding 2°C - 8°C (35.6°F - 46.4°F).
Incompatible materials : Oxidizing agent. Strong acids. Alkalis and caustic products.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters - exposure standards**

Acetic acid (64-19-7)		
Australia	Local name	Acetic acid
Australia	TWA (mg/m ³)	25 mg/m ³
Australia	TWA (ppm)	10 ppm
Australia	STEL (mg/m ³)	37 mg/m ³
Australia	STEL (ppm)	15 ppm
USA - ACGIH	Local name	Acetic acid
USA - ACGIH	ACGIH TWA (ppm)	10 ppm
USA - ACGIH	ACGIH STEL (ppm)	15 ppm
USA - ACGIH	Remark (ACGIH)	TLV® Basis: URT & eye irr; pulm func
USA - ACGIH	Regulatory reference	ACGIH 2019

Propane 1,2-diol (57-55-6)		
Australia	Local name	Propane-1,2-diol
Australia	TWA (mg/m ³)	474 mg/m ³ vapour & particulates 10 mg/m ³ particulates only
Australia	TWA (ppm)	150 ppm vapour & particulates

Exposure limit values for the other components

No additional information available

8.2. Monitoring

No additional information available

8.3. Appropriate engineering controls

Appropriate engineering controls : For bulk solution, ensure good ventilation of the work station. Use process enclosures, local exhaust ventilation or other engineering controls to eliminate airborne exposures.

8.4. Personal protective equipment

Hand protection : Protective gloves. neoprene or natural rubber gloves. Nitrile rubber.

Eye protection : Safety glasses.

Skin and body protection : Personal protective equipment consisting of disposable impervious gloves and protective eye glasses should be worn when handling the product during medical treatment. For bulk solution, when skin contact is possible, protective clothing including gloves, apron, sleeves, boots, head and face protection must be worn. Long sleeved protective clothing

Respiratory protection : Not expected to present a significant inhalation hazard under anticipated conditions of normal use

Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

Physical state : Liquid

Appearance : Clear.

Colour : Clear to pale yellow

Odour : Not known

Odour threshold : No data available

pH : 4.3 - 5.1

Relative evaporation rate (butylacetate=1) : No data available

Melting point / Freezing point : No data available

Boiling point : No data available

Flash point : No data available

Auto-ignition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure : No data available

Relative density : No data available

Density : Density : 1.03 g/ml

Solubility : Soluble in propyleneglycol.
Water: Insoluble

Log Pow : No data available

Explosive properties	: No data available
Explosive limits	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Minimum ignition energy	: No data available
Fat solubility	: No data available

SECTION 10: Stability and reactivity

Reactivity	: The product is non-reactive under normal conditions of use, storage and transport. The product is non-reactive under normal conditions of use, storage and transport
Chemical stability	: Stable under normal conditions. Stable in use and storage conditions as recommended in item 7.
Possibility of hazardous reactions	: No dangerous reactions known under normal conditions of use.
Conditions to avoid	: Elevated temperature.
Incompatible materials	: Oxidizing agent. Strong acids. Alkalis and caustic products.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced. Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases.

SECTION 11: Toxicological information

Likely routes of exposure	: Ingestion. Inhalation. Skin and eyes contact
Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met).
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met).
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met).

Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
LC50 inhalation rat (mg/l)	11.4 mg/l/4h

1,2-Propanediol (57-55-6)	
LD50 oral rat	20 g/kg
LD50 dermal rabbit	20800 mg/kg

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)	
Maximum Tolerated Dose:	
IV Acute Infusion (Dog)	0.150 mg/kg in male dog, single dose infused over 15 minutes
Subcutaneous (Dog)	Not known, dog study was inconclusive; single dose
IV Acute Infusion (Rat)	0.225 mg/kg in rats, single dose infused over 15 minutes

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 3.5 - 5.1
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 3.5 - 5.1
Respiratory or skin sensitisation	: Not classified (Lack of data)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)	
Did not induce gene mutations by either frameshift or base-pair changes either in the presence or absence of metabolic activation in bacteria (AMES test).	

Carcinogenicity : Not classified (Lack of data)

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)	
Carcinogenicity studies are not required for compounds indicated for the treatment of cancer.	

Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)	
Maximum Tolerated Dose:	
IV Repeat Infusion (Dog)	0.100 mg/kg in dogs, weekly, administered over 15 minutes
Severely Toxic Dose in 10% rats (STD ₁₀)	0.100 mg/kg in rats, once weekly, 15 minute IV infusion for three weeks

Aspiration hazard : Not classified (Lack of data)

Occupational Exposure Limit for Inhalation Route : 285.8 ng/m³/day
 Permitted Daily Exposure for Intravenous Route : 200 ng/kg body weight/week (equivalent to 28.6 ng/kg body weight/day)

SECTION 12: Ecological information

According to the National Code of Practice for the Preparation of Material Safety Data Sheets, Environmental classification information is not mandatory. Information relevant for GHS classification is available on request

12.1. Ecotoxicity

Ecology - general : This material has not been tested for environmental effects.
 Acute aquatic toxicity : Not classified (Based on available data, the classification criteria are not met)
 Chronic aquatic toxicity : Not classified (Based on available data, the classification criteria are not met)

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)

Log Pow	3.8
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Acetic acid (64-19-7)

LC50 fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
LC50 fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
Log Pow	-0.31 (at 20 °C)

Propane 1,2-diol (57-55-6)

LC50 fish 1	40613 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss)
EC50 Daphnia 1	18340 mg/l (Species: Ceriodaphnia dubia)
EC50 96h algae (1)	19000 mg/l (Species: Pseudokirchneriella subcapitata)
BCF fish 1	< 1

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)

Log Pow	See section 12.1 on ecotoxicology
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Acetic acid (64-19-7)

Log Pow	See section 12.1 on ecotoxicology
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Propane 1,2-diol (57-55-6)

BCF fish 1	See section 12.1 on ecotoxicology
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12.4. Mobility in soil

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)

Log Pow	See section 12.1 on ecotoxicology
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Acetic acid (64-19-7)

Log Pow	See section 12.1 on ecotoxicology
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12.5. Other adverse effects

Ozone : Not classified
 Other adverse effects : No additional information available

Tigilanol Tiglate Injection

Fluorinated greenhouse gases	False
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12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)

Fluorinated greenhouse gases	False
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Sodium acetate trihydrate (6131-90-4)

Fluorinated greenhouse gases	False
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Acetic acid (64-19-7)

Fluorinated greenhouse gases	False
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Propane 1,2-diol (57-55-6)

Fluorinated greenhouse gases	False
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Water (7732-18-5)

Fluorinated greenhouse gases	False
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SECTION 13: Disposal considerations

Product/Packaging disposal recommendations : Any unused medicinal product or waste materials derived from such medicinal products should be disposed of in accordance with local requirements. For bulk disposal, mix Stelfonta® with a 10% sodium hydroxide solution and let stand for a period of time up to 2 hours then dispose of the material through a liquid waste disposal program.

SECTION 14: Transport information**14.1. UN number**

Not regulated for transport

14.2. Proper Shipping Name - Addition

Not applicable

14.3. Transport hazard class(es)**ADG**

Transport hazard class(es) (ADG) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

14.4. Packing group

Packing group (ADG) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards

Marine pollutant : No

14.6. Special precautions for user

Specific storage requirement : No data available

Shock sensitivity : No data available

14.7. Additional information

Other information : No supplementary information available

Transport by road and rail

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

14.8. Hazchem or Emergency Action Code

Hazchem Code : None assigned

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)**

Relevant Poisons Schedule number : Poisons Schedule number: not covered under Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

15.2. International agreements

No additional information available

SECTION 16: Any other relevant information

Abbreviations and acronyms : ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road
 IMDG - International Maritime Dangerous Goods
 IATA - International Air Transport Association
 ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 RID - Regulations concerning the International Carriage of Dangerous Goods by Rail
 GHS - GHS - Globally Harmonised System

Revision date : 22 November 2019

Classification:

Not classified	
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Full text of H-statements:

Eye Irrit. 2A	Serious eye damage/eye irritation, Category 2A
Flam. Liq. 3	Flammable liquids, Category 3
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Irrit. 2	Skin corrosion/irritation, Category 2
H226	Flammable liquid and vapour.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

On the GHS scale of Category 1-4, 1 = the greatest hazard and 4 = the least.

SDS Australia

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