

SECTION 1: Identification

1.1. Identification

Product form : Mixture
 Trade name : Stelfonta[®]
 Synonyms : Tigilanol Tiglate Injection, 1 mg/mL
 EBC-46 Injection, 1 mg/mL

1.2. Recommended use and restrictions on use

Use of the substance/mixture : Stelfonta[®] is used for the treatment of solid tumors in veterinary applications only.

1.3. Supplier

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

Telephone: +61 7 3870 8933

1.4. Emergency telephone number

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

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Not classified

2.2. GHS Label elements, including precautionary statements

GHS US labeling

No labeling applicable

2.3. Other hazards which do not result in classification

Other hazards not contributing to the classification : None under normal conditions.

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	60	Not classified
1,2-Propanediol	(CAS-No.) 57-55-6	40	Not classified
12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one	(CAS-No.) 943001-56-7	0.1	Skin Irrit. 2, H315 Eye Irrit. 2A, H319
Sodium acetate trihydrate	(CAS-No.) 6131-90-4	< 0.1	Not classified
Acetic acid	(CAS-No.) 64-19-7	< 0.1	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318

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.

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| 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/doctor/physician if you feel unwell. |

4.2. Most important symptoms and effects (acute and delayed)

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| 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. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

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

5.2. Specific hazards arising from the chemical

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| 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. |

5.3. Special protective equipment and precautions for fire-fighters

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| Protection during firefighting | : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing. |
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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| General measures | : Evacuate unnecessary personnel. |
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6.1.1. For non-emergency personnel

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| 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

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

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| 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 labeled containers and dispose according to local legislation. Prevent runoff from entering water courses, sewers and basements. |
| Other information | : 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. |

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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| 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. Keep out of 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

12-Tigloyl-13-(2-methylbutanoyl)-6,7-epoxy-4,5,9,12,13,20-hexahydroxy-1-tigliaen-3-one (943001-56-7)		
Not applicable		
Sodium acetate trihydrate (6131-90-4)		
No additional information available		
Acetic acid (64-19-7)		
ACGIH	Local name	Acetic acid
ACGIH	ACGIH TWA (ppm)	10 ppm
ACGIH	ACGIH STEL (ppm)	15 ppm
ACGIH	Remark (ACGIH)	TLV® Basis: URT & eye irr; pulm func
ACGIH	Regulatory reference	ACGIH 2019
OSHA	OSHA PEL (TWA) (mg/m³)	25 mg/m³
OSHA	OSHA PEL (TWA) (ppm)	10 ppm
OSHA	Regulatory reference (US-OSHA)	OSHA Annotated Table Z-1
IDLH	US IDLH (ppm)	50 ppm
NIOSH	NIOSH REL (TWA) (mg/m³)	25 mg/m³
NIOSH	NIOSH REL (TWA) (ppm)	10 ppm
NIOSH	NIOSH REL (STEL) (mg/m³)	37 mg/m³
NIOSH	NIOSH REL (STEL) (ppm)	15 ppm
1,2-Propanediol (57-55-6)		
AIHA	WEEL TWA (mg/m³)	10 mg/m³
Water (7732-18-5)		
No additional information available		

8.2. 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.
- Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Appearance : Clear.
- Color : Clear to pale yellow
- Odor : Not known
- Odor threshold : No data available

pH	: 4.3 - 5.1
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Specific gravity / density	: 1.03 g/ml
Solubility	: Soluble in propylene glycol. Water: Insoluble
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions. Stable under use and storage conditions as recommended in section 7.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Elevated temperature.

10.5. Incompatible materials

Oxidizing agent. Strong acids. Alkalis and caustic products.

10.6. 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

11.1. Information on toxicological effects

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: 4.3 - 5.1
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according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 4.3 - 5.1
Respiratory or skin sensitization	: 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)
Specific target organ toxicity – single exposure	: Not classified (Lack of data)
Specific target organ toxicity – 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)
Viscosity, kinematic	: No data available
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.
Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : This material has not been tested for environmental effects.

Acetic acid (64-19-7)

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

1,2-Propanediol (57-55-6)

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

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	3.8
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Acetic acid (64-19-7)

Log Pow	-0.31 (at 20 °C)
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1,2-Propanediol (57-55-6)

BCF fish 1	< 1
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Disposal methods

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

Department of Transportation (DOT)

In accordance with DOT

Not regulated

Transportation of Dangerous Goods

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

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

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium acetate trihydrate (6131-90-4)

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Acetic acid (64-19-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

CERCLA RQ

5000 lb

1,2-Propanediol (57-55-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

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

Not listed on the Canadian DSL (Domestic Substances List)/NDSL (Non-Domestic Substances List)

Sodium acetate trihydrate (6131-90-4)

Not listed on the Canadian DSL (Domestic Substances List)

Acetic acid (64-19-7)

Listed on the Canadian DSL (Domestic Substances List)

1,2-Propanediol (57-55-6)

Listed on the Canadian DSL (Domestic Substances List)

Water (7732-18-5)

No additional information available

EU-Regulations

Sodium acetate trihydrate (6131-90-4)

No additional information available

Acetic acid (64-19-7)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

1,2-Propanediol (57-55-6)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Water (7732-18-5)

No additional information available

National regulations

Sodium acetate trihydrate (6131-90-4)

No additional information available

Acetic acid (64-19-7)

Listed on the AICS (Australian Inventory of Chemical Substances)
 Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
 Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
 Listed on the Japanese ISHL (Industrial Safety and Health Law)
 Listed on the Korean ECL (Existing Chemicals List)
 Listed on NZIoC (New Zealand Inventory of Chemicals)
 Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
 Listed on INSQ (Mexican National Inventory of Chemical Substances)
 Listed on the TCSI (Taiwan Chemical Substance Inventory)

1,2-Propanediol (57-55-6)

Listed on the AICS (Australian Inventory of Chemical Substances)
 Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
 Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
 Listed on the Japanese ISHL (Industrial Safety and Health Law)
 Listed on the Korean ECL (Existing Chemicals List)
 Listed on NZIoC (New Zealand Inventory of Chemicals)
 Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
 Listed on INSQ (Mexican National Inventory of Chemical Substances)
 Listed on the TCSI (Taiwan Chemical Substance Inventory)

Water (7732-18-5)

No additional information available

15.3. US State regulations

No additional information available

SECTION 16: Other information

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date : 16 September 2019

Full text of H-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
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
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Comb. Dust	Combustible Dust
H226	Flammable liquid and vapor
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H318	Causes serious eye damage
H319	Causes serious eye irritation

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

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

SDS US (GHS HazCom 2012)

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