

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

---

### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

##### 1.1 Product identifier

Tri-Solfen

HSNO Approval Number : HSR100759

ACVM number : A011409

##### 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](mailto: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

6.1: Acute toxicity (Oral) : Category E  
6.3: Skin irritation : Category B  
6.4: Eye irritation : Category A  
6.5: Respiratory sensitisation : Category A  
6.5: Skin sensitisation : Category B  
6.6: Germ cell mutagenicity : Category B  
6.7: Carcinogenicity : Category B  
6.9: Specific Target Organ Toxicity (Oral) : Category B  
9.1: Aquatic toxicity (Acute or Chronic) : Category B

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

9.3: Ecotoxic to terrestrial vertebrates : Category C

### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H303 May be harmful if swallowed.  
H316 Causes mild skin irritation.  
H317 May cause an allergic skin reaction.  
H320 Causes eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H341 Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).  
H351 Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard).  
H371 May cause damage to organs if swallowed.  
H411 Toxic to aquatic life with long lasting effects.  
H433 Harmful to terrestrial vertebrates.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.

### 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)
Lidocaine Hydrochloride Monohydrate	6108-05-0	>= 1 -< 10
Cetrimide	8044-71-1	>= 0,25 -< 1
Disodium disulphite	7681-57-4	>= 0,1 -< 0,25

## SECTION 4. FIRST AID MEASURES

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

---

- 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 : If swallowed, seek medical advice immediately and show this container or label.
- Most important symptoms and effects, both acute and delayed : No information available.  
No information available.
- Notes to physician : No information available.
- 

### 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 (CO<sub>2</sub>)
- 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.
- 

### 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,
-

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

acid binder, universal binder, sawdust).  
Place in closed containers. Label for proper disposal.

### 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.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Disodium disulphite	7681-57-4	WES-TWA	5 mg/m <sup>3</sup>	NZ OEL
		TWA	5 mg/m <sup>3</sup>	ACGIH

#### Personal protective equipment

- Respiratory protection : Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)
- 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

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

---

can be expected.  
Wear suitable protective equipment.

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
Explosive properties : No statements available.  
Oxidizing properties : No data available  
Impact sensitivity : No data available  
Minimum ignition energy : No data available

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : No data available  
Chemical stability : No data available  
Possibility of hazardous reactions : No data available  
Conditions to avoid : No data available  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

##### **Product:**

Acute oral toxicity : Acute toxicity estimate (ATE): 1.980 mg/kg  
Method: Calculation method  
Acute inhalation toxicity : Acute toxicity estimate (ATE): > 40 mg/l  
Exposure time: 4 h  
Test atmosphere: vapour  
Method: Calculation method  
Acute dermal toxicity : Acute toxicity estimate (ATE): > 5.000 mg/kg  
Method: Calculation method

---

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

---

### Components:

#### **Lidocaine Hydrochloride Monohydrate:**

Acute oral toxicity : LD50 (Rat): 317 mg/kg  
LD50 (Mouse): 220 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 570 mg/kg  
Application Route: Subcutaneous

LD50 (Mouse): 22 mg/kg  
Application Route: intravenous

LD50 (Mouse): 119 mg/kg  
Application Route: Intraperitoneal

#### **Cetrimide:**

Acute oral toxicity : LD50 (Rat): 1.000 mg/kg

#### **Disodium disulphite:**

Acute oral toxicity : LD50 (Rat): 1.540 mg/kg  
Method: OECD 401

### **Skin corrosion/irritation**

#### Components:

#### **Lidocaine Hydrochloride Monohydrate:**

Result: Mild skin irritation

#### **Disodium disulphite:**

Species: Rabbit  
Method: OECD 404  
Result: No skin irritation

### **Serious eye damage/eye irritation**

#### Components:

#### **Lidocaine Hydrochloride Monohydrate:**

Result: Mild eye irritation

#### **Disodium disulphite:**

Species: Rabbit  
Result: Risk of serious damage to eyes.  
Assessment: Causes serious eye damage.  
Method: OECD 405

# SAFETY DATA SHEET

## Tri-Solfen



Version  
1.1

Revision Date:  
15.01.2019

SDS Number:  
122000017643

Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

### Respiratory or skin sensitisation

#### Components:

##### **Cetrimide:**

Test Type: Skin sensitisation

Result: May cause sensitisation by skin contact.

##### **Disodium disulphite:**

Species: Guinea pig

Result: Does not cause skin sensitisation.

Remarks: May cause sensitisation of susceptible persons by skin contact.

### Chronic toxicity

### Germ cell mutagenicity

#### Components:

##### **Lidocaine Hydrochloride Monohydrate:**

Genotoxicity in vitro

: Test Type: Ames test

Test system: Salmonella typhimurium

Result: negative

Test Type: In vitro gene mutation study in mammalian cells

Test system: Hamster ovary-cells

Result: negative

Test Type: DNA damage and/or repair

Result: negative

##### **Disodium disulphite:**

Genotoxicity in vitro

: Test Type: Ames test

Method: OECD 471

Result: negative

Test Type: Micronucleus test

Result: negative

### Reproductive toxicity

#### Components:

##### **Lidocaine Hydrochloride Monohydrate:**

Effects on fertility

: Species: Rat

Application Route: Subcutaneous

General Toxicity - Parent: NOAEL: 30 mg/kg

General Toxicity F1: NOAEL: 30 mg/kg

# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

---

### Further information

#### Components:

##### **Lidocaine Hydrochloride Monohydrate:**

Pharmaceutic effects  
Remarks: Local anesthetic

---

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Cetrimide:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Gammarus salinus (seawater shrimp)): 0,1 mg/l  
Exposure time: 48 h

Toxicity to algae : EC50 (Microcystis aeruginosa (blue-green algae)): 0,03 mg/l  
Exposure time: 96 h

M-Factor (Acute aquatic toxicity) : 10

##### **Disodium disulphite:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 150 - 220 mg/l  
Exposure time: 96 h  
Method: DIN 38412

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 89 mg/l  
Exposure time: 48 h  
Method: OECD 202

Toxicity to algae : IC50 (Desmodesmus subspicatus (green algae)): 48 mg/l  
Exposure time: 72 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): 56 mg/l  
Exposure time: 17 h

### Ecotoxicology Assessment

Acute aquatic toxicity : Harmful to aquatic life.

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

### Persistence and degradability

#### Components:

##### **Disodium disulphite:**

Chemical Oxygen Demand (COD) : 165 mg/g



# SAFETY DATA SHEET

## Tri-Solfen



Version 1.1      Revision Date: 15.01.2019      SDS Number: 122000017643      Date of last issue: 21.08.2018  
Date of first issue: 21.08.2018

---

### Bioaccumulative potential

#### Components:

##### **Lidocaine Hydrochloride Monohydrate:**

Partition coefficient: n-octanol/water : log Pow: 2,1

##### **Disodium disulphite:**

Partition coefficient: n-octanol/water : log Pow: -3,7 (25 °C)

### 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**

UN/ID No. : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Cetrimide)  
Class : 9  
Packing group : III  
Labels : 9  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

#### **IMDG-Code**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Cetrimide)

---

# SAFETY DATA SHEET

## Tri-Solfen



Version	Revision Date:	SDS Number:	Date of last issue: 21.08.2018
1.1	15.01.2019	122000017643	Date of first issue: 21.08.2018

Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

---

## SECTION 15. REGULATORY INFORMATION

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

#### HSNO Approval Number

HSR100759

#### 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 : Not 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;

# SAFETY DATA SHEET

## Tri-Solfen



Version	Revision Date:	SDS Number:	Date of last issue: 21.08.2018
1.1	15.01.2019	122000017643	Date of first issue: 21.08.2018

---

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 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

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.

NZ / EN