

### Sulfamethoxazole / Trimethoprim Injection Formulation

| Version<br>3.0            | Revision Date: 06.04.2024 | SDS Number:<br>7848268-00010 | Date of last issue: 30.09.2023<br>Date of first issue: 03.03.2021 |  |
|---------------------------|---------------------------|------------------------------|---|--|
|                           |                           |                              |   |  |
| Section 1                 | dontification             |                              |   |  |
| Section 1: Identification |                           |                              |   |  |

| Product identifier :                       | Sulfamethoxazole / Trimethoprim Injection Formulation   |  |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
| Recommended use of the chen                | Recommended use of the chemical and restrictions on use |  |  |  |  |  |  |
| Recommended use :<br>Restrictions on use : | Veterinary product<br>Not applicable                    |  |  |  |  |  |  |
| Manufacturer or supplier's deta            | ills  |  |  |  |  |  |  |
| Company :                                  | MSD   |  |  |  |  |  |  |
| Address :                                  | 50 Tuas West Drive<br>Singapore - Singapore 638408      |  |  |  |  |  |  |
| Telephone :                                | +1-908-740-4000   |  |  |  |  |  |  |
| Emergency telephone number :               | 65 6697 2111 (24/7/365)                                 |  |  |  |  |  |  |
| E-mail address :                           | EHSDATASTEWARD@msd.com                                  |  |  |  |  |  |  |

#### Section 2: Hazard identification

#### Classification of the substance or mixture

| Skin corrosion/irritation                          | : | Category 1               |
|--|---|--------------------------|
| Serious eye damage/eye irri-<br>tation             | : | Category 1               |
| Reproductive toxicity                              | : | Category 2               |
| Specific target organ toxicity - single exposure   | : | Category 3               |
| Specific target organ toxicity - repeated exposure | : | Category 2 (Bone marrow) |
| Short-term (acute) aquatic hazard                  | : | Category 1               |
| Long-term (chronic) aquatic hazard                 | : | Category 1               |

#### GHS Label elements, including precautionary statements



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|--------------|------------------------------|--|--|
| Haza         | rd pictograms                |  |  |
| Signa        | l word                       | : Danger   | • • •  |
| Haza         | rd statements                | H335 May cau<br>H361d Suspec<br>H373 May cau<br>prolonged or re  | severe skin burns and eye damage.<br>Ise respiratory irritation.<br>Ised of damaging the unborn child.<br>Ise damage to organs (Bone marrow) through<br>epeated exposure.<br>Is to aquatic life with long lasting effects.   |
| THECS        | autionary statements         | P202 Do not h<br>and understoo<br>P260 Do not b<br>P264 Wash sk<br>P271 Use only<br>P273 Avoid re<br>P280 Wear pro   | pecial instructions before use.<br>andle until all safety precautions have been re<br>d.<br>reathe mist or vapours.<br>tin thoroughly after handling.<br>y outdoors or in a well-ventilated area.<br>lease to the environment.<br>otective gloves/ protective clothing/ eye protected.   |
|              |                              | Do NOT induc<br>CENTER/ doc<br>P303 + P361 -<br>immediately al<br>shower. Imme<br>P304 + P340 -<br>and keep com<br>POISON CEN<br>P305 + P351 -<br>water for seve<br>and easy to do<br>CENTER/ doc<br>P308 + P313 I<br>attention. | <ul> <li>P353 + P310 IF ON SKIN (or hair): Take off</li> <li>I contaminated clothing. Rinse skin with water</li> <li>diately call a POISON CENTER/ doctor.</li> <li>P310 IF INHALED: Remove person to fresh a fortable for breathing. Immediately call a TER/ doctor.</li> <li>P338 + P310 IF IN EYES: Rinse cautiously v ral minutes. Remove contact lenses, if present b. Continue rinsing. Immediately call a POISON tor.</li> <li>F exposed or concerned: Get medical advice/</li> <li>ontaminated clothing before reuse.</li> </ul> |
|              |                              | <b>Storage:</b><br>P405 Store loc  |  |
|              |                              | Disposal:  | of contents/ container to an approved waste  |



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#### Other hazards which do not result in classification None known.

#### Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

#### Components

| Chemical name    | CAS-No.   | Concentration (% w/w) |
|------------------|-----------|-----------------------|
| 1,3-Dioxan-5-ol  | 4740-78-7 | >= 70 -< 90           |
| Sulfamethoxazole | 723-46-6  | >= 10 -< 20           |
| Ethanolamine     | 141-43-5  | >= 5 -< 10            |
| Trimethoprim     | 738-70-5  | >= 3 -< 10            |

#### Section 4: First-aid measures

| Description of necessary first-aid measures |  |  |  |  |  |  |
|---|--|--|--|--|--|--|
| General advice                              | <ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>   |  |  |  |  |  |
| If inhaled                                  | <ul> <li>If inhaled, remove to fresh air.</li> <li>If not breathing, give artificial respiration.</li> <li>If breathing is difficult, give oxygen.</li> <li>Get medical attention immediately.</li> </ul>  |  |  |  |  |  |
| In case of skin contact                     | <ul> <li>In case of contact, immediately flush skin with plenty of water<br/>for at least 15 minutes while removing contaminated clothing<br/>and shoes.</li> <li>Get medical attention immediately.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul> |  |  |  |  |  |
| In case of eye contact                      | <ul> <li>In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.</li> <li>If easy to do, remove contact lens, if worn.</li> <li>Get medical attention immediately.</li> </ul>   |  |  |  |  |  |
| If swallowed                                | <ul> <li>If swallowed, DO NOT induce vomiting.</li> <li>If vomiting occurs have person lean forward.</li> <li>Call a physician or poison control centre immediately.</li> <li>Rinse mouth thoroughly with water.</li> <li>Never give anything by mouth to an unconscious person.</li> </ul>        |  |  |  |  |  |
| Most important symptoms ar                  | d effects, both acute and delayed  |  |  |  |  |  |
| Risks                                       | <ul> <li>Causes serious eye damage.</li> <li>May cause respiratory irritation.</li> <li>Suspected of damaging the unborn child.</li> <li>May cause damage to organs through prolonged or repeated exposure.</li> <li>Causes severe burns.</li> <li>Causes digestive tract burns.</li> </ul>        |  |  |  |  |  |



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|                |   |           |   |  |
| Prot           | ection of first-aiders  | :         | and use the recor   | ers should pay attention to self-protection,<br>nmended personal protective equipment<br>I for exposure exists (see section 8).  |
| Indi           | cation of any immediate   | me        | dical attention an  | d special treatment needed   |
| Trea           | atment  | :         | Treat symptomati  | cally and supportively.  |
| Section        | 5: Fire-fighting measure  | S         |   |  |
| Extir          | nguishing media   |           |   |  |
| Suit           | able extinguishing media  | :         | Water spray<br>Alcohol-resistant<br>Carbon dioxide (C<br>Dry chemical           |  |
| Uns<br>med     | uitable extinguishing<br>lia  | :         | None known.   |  |
| Spe            | cial hazards arising fror   | n th      | e substance or m  | ixture   |
| Spe<br>fight   | cific hazards during fire-  | :         | Exposure to comb  | pustion products may be a hazard to health.  |
| Haz<br>ucts    | ardous combustion prod-   | :         | Nitrogen oxides (I<br>Sulphur oxides<br>Carbon oxides                           | NOX)   |
| Spe            | cial protective actions f   | or fi     | ire-fighters  |  |
| for f          | cial protective equipment<br>irefighters<br>cific extinguishing meth- | :         | Use personal prof<br>Use extinguishing<br>cumstances and t<br>Use water spray t | e, wear self-contained breathing apparatus.<br>ective equipment.<br>measures that are appropriate to local cir-<br>he surrounding environment.<br>o cool unopened containers.<br>ged containers from fire area if it is safe to de |
| Section        | 6: Accidental release mo  | eas       | ures  |  |
|                | I precautions, protective<br>sonal precautions                        | e eq<br>: | Use personal prot<br>Follow safe handl  |  |

#### **Environmental precautions**

| Environmental precautions | <ul> <li>Avoid release to the environment.<br/>Prevent further leakage or spillage if safe to do so.<br/>Prevent spreading over a wide area (e.g. by containment or oil<br/>barriers).<br/>Retain and dispose of contaminated wash water.<br/>Local authorities should be advised if significant spillages<br/>cannot be contained.</li> </ul> |
|---------------------------|--|
|---------------------------|--|



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#### Methods and materials for containment and cleaning up

| Methods for cleaning up | : | Soak up with inert absorbent material.<br>For large spills, provide dyking or other appropriate contain-<br>ment to keep material from spreading. If dyked material can<br>be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absor-<br>bent.<br>Local or national regulations may apply to releases and dis-<br>posal of this material, as well as those materials and items<br>employed in the cleanup of releases. You will need to deter-<br>mine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding<br>certain local or national requirements. |
|-------------------------|---|--|
|                         |   |  |

#### Section 7: Handling and storage

#### Precautions for safe handling

|  | • |   |  |  |  |  |
|--|---|---|--|--|--|--|
| Technical measures   | : | See Engineering measures under EXPOSURE<br>CONTROLS/PERSONAL PROTECTION section.  |  |  |  |  |
| Local/Total ventilation                                      | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.   |  |  |  |  |
| Advice on safe handling                                      | : | Do not get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety<br>practice, based on the results of the workplace exposure as-<br>sessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible<br>to asthma, allergies, chronic or recurrent respiratory disease,<br>should consult their physician regarding working with respira-<br>tory irritants or sensitisers.<br>Do not eat, drink or smoke when using this product.<br>Take care to prevent spills, waste and minimize release to the |  |  |  |  |
|  |   | environment.  |  |  |  |  |
| Hygiene measures   | : | If exposure to chemical is likely during typical use, provide eye<br>flushing systems and safety showers close to the working<br>place.   |  |  |  |  |
|  |   | When using do not eat, drink or smoke.  |  |  |  |  |
|  |   | Wash contaminated clothing before re-use.   |  |  |  |  |
|  |   | The effective operation of a facility should include review of<br>engineering controls, proper personal protective equipment,<br>appropriate degowning and decontamination procedures,<br>industrial hygiene monitoring, medical surveillance and the<br>use of administrative controls.  |  |  |  |  |
| Conditions for safe storage, including any incompatibilities |   |   |  |  |  |  |
| Conditions for sofe storage                                  |   | Kaap in properly labelled containers  |  |  |  |  |

#### Conditions for safe storage : Keep in properly labelled containers.



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| Materi  | als to avoid   | Store in accorda<br>: Do not store with | eed.<br>well-ventilated place.<br>ance with the particular national regulations.<br>h the following product types:<br>ostances and mixtures<br>es |

#### Section 8: Exposure controls/personal protection

#### **Control parameters**

#### Occupational Exposure Limits

| Components       | CAS-No.  | Value type<br>(Form of<br>exposure) | Control parame-<br>ters / Permissible<br>concentration | Basis    |
|------------------|----------|-------------------------------------|--|----------|
| Sulfamethoxazole | 723-46-6 | TWA                                 | OEB 2 (>= 100 <<br>1000 μg/m3)                         | Internal |
| Ethanolamine     | 141-43-5 | PEL (long<br>term)                  | 3 ppm<br>7.5 mg/m3                                     | SG OEL   |
|                  |          | PEL (short<br>term)                 | 6 ppm<br>15 mg/m3                                      | SG OEL   |
|                  |          | TWA                                 | 3 ppm  | ACGIH    |
|                  |          | STEL                                | 6 ppm  | ACGIH    |
| Trimethoprim     | 738-70-5 | TWA                                 | 400 μg/m3 (OEB<br>2)                                   | Internal |

| Appropriate engineering :<br>control measures | Use appropriate engineering controls and manufacturing<br>technologies to control airborne concentrations (e.g., drip-<br>less quick connections).<br>All engineering controls should be implemented by facility<br>design and operated in accordance with GMP principles to<br>protect products, workers, and the environment.<br>Laboratory operations do not require special containment. |
|---|--|
| Individual protection measures                | s, such as personal protective equipment (PPE)   |
| Eye/face protection :                         | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions,<br>mists or aerosols, wear the appropriate goggles.<br>Wear a faceshield or other full face protection if there is a<br>potential for direct contact to the face with dusts, mists, or<br>aerosols.  |
| Skin protection :<br>Respiratory protection : | Work uniform or laboratory coat.<br>If adequate local exhaust ventilation is not available or expo-<br>sure assessment demonstrates exposures outside the rec-<br>ommended guidelines, use respiratory protection.   |



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|------------------|--|-------|--------------------------|---|--|--|
| Hand             | Filter type<br>Hand protection<br>Material   |       | Combined particu         | ulates and organic vapour type<br>nt gloves                       |  |  |
| Section 9        | : Physical and chemica                       | al pr | operties                 |   |  |  |
| Арре             | arance                                       | :     | liquid                   |   |  |  |
| Colou            | ır   | :     | light yellow             |   |  |  |
| Odou             | ır   | :     | No data availabl         | e   |  |  |
| Odou             | ır Threshold                                 | :     | No data availabl         | e   |  |  |
| рН               |  | :     | 9.5 - 10.5               |   |  |  |
| Meltir           | ng point/freezing point                      | :     | No data availabl         | e   |  |  |
| Initial<br>range | boiling point and boiling                    | :     | No data availabl         | e   |  |  |
| Flash            | n point                                      | :     | No data availabl         | e   |  |  |
| Evap             | oration rate                                 | :     | No data availabl         | e   |  |  |
| Flam             | mability (solid, gas)                        | :     | Not applicable           |   |  |  |
| Flam             | mability (liquids)                           | :     | No data availabl         | e   |  |  |
|                  | er explosion limit / Upper<br>nability limit | :     | No data availabl         | e   |  |  |
|                  | er explosion limit / Lower<br>nability limit | :     | No data availabl         | e   |  |  |
| Vapo             | ur pressure                                  | :     | No data availabl         | e   |  |  |
| Relat            | ive vapour density                           | :     | No data availabl         | e   |  |  |
| Relat            | ive density                                  | :     | No data availabl         | e   |  |  |
| Dens             | ity  | :     | 1.050 - 1.230 g/d        | cm <sup>3</sup>   |  |  |
|                  | bility(ies)<br>/ater solubility              | :     | No data availabl         | e   |  |  |
|                  | ion coefficient: n-                          | :     | Not applicable           |   |  |  |
|                  | ol/water<br>ignition temperature             | :     | No data availabl         | e   |  |  |



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|                |                              |   |                          |   |
| Deco           | mposition temperature        | : | No data available        | e   |
| Visco<br>V     | osity<br>iscosity, kinematic | : | No data available        | e   |
| Explo          | osive properties             | : | Not explosive            |   |
| Oxid           | izing properties             | : | The substance o          | r mixture is not classified as oxidizing.                         |
| Mole           | cular weight                 | : | No data available        | e   |

| Particle characteristics<br>Particle size | : | Not applicable |
|---|---|----------------|
|   |   |                |

#### Section 10: Stability and reactivity

| Reactivity<br>Chemical stability<br>Possibility of hazardous reac-<br>tions | :: | Not classified as a reactivity hazard.<br>Stable under normal conditions.<br>Can react with strong oxidizing agents. |
|---|----|--|
| Conditions to avoid   | :  | None known.  |
| Incompatible materials  | :  | Oxidizing agents<br>Acids  |
| Hazardous decomposition<br>products   | :  | No hazardous decomposition products are known.   |

#### Section 11: Toxicological information

| Information on likely routes of | : | Inhalation   |
|---------------------------------|---|--------------|
| exposure                        |   | Skin contact |
|                                 |   | Ingestion    |
|                                 |   | Eye contact  |

#### Acute toxicity

Not classified based on available information.

#### Product:

| Acute oral toxicity       | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method  |
|---------------------------|---|---|
| Acute inhalation toxicity | : | Acute toxicity estimate: > 20 mg/l<br>Exposure time: 4 h<br>Test atmosphere: vapour<br>Method: Calculation method |
| Acute dermal toxicity     | : | Acute toxicity estimate: > 2,000 mg/kg<br>Method: Calculation method  |



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|                |   |       |  |   |
| <u>Co</u>      | mponents:                                     |       |  |   |
| 1,3            | B-Dioxan-5-ol:                                |       |  |   |
| Ac             | ute oral toxicity                             | :     | LD50 (Rat): > 5,00   | 00 mg/kg  |
| Ac             | ute dermal toxicity                           | :     | LD50 (Rat): > 2,00<br>Remarks: Based o   | 00 mg/kg<br>on data from similar materials                        |
| Su             | lfamethoxazole:                               |       |  |   |
| Ac             | ute oral toxicity                             | :     | LD50 (Mouse): 2,3  | 300 mg/kg   |
| Etł            | nanolamine:                                   |       |  |   |
| Ac             | ute oral toxicity                             | :     | LD50 (Rat): 1,089  | mg/kg   |
| Ac             | ute inhalation toxicity                       | :     | Acute toxicity estin<br>Exposure time: 4<br>Test atmosphere:<br>Method: Expert ju<br>Remarks: Based of | h<br>vapour   |
| Ac             | ute dermal toxicity                           | :     | LD50 (Rabbit, fem  | nale): 1,018 mg/kg  |
| n<br>Tri       | methoprim:                                    |       |  |   |
|                | ute oral toxicity                             | :     | LD50 (Rat): 1,500  | - 5,300 mg/kg   |
|                |   |       | LD50 (Mouse): 1,9  | 910 - 7,000 mg/kg   |
|                | ute toxicity (other routes of ministration)   | :     | LD50 (Rat): 400 -<br>Application Route   |   |
|                |   |       | LD50 (Dog): 90 m<br>Application Route  |   |
|                |   |       | LD50 (Mouse): 13<br>Application Route  |   |
| -              | in corrosion/irritation<br>uses severe burns. |       |  |   |
| <u>Co</u>      | mponents:                                     |       |  |   |
| 1,3            | B-Dioxan-5-ol:                                |       |  |   |
| Me<br>Re       | ecies<br>ethod<br>sult<br>marks               | : : : | Rabbit<br>OECD Test Guide<br>No skin irritation<br>Based on data fro                                   | eline 404<br>m similar materials                                  |

#### Sulfamethoxazole:



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| Speci          |  | :      | Rabbit                             |   |
| Resu           |  | :      | No skin irritation                 |   |
| Ethar<br>Speci | nolamine:                                |        | Rabbit                             |   |
| Resu           |  | :      |                                    | minutes to 1 hour of exposure                                     |
|                | us eye damage/eye iı                     |        | on                                 |   |
|                | es serious eye damage                    | Э.     |                                    |   |
| -              | oonents:                                 |        |                                    |   |
| 1,3-D<br>Speci | ioxan-5-ol:                              |        | Rabbit                             |   |
| Resu           |  | :      | Irritation to eyes,                | reversing within 21 days  |
| Metho<br>Rema  |  | :      | OECD Test Guid<br>Based on data fr | eline 405<br>om similar materials                                 |
|                |  | •      |                                    |   |
| Ethar          | nolamine:                                |        |                                    |   |
| Speci<br>Resu  |  | :      | Rabbit<br>Irreversible effec       | ts on the eye   |
| Resp           | iratory or skin sensit                   | isatio | on                                 |   |
| -              | sensitisation<br>lassified based on avai | lable  | information.                       |   |
|                | iratory sensitisation                    |        |                                    |   |
| -              | lassified based on avai                  | lable  | information.                       |   |
| <u>Com</u>     | oonents:                                 |        |                                    |   |
| 1,3-D          | ioxan-5-ol:                              |        |                                    |   |
| Test           |  | :      | Maximisation Te                    | st  |
| Expos          | sure routes<br>es                        | :      | Skin contact<br>Guinea pig         |   |
| Metho          | bd                                       | :      | OECD Test Guid                     | eline 406   |
| Resu<br>Rema   |  | :      | negative<br>Based on data fr       | om similar materials  |
| Sulfa          | methoxazole:                             |        |                                    |   |
| Test           | Гуре                                     | :      | Magnusson-Kligr                    | nan-Test  |
| Expos<br>Speci | sure routes                              | :      | Skin contact<br>Guinea pig         |   |
| Resu           | lt                                       | :      | negative                           |   |
|                |  |        |                                    |   |

#### Ethanolamine:

Test Type

: Maximisation Test



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|------------------------|---|------------|---|---|--|--|
| Expos<br>Speci<br>Resu |   | : (        | Skin contact<br>Guinea pig<br>negative  |   |  |  |
| Trime                  | ethoprim:   |            |   |   |  |  |
| Test                   | Гуре<br>sure routes<br>es                         | : [<br>: ( | Maximisation T<br>Dermal<br>Guinea pig<br>Not a skin sens   |   |  |  |
|                        | <b>cell mutagenicity</b><br>lassified based on av | ailable ir | formation.  |   |  |  |
| <u>Com</u>             | oonents:  |            |   |   |  |  |
| 1,3-D                  | ioxan-5-ol:                                       |            |   |   |  |  |
| Geno                   | toxicity in vitro                                 |            | Fest Type: Bac<br>Result: negativ   | terial reverse mutation assay (AMES)<br>e                         |  |  |
|                        |   |            | Fest Type: In v<br>Result: negativ  | itro mammalian cell gene mutation test<br>e                       |  |  |
| Geno                   | toxicity in vivo                                  |            | cytogenetic ass<br>Species: Mous<br>Result: negativ   | e   |  |  |
| II<br>Sulfa            | methoxazole:                                      |            |   |   |  |  |
|                        | toxicity in vitro                                 |            | Fest Type: Bac<br>Result: negativ   | terial reverse mutation assay (AMES)<br>e                         |  |  |
|                        |   |            | Fest Type: Chr<br>Result: negativ   | omosome aberration test in vitro<br>e                             |  |  |
| Geno                   | toxicity in vivo                                  | 0          | : Test Type: Mutagenicity (in vivo mammalian bone-mar<br>cytogenetic test, chromosomal analysis)<br>Species: Humans<br>Result: negative |   |  |  |
| Ethar                  | nolamine:   |            |   |   |  |  |
| Geno                   | toxicity in vitro                                 |            | Fest Type: Bac<br>Result: negativ   | terial reverse mutation assay (AMES)<br>e                         |  |  |
|                        |   | ſ          |   | itro mammalian cell gene mutation test<br>Test Guideline 476      |  |  |



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|----------------|--|--|--|
|                |  | Result: neg  |  |
| Genc           | otoxicity in vivo                      | cytogenetic<br>Species: M<br>Application           | ouse<br>Route: Ingestion<br>ECD Test Guideline 474                                 |
| Trim           | ethoprim:                              |  |  |
| Geno           | otoxicity in vitro                     | : Test Type:<br>Result: neg                        | Bacterial reverse mutation assay (AMES)<br>ative                                   |
|                |  | Test Type:<br>Result: neg                          | Chromosomal aberration<br>ative  |
|                |  | Test Type:<br>Result: neg                          | In vitro mammalian cell gene mutation test<br>ative                                |
|                |  |  | DNA damage and repair, unscheduled DNA syn-<br>ammalian cells (in vitro)<br>jative |
| Genc           | otoxicity in vivo                      | : Test Type:<br>Species: R<br>Result: neg          |  |
|                |  | Test Type:<br>Species: H<br>Result: neç            |  |
| Carc           | inogenicity<br>lassified based on avai | lable information.                                 |  |
| Com            | ponents:                               |  |  |
| Sulfa          | methoxazole:                           |  |  |
|                | cation Route<br>sure time              | : Mouse<br>: Ingestion<br>: 26 weeks<br>: negative |  |

#### **Reproductive toxicity**

Suspected of damaging the unborn child.

#### **Components:**

#### Ethanolamine:

Effects on fertility

: Test Type: Two-generation reproduction toxicity study



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|----------------|--------------------------------------|--|---|
| Effec          | ts on foetal develop-                | Method: OEC<br>Result: negati<br>Remarks: Bas    | oute: Ingestion<br>D Test Guideline 416<br>ve<br>sed on data from similar materials<br>nbryo-foetal development |
| ment           |                                      | Application Ro                                   | oute: Ingestion<br>D Test Guideline 414<br>ve   |
|                | <b>ethoprim:</b><br>its on fertility | : Test Type: Fe                                  | rtility   |
| Liice          |                                      | Species: Rat<br>Application Ro<br>Fertility: NOA |   |
| Effec<br>ment  | ts on foetal develop-                | Result: Effects                                  | oute: Oral<br>al Toxicity: LOAEL: 70 mg/kg body weight  |
|                |                                      | Result: Embry                                    |   |
|                |                                      |  |   |
|                |                                      |  | ster  |
|                |                                      |  | pit   |



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|-----------------------|------------------------------|------------------------------|---|
| Repro                 | oductive toxicity - As-      | : Suspected of               | damaging the unborn child.  |
| sessn                 | •                            | ·                            | 5 5   |
| STOT                  | F - single exposure          |                              |   |
| May o                 | cause respiratory irritat    | tion.                        |   |
| <u>Comp</u>           | ponents:                     |                              |   |
| Ethar                 | nolamine:                    |                              |   |
| Asses                 | ssment                       | : May cause res              | spiratory irritation.   |
|                       |                              |                              |   |
|                       | - repeated exposure          |                              |   |
|                       |                              | ns (Bone marrow) thr         | ough prolonged or repeated exposure.                              |
| Com                   | ponents:                     |                              |   |
| Ethar                 | nolamine:                    |                              |   |
| Asses                 | ssment                       |                              | health effects observed in animals at concentr                    |
| 11                    |                              |                              | g/l/6h/d or less.   |
| Trime                 | ethoprim:                    |                              |   |
|                       | et Organs                    | : Bone marrow                |   |
|                       | ssment                       |                              | ge to organs through prolonged or repeated                        |
| 11                    |                              | exposure.                    |   |
| Repe                  | ated dose toxicity           |                              |   |
|                       | -                            |                              |   |
| Com                   | ponents:                     |                              |   |
|                       | nolamine:                    |                              |   |
| Speci<br>NOAE         |                              | : Rat<br>: > 120 mg/kg       |   |
|                       | cation Route                 | : Ingestion                  |   |
|                       | sure time                    | : > 75 Days                  |   |
| Rema                  | arks                         | : Based on data              | a from similar materials  |
| Speci                 | ies                          | : Rat                        |   |
| NOAE                  |                              | : >= 0.15 mg/l               |   |
|                       | cation Route<br>sure time    | : inhalation (due            | st/mist/tume)   |
| Metho                 |                              | : 28 Days<br>: OECD Test G   | uideline 412  |
|                       |                              |                              |   |
|                       | ethoprim:                    |                              |   |
| Trime                 |                              | : Rat                        |   |
| Speci                 |                              |                              |   |
| Speci<br>NOAE         | ΞL                           | : 100 mg/kg                  |   |
| Speci<br>NOAE<br>LOAE | ΞL                           |                              |   |



## Sulfamethoxazole / Trimethoprim Injection Formulation

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|                |                           |                              |   |
| Targe          | et Organs                 | : Bone marrow, L             | iver, Pituitary gland, Thyroid                                    |
|                | _                         | _                            |   |

| Species           | : Rat         |
|-------------------|---------------|
| LOAEL             | : 300 mg/kg   |
| Application Route | : Oral        |
| Exposure time     | : 3 Months    |
| Target Organs     | : Bone marrow |
| Species           | : Dog         |
| NOAEL             | : 2.5 mg/kg   |

| NOAEL<br>LOAEL    | : | 2.5 mg/kg      |
|-------------------|---|----------------|
| LOAEL             | : | 45 mg/kg       |
| Application Route | : | Oral           |
| Exposure time     | : | 3 Months       |
| Target Organs     | : | Blood, Thyroid |

#### Aspiration toxicity

Not classified based on available information.

#### Experience with human exposure

#### **Components:**

#### Trimethoprim:

Ingestion

: Target Organs: Bone marrow Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

#### Section 12: Ecological information

#### Toxicity

**Components:** 

### 1,3-Dioxan-5-ol:

| Toxicity to fish                                    | : | LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials   |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EL50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials   |
| Toxicity to algae/aquatic<br>plants                 | : | EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials<br>NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials |



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|                           |   |   |  |   |
| Toxic                     | ity to microorganisms                                 | : |  |   |
| Sulfa                     | methoxazole:  |   |  |   |
| Toxic                     | ity to fish   | : | LC50 (Oryzias la<br>Exposure time: 9             | atipes (Japanese medaka)): 562.5 mg/l<br>96 h                               |
|                           | ity to daphnia and other tic invertebrates            | : | EC50 (Ceriodap<br>Exposure time: 4               | hnia dubia (water flea)): 0.21 mg/l<br>48 h                                 |
| Toxic<br>plants           | ity to algae/aquatic                                  | : | EC50 (Synecho<br>0.0268 mg/l<br>Exposure time: 9 | coccus leopoliensis (blue-green algae)):<br>96 h                            |
|                           |   |   | NOEC (Synecho<br>0.0059 mg/l<br>Exposure time: 9 | ococcus leopoliensis (blue-green algae)):<br>96 h                           |
|                           | ctor (Acute aquatic tox-                              | : | 10   |   |
| icity)<br>Toxic<br>icity) | ity to fish (Chronic tox-                             | : | NOEC (Danio re<br>Exposure time: 2               | erio (zebra fish)): 0.533 mg/l<br>21 d                                      |
|                           | ity to daphnia and other<br>tic invertebrates (Chron- | : | NOEC (Daphnia<br>Exposure time: 3                | i magna (Water flea)): 0.01 mg/l<br>30 d                                    |
| M-Fa                      | ctor (Chronic aquatic                                 | : | 10   |   |
| toxici<br>Toxic           | ity to microorganisms                                 | : |  | d sludge): 3.76 mg/l<br>Test Guideline 301D                                 |
| Ethar                     | nolamine:   |   |  |   |
| Toxic                     | ity to fish   | : | Exposure time:                                   | carpio (Carp)): 349 mg/l<br>96 h<br>⁄e 67/548/EEC, Annex V, C.1.            |
|                           | ity to daphnia and other<br>tic invertebrates         | : | Exposure time:                                   | magna (Water flea)): 65 mg/l<br>48 h<br>⁄e 67/548/EEC, Annex V, C.2.        |
| Toxic<br>plants           | ity to algae/aquatic<br>S                             | : | mg/l<br>Exposure time:                           | kirchneriella subcapitata (green algae)): 2.8<br>72 h<br>Test Guideline 201 |
|                           |   |   | NOEC (Pseudol                                    | kirchneriella subcapitata (green algae)): 1 m                               |



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|-------------------|--|---|---|--|
|                   |  |   |   |  |
|                   |  |   | Exposure time: 7<br>Method: OECD T  | 2 h<br>Test Guideline 201  |
| Toxici<br>icity)  | ty to fish (Chronic tox-                             | : | Exposure time: 4  | atipes (Orange-red killifish)): 1.24 mg/l<br>1 d<br><sup>-</sup> est Guideline 210 |
| aquat             | ity to daphnia and other<br>ic invertebrates (Chron- | : | NOEC (Daphnia<br>Exposure time: 2   | magna (Water flea)): 0.85 mg/l<br>1 d  |
| ic toxi<br>Toxici | city)<br>ty to microorganisms                        | : | Exposure time: 3  | onas putida): > 1,000 mg/l<br>0 min<br>ēst Guideline 209                           |
| Trime             | ethoprim:  |   |   |  |
|                   | ty to fish   | : | LC50 (Pimephale<br>Exposure time: 9                                       | es promelas (fathead minnow)): 100 mg/l<br>6 h                                     |
|                   | ty to daphnia and other ic invertebrates             | : | EC50 (Daphnia n<br>Exposure time: 4                                       | nagna Straus): 92 mg/l<br>8 h  |
| Toxici<br>plants  | ty to algae/aquatic                                  | : | EC50 (Pseudokir<br>mg/l<br>Exposure time: 7                               | chneriella subcapitata (microalgae)): 80.3<br>2 h                                  |
|                   |  |   | NOEC (Pseudoki<br>mg/l<br>Exposure time: 7                                | rchneriella subcapitata (green algae)): 16<br>2 h                                  |
|                   |  |   | EC50 (Anabaena<br>Exposure time: 7  | ı flos-aquae): 253 mg/l<br>2 h   |
|                   |  |   | EC10 (Anabaena<br>Exposure time: 7  | ı flos-aquae): 26 mg/l<br>2 h  |
| Toxici<br>icity)  | ty to fish (Chronic tox-                             | : | NOEC (Zebrafish<br>Exposure time: 2                                       |  |
|                   | ty to daphnia and other<br>ic invertebrates (Chron-  | : | NOEC (Daphnia<br>Exposure time: 2   | magna (Water flea)): 6 mg/l<br>1 d   |
|                   | ity to microorganisms                                | : | EC10: 16.7 mg/l<br>Exposure time: 3<br>Test Type: Respi<br>Method: OECD T |  |
|                   |  |   | EC50: > 1,000 m<br>Exposure time: 3<br>Test Type: Respi<br>Method: OECD T | hrs  |



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## 

| Persistence and degradabil                 | ity |   |
|--|-----|---|
| Components:                                |     |   |
| 1,3-Dioxan-5-ol:                           |     |   |
| Biodegradability                           | :   | Result: Inherently biodegradable.<br>Remarks: Based on data from similar materials                                      |
| Sulfamethoxazole:                          |     |   |
| Biodegradability                           | :   | Result: Not readily biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D    |
| Ethanolamine:                              |     |   |
| Biodegradability                           | :   | Result: Readily biodegradable.<br>Biodegradation: > 90 %<br>Exposure time: 21 d<br>Method: OECD Test Guideline 301A     |
| Trimethoprim:                              |     |   |
| Biodegradability                           | :   | Result: Not readily biodegradable.<br>Biodegradation: 4 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301D    |
|  |     | Result: Not inherently biodegradable.<br>Biodegradation: 0 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 302B |
| Bioaccumulative potential                  |     |   |
| Components:                                |     |   |
| 1,3-Dioxan-5-ol:                           |     |   |
| Partition coefficient: n-<br>octanol/water | :   | log Pow: -0.65  |
| Sulfamethoxazole:                          |     |   |
| Bioaccumulation                            | :   | Species: Cyprinus carpio (Carp)<br>Bioconcentration factor (BCF): < 120   |
| Partition coefficient: n-<br>octanol/water | :   | log Pow: 0.89   |
| Ethanolamine:                              |     |   |



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|   | on coefficient: n-<br>bl/water     | : log Pow: -2.3<br>Method: OECI | D Test Guideline 107  |  |
| Trimethoprim:<br>Partition coefficient: n-<br>octanol/water |                                    | : log Pow: 0.91                 |   |  |
|   | <b>ity in soil</b><br>ta available |                                 |   |  |
|   | adverse effects<br>ta available    |                                 |   |  |

Section 13: Disposal considerations

| : Do not dispose of waste into sewer.                        |
|--|
| Dispose of in accordance with local regulations.             |
| : Empty containers should be taken to an approved waste han- |
| dling site for recycling or disposal.                        |
| If not otherwise specified: Dispose of as unused product.    |
|  |

#### Section 14: Transport information

#### International Regulations

| UNRTDG<br>UN number<br>UN proper shipping name<br>Transport hazard class(es)<br>Packing group<br>Labels<br>Environmental hazards  | : | UN 2491<br>ETHANOLAMINE SOLUTION<br>8<br>III<br>8<br>no                 |
|---|---|---|
| IATA-DGR<br>UN/ID No.<br>UN proper shipping name<br>Transport hazard class(es)<br>Packing group<br>Labels<br>Packing instruction (cargo<br>aircraft)<br>Packing instruction (passen-<br>ger aircraft) |   | UN 2491<br>Ethanolamine solution<br>8<br>III<br>Corrosive<br>856<br>852 |
| IMDG-Code<br>UN number<br>Proper shipping name<br>Transport hazard class(es)<br>Packing group   | : | UN 2491<br>ETHANOLAMINE SOLUTION<br>(Sulfamethoxazole)<br>8<br>III      |



## Sulfamethoxazole / Trimethoprim Injection Formulation

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| Labels           | : | 8        |
|------------------|---|----------|
| EmS Code         | : | F-A, S-B |
| Marine pollutant | : | yes      |

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### Section 15: Regulatory information

#### Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable Regulations

#### The components of this product are reported in the following inventories:

| DSL   | : | not determined |
|-------|---|----------------|
| AICS  | : | not determined |
| IECSC | : | not determined |

#### Section 16: Other information

| Revision Date  | : | 06.04.2024   |  |
|--|---|--|--|
| Further information  |   |  |  |
| Sources of key data used to<br>compile the Safety Data<br>Sheet                                | : | Internal technical data, data from raw material SDSs, OECD<br>eChem Portal search results and European Chemicals Agen-<br>cy, http://echa.europa.eu/ |  |
| Itoms where changes have been made to the provinus version are highlighted in the bedy of this |   |  |  |

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

| Date format                     | :   | dd.mm.yyyy                              |
|---------------------------------|-----|---|
| Full text of other abbreviation | ons |   |
| ACGIH                           | :   | USA. ACGIH Threshold Limit Values (TLV) |



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|--|------------------------------|---|---|--|
| SG OEL   |                              | : Singapore. Workplace Safety and Health (General Pl<br>Regulations - First Schedule Permissible Exposure L |   |  |
| ACGIH / TWA<br>ACGIH / STEL<br>SG OEL / PEL (long term)<br>SG OEL / PEL (short term) |                              | : Short-term exp<br>: Permissible Ex  | eighted average   |  |

AIIC - Australian Inventory of Industrial Chemicals; 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; 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; 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; TECI - Thailand Existing Chemicals Inventory; 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

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

SG / EN