SAFETY DATA SHEET



Tulathromycin Formulation

| Version | Revision Date: 2023/09/30 | SDS Number: | Date of last issue: 2023/04/04 |
|---------|---------------------------|---------------|---------------------------------|
| 7.0 | | 5297463-00010 | Date of first issue: 2019/11/13 |
| | | | |

1. PRODUCT AND COMPANY IDENTIFICATION

| Chemical product name | : | Tulathromycin Formulation |
|---|---|--|
| Supplier's company name, ad Company name of supplier | | ess and phone number MSD |
| Address | : | Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory |
| Telephone | : | 048-588-8411 |
| E-mail address | : | EHSDATASTEWARD@msd.com |
| Emergency telephone number | : | +1-908-423-6000 |
| | | |

Recommended use of the chemical and restrictions on use

| Recommended use | : | Veterinary product |
|---------------------|---|--------------------|
| Restrictions on use | : | Not applicable |

2. HAZARDS IDENTIFICATION

| Skin corrosion/irritation | : | Category 2 |
|--|---|-------------------------|
| Serious eye damage/eye irri- tation | : | Category 1 |
| Skin sensitisation | : | Category 1 |
| Reproductive toxicity | : | Category 2 |
| Specific target organ toxicity - repeated exposure (Oral) | : | Category 1 (Liver, Eye) |
| Short-term (acute) aquatic hazard | : | Category 1 |
| Long-term (chronic) aquatic hazard | : | Category 1 |
| GHS label elements Hazard pictograms | : | |





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|--------------------------|---------------------------------|---|--|--|--|--|
| Signa | l word | : Danger | | | | |
| Hazard statements | | H317 May caus H318 Causes s H361 Suspecte H372 Causes o or repeated exp | H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H361 Suspected of damaging fertility or the unborn child. H372 Causes damage to organs (Liver, Eye) through prolonge or repeated exposure if swallowed. H410 Very toxic to aquatic life with long lasting effects. | | | |
| Precautionary statements | | P202 Do not ha and understood P260 Do not br P264 Wash ski P270 Do not ea P272 Contamir the workplace. P273 Avoid rele | eathe mist or vapours. n thoroughly after handling. at, drink or smoke when using this product. nated work clothing should not be allowed out o ease to the environment. tective gloves/ protective clothing/ eye protec- | | | |
| | | P305 + P351 + water for sever and easy to do CENTER/ docto P308 + P313 IF attention. P333 + P313 If vice/ attention. | exposed or concerned: Get medical advice/ skin irritation or rash occurs: Get medical ad- ake off contaminated clothing and wash it before | | | |
| | | Storage: P405 Store loc | ked up. | | | |
| | | Disposal: P501 Dispose o disposal plant. | of contents/ container to an approved waste | | | |
| None | r hazards which do no known. | | | | | |

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture

: Mixture



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|--|----------------|------------------------------|------------------------------|---|--|

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|----------------------------|-------------|-----------------------|----------|
| Propylene glycol | 57-55-6 | >= 50 - < 60 | 2-234 |
| Tulathromycin | 217500-96-4 | >= 10 - < 20 | |
| Hydrochloric acid | 7647-01-0 | >= 3 - < 5 | 1-215 |
| Citric acid | 77-92-9 | >= 1 - < 10 | 2-1318 |
| Sodium hydroxide | 1310-73-2 | >= 1 - < 2 | 1-410 |
| 3-Mercaptopropane-1,2-diol | 96-27-5 | >= 0.1 - < 1 | 9-805 |

4. FIRST AID MEASURES

| General advice | : | In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
|---|---|--|
| If inhaled | : | If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : | |
| If swallowed | : | If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | Causes skin irritation. May cause an allergic skin reaction. Causes serious eye damage. Suspected of damaging fertility or the unborn child. Causes damage to organs through prolonged or repeated |
| Protection of first-aiders | : | exposure if swallowed. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : | Treat symptomatically and supportively. |
| | | |

5. FIREFIGHTING MEASURES

Suitable extinguishing media :

Water spray Alcohol-resistant foam



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| Uns | suitable extinguishing dia | : | Carbon dioxide (C Dry chemical None known. | CO2) | |
| figh | ecific hazards during fire- iting zardous combustion prod- s | : | Exposure to comb Carbon oxides Chlorine compour Metal oxides | bustion products may be a hazard to health. | |
| • | Specific extinguishing meth- ods | | Use extinguishing measures that are appropriate to local cir- cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area. | | |
| | Special protective equipment for firefighters | | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. | | |
| 6. ACCI | DENTAL RELEASE MEAS | SUF | RES | | |
| tive | rsonal precautions, protec- equipment and emer- ncy procedures | : | Follow safe handl | ective equipment. ing advice (see section 7) and personal pro- recommendations (see section 8). | |
| Env | Environmental precautions : | | Prevent spreading barriers). Retain and dispos | akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages | |
| | thods and materials for ntainment and cleaning up | : | For large spills, pument to keep mat be pumped, store Clean up remaining bent. Local or national uposal of this mate employed in the of mine which regula Sections 13 and 1 | t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. ng materials from spill with suitable absor- regulations may apply to releases and dis- rial, as well as those materials and items leanup of releases. You will need to deter- ations are applicable. 5 of this SDS provide information regarding tional requirements. | |

7. HANDLING AND STORAGE

Handling

| Technical measures | : See Engineering measures under EXPOSURE |
|--------------------|---|
| | CONTROLS/PERSONAL PROTECTION section. |



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| Advid | cal/Total ventilation: Use only with adedvice on safe handling: Do not get on skidvice on safe handling: Do not breatherDo not swallow.Do not swallow.Do not get in eyeWash skin thorouHandle in accordpractice, based osessmentKeep container tiDo not eat, drinkTake care to prevenvironment.voidance of contact//giene measures: If exposure to charflushing systemsplace.When using do nContaminated woworkplace.Wash contaminaThe effective opeengineering contraappropriate degoindustrial hygiene | | Do not get in eyes Wash skin thorou Handle in accords practice, based o sessment Keep container tig Do not eat, drink Take care to prevenvironment. Oxidizing agents If exposure to che flushing systems place. When using do not Contaminated wo workplace. Wash contaminat The effective ope engineering contr appropriate dego | n or clothing. ist or vapours. s. ghly after handling. ance with good industrial hygiene and safety in the results of the workplace exposure as- ghtly closed. or smoke when using this product. rent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working of eat, drink or smoke. rk clothing should not be allowed out of the red clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, emonitoring, medical surveillance and the |
| Stora | - | | | |
| | litions for safe storage rials to avoid | : | Store locked up. Keep tightly close Store in accordar | ce with the particular national regulations. the following product types: |
| Pack | aging material | : | Unsuitable mater | al: None known. |

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Threshold limit value and permissible exposure limits for each component in the work en- |
|--|
| vironment |

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Reference concentration / Permissible con- centration | Basis | | |
|-------------------|---------------------------|-------------------------------------|--|----------------|--|--|
| Tulathromycin | 217500-96-4 | TWA | 300 µg/m3 (OEB 2) | Internal | | |
| | Further information: DSEN | | | | | |
| | | Wipe limit | 100 µg/100 cm2 | Internal | | |
| Hydrochloric acid | 7647-01-0 | OEL-C | 2 ppm 3 mg/m3 | JP OEL JSOH | | |



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|---|--|--|--|--|--|

| | | С | 2 ppm | ACGIH | | | |
|--------------------------------|---|--|--|-----------------|--|--|--|
| Sodium hydroxide | 1310-73 | -2 OEL-C | 2 mg/m3 | JP OEL | | | |
| | | | | JSOH | | | |
| | | С | 2 mg/m3 | ACGIH | | | |
| Engineering measures | design a protect Essentia Use clo If handle cabinet tial exis | All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the poten- tial exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops. | | | | | |
| Personal protective equipm | | over lined trays of | benchiops. | | | | |
| Respiratory protection | : If adequ sure as | If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. | | | | | |
| Filter type Hand protection | | Combined particulates and acidic gas/vapour type | | | | | |
| Material | : Chemic | Chemical-resistant gloves | | | | | |
| Remarks Eye protection | : Wear sa If the we mists or Wear a potentia | Consider double gloving. Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. | | | | | |
| Skin and body protection | : Work ur Additior task bei posable Use app | niform or laborato nal body garments ng performed (e.g suits) to avoid ex | ry coat. s should be used bas g., sleevelets, apron, xposed skin surfaces ng techniques to rem | gauntlets, dis- | | | |

9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state | : liquid |
|--|----------------------------|
| Colour | : Colorless to pale yellow |
| Odour | : slight |
| Odour Threshold | : No data available |
| Melting point/freezing point | : 190 - 192 °C |
| Boiling point, initial boiling point and boiling range | : No data available |

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| | | | | | |
| | | | | | |
| F | Flammat | pility (solid, gas) | : | Not applicable | |
| F | Flammat | pility (liquids) | : | No data available |) |
| L | Upper | plosion limit and uppe r explosion limit / Up- ammability limit | | | |
| | | r explosion limit / r flammability limit | : | No data available | |
| F | Flash poi | int | : | No data available |) |
| [| Decompo | osition temperature | : | No data available |) |
| ŗ | рH | | : | 5.1 - 5.7 | |
| E | Evaporat | tion rate | : | No data available | 9 |
| ļ | Auto-igni | tion temperature | : | No data available | |
| ١ | Viscosity Visco | sity, kinematic | : | No data available | 9 |
| ç | Solubility Water | r(ies) r solubility | : | > 1,000 mg/l | |
| | Partition octanol/w | coefficient: n- vater | : | log Pow: -1.41 | |
| ١ | Vapour p | pressure | : | No data available |) |
| [| | and / or relative densit ive density | iy : | No data available | |
| | Densi | ity | : | 1.07 g/cm ³ | |
| F | Relative | vapour density | : | No data available |) |
| E | Explosive | e properties | : | Not explosive | |
| (| Oxidizing | properties | : | The substance or | mixture is not classified as oxidizing. |
| ſ | Molecula | ır weight | : | 806.09 g/mol | |
| F | | characteristics le size | : | Not applicable | |



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| Possi tions Cond Incon | nical stability ibility of hazardous reac- litions to avoid npatible materials rdous decomposition | | Stable under no Can react with s None known. Oxidizing agent | s a reactivity hazard. ormal conditions. strong oxidizing agents. s lecomposition products are known. |
| 11. TOXIC | OLOGICAL INFORMA | τιο | N | |
| Inforr expos | nation on likely routes of sure | f: | Inhalation Skin contact Ingestion Eye contact | |
| | e toxicity lassified based on availa | able | information. | |
| Prod Acute | uct: inhalation toxicity | : | Acute toxicity es Exposure time: 4 Test atmosphere Method: Calcula | 4 h e: dust/mist |
| Acute | e dermal toxicity | : | Acute toxicity es Method: Calcula | timate: > 2,000 mg/kg tion method |
| <u>Com</u> | ponents: | | | |
| | ylene glycol: | | | |
| Acute | e oral toxicity | : | LD50 (Rat): 22,0 | 100 mg/kg |
| Acute | e inhalation toxicity | : | LC50 (Rat): > 44 Exposure time: 4 Test atmosphere | 1 h |
| Acute | e dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute toxicity | |
| Tulat | hromycin: | | | |
| Acute | e oral toxicity | : | LD50 (Dog): > 1 Target Organs: (| ,000 mg/kg Gastrointestinal tract |
| | | | LD50 (Rat): > 2, Target Organs: (| 000 mg/kg Gastrointestinal tract |
| Acute | e dermal toxicity | : | LD50 (Rabbit): > Target Organs: (| 2,000 mg/kg Gastrointestinal tract |



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| | ochloric acid: inhalation toxicity | |): 8.3 mg/l time: 30 min sphere: dust/mist | | | |
| II Citric | acid | | | | | |
| | oral toxicity | : LD50 (Mo | use): 5,400 mg/kg | | | |
| Acute | dermal toxicity | Method: C | LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dern toxicity | | | |
| | ım hydroxide: | | | | | |
| Acute | inhalation toxicity | : Assessme | nt: Corrosive to the respiratory tract. | | | |
| | captopropane-1,2-d | |): 645 mg/kg | | | |
| Acute | inhalation toxicity | Exposure Test atmo |): > 0.5 - 1 mg/l time: 4 h sphere: dust/mist Based on data from similar materials | | | |
| Acute | dermal toxicity | : LD50 (Rat | LD50 (Rabbit): 670 mg/kg | | | |
| | corrosion/irritation es skin irritation. | | | | | |
| <u>Comp</u> | oonents: | | | | | |
| Propy | /lene glycol: | | | | | |
| Speci Metho Resul | od | : Rabbit : OECD Tes : No skin irr | at Guideline 404 tation | | | |
| Tulat | hromycin: | | | | | |
| Speci Resul | | : Rabbit : No skin irr | tation | | | |
| Hydro | ochloric acid: | | | | | |
| Speci Metho | es | | reconstructed human epidermis (RhE)OECD Test Guideline 431 | | | |
| Resul | t | : Corrosive | after 3 minutes or less of exposure | | | |
| Citric | | | | | | |



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| | | | | |
| Spec Metho Resu | od | : | Rabbit OECD Test Gui No skin irritatior | |
| Sodiu | um hydroxide: | | | |
| Resu | lt | : | Corrosive after | 3 minutes or less of exposure |
| | rcaptopropane-1,2-d | | | |
| Spec Resu | ies It | : | Rabbit Skin irritation | |
| | ous eye damage/eye es serious eye damag | | ion | |
| | ponents: |) - | | |
| Prop | ylene glycol: | | | |
| Spec Resu | | : | Rabbit No eye irritation | |
| Metho | | : | OECD Test Gui | |
| Tulat | hromycin: | | | |
| Spec Resu | | : | Rabbit Irreversible effe | cts on the eye |
| Hydr | ochloric acid: | | | |
| Spec Metho | | : | Bovine cornea OECD Test Gui | deline 437 |
| Resu | lt | : | Irreversible effe | cts on the eye |
| Citric | acid: | | | |
| Spec | •. | : | Rabbit | reversing within 21 days |
| Resu Metho | | : | OECD Test Gui | s, reversing within 21 days deline 405 |
| Sodiu | um hydroxide: | | | |
| Resu Rema | | : | Irreversible effe Based on skin o | |
| | rcaptopropane-1,2-d | iol: | | |
| Spec Resu | | : | Rabbit No eye irritation | |
| III 1650 | | • | NO EYE IMIANON | |



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|----------------|--|---------------|---|---|--|--|--|--|
| | | | | | | | | |
| Resp | iratory or skin sensit | sation | | | | | | |
| ••••• | Skin sensitisation May cause an allergic skin reaction. | | | | | | | |
| - | Respiratory sensitisation Not classified based on available information. | | | | | | | |
| <u>Com</u> | Components: | | | | | | | |
| Test | sure routes | : Ski : Gu | ximisation Tes n contact inea pig jative | st | | | | |

Tulathromycin:

| Test Type | : | Maximisation Test |
|---|---|--|
| Exposure routes | : | Skin contact |
| Species | : | Guinea pig |
| Assessment | : | May cause sensitisation by skin contact. |
| Test Type Exposure routes Species Assessment Result | : | Causes sensitisation. |

Hydrochloric acid:

| Test Type | : Maximisation Test |
|---|---------------------------|
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Method | : OECD Test Guideline 406 |
| Test Type Exposure routes Species Method Result | : negative |
| | |

Sodium hydroxide:

| Test Type Exposure routes Result | : | Human repeat insult patch test (HRIPT) |
|--|---|--|
| Exposure routes | : | Skin contact |
| Result | : | negative |

3-Mercaptopropane-1,2-diol:

| Test Type Exposure routes | : Maximisation Test |
|------------------------------|--|
| Exposure routes | : Skin contact |
| Species | : Guinea pig |
| Species Method | : OECD Test Guideline 406 |
| Result Remarks | : positive |
| Remarks | : Based on data from similar materials |
| Assessment | : Probability or evidence of low to moderate skin sensitisation rate in humans |

Germ cell mutagenicity

Not classified based on available information.



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| Comp | oonents: | | |
| Pron | /lene glycol: | | |
| | toxicity in vitro | : Test Type: Ba Result: negativ | cterial reverse mutation assay (AMES) /e |
| | | | romosome aberration test in vitro D Test Guideline 473 /e |
| Geno | toxicity in vivo | cytogenetic as Species: Mous | se fute: Intraperitoneal injection |
| Tulati | nromycin: | | |
| | toxicity in vitro | : Test Type: Ba Result: negativ | cterial reverse mutation assay (AMES) /e |
| | | Test Type: Ch Result: negativ | romosome aberration test in vitro /e |
| Geno | toxicity in vivo | : Test Type: Ma cytogenetic as Species: Rat Result: negativ | |
| | cell mutagenicity - sment | : Weight of evid cell mutagen. | ence does not support classification as a gerr |
| II Hvdro | ochloric acid: | | |
| | toxicity in vitro | : Test Type: Sa assay (in vitro) Result: negativ | |
| Citric | acid: | | |
| | toxicity in vitro | : Test Type: Ba Result: negativ | cterial reverse mutation assay (AMES) /e |
| | | Test Type: in v Result: positiv | <i>v</i> itro micronucleus test e |
| | | Test Type: Ba Result: negativ | cterial reverse mutation assay (AMES) /e |
| Geno | toxicity in vivo | | tagenicity (in vivo mammalian bone-marrow st, chromosomal analysis) |



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| | | | |
| II | | Result: negat | ive |
| II Carci | nogenicity | | |
| | assified based on avai | ilable information. | |
| Comp | oonents: | | |
| | /lene glycol: | | |
| Speci | | : Rat | |
| | cation Route | : Ingestion | |
| Expos | sure time | : 2 Years | |
| Resul | t | : negative | |
| Tulatl | hromycin: | | |
| Carcir ment | nogenicity - Assess- | : No data avail | able |
| Hydro | ochloric acid: | | |
| Speci | | : Rat | |
| | cation Route | : Inhalation | |
| Resul | sure time t | : 128 weeks : negative | |
| | | | |
| Suspe | oductive toxicity ected of damaging ferti conents: | ility or the unborn ch | ild. |
| Suspe <u>Comp</u> | ected of damaging ferti | ility or the unborn ch | ild. |
| Suspe <u>Comp</u> Propy | ected of damaging ferti conents: | : Test Type: Tv | wo-generation reproduction toxicity study |
| Suspe <u>Comp</u> Propy | ected of damaging ferti ponents: ylene glycol: | : Test Type: Ty Species: Mou | wo-generation reproduction toxicity study |
| Suspe <u>Comp</u> Propy | ected of damaging ferti ponents: ylene glycol: | : Test Type: Ty Species: Mou | wo-generation reproduction toxicity study ise oute: Ingestion |
| Suspe <u>Comp</u> Propy Effect | ected of damaging ferti ponents: ylene glycol: | : Test Type: Ty Species: Mou Application R Result: negat | wo-generation reproduction toxicity study ise oute: Ingestion |
| Suspe <u>Comp</u> Propy Effect | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility | : Test Type: To Species: Mou Application R Result: negat : Test Type: En Species: Mou | wo-generation reproduction toxicity study ise oute: Ingestion ive mbryo-foetal development ise |
| Suspe <u>Comp</u> Propy Effect | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility | : Test Type: To Species: Mou Application R Result: negat : Test Type: En Species: Mou | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion |
| Suspe <u>Comp</u> Propy Effect Effect ment | ected of damaging ferti <u>conents:</u> ylene glycol: s on fertility s on foetal develop- | : Test Type: Ty Species: Mou Application R Result: negat : Test Type: En Species: Mou Application R | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion |
| Suspe Comp Propy Effect Effect ment | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin: | Test Type: Type: Type: Type: Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion |
| Suspe Comp Propy Effect Effect ment | ected of damaging ferti <u>conents:</u> ylene glycol: s on fertility s on foetal develop- | Test Type: Type: Type: Type: Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Ration | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive |
| Suspe Comp Propy Effect Effect ment | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin: | Test Type: Type: Type: Type: Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Rat Application R | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral |
| Suspe Comp Propy Effect Effect ment | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin: | Test Type: Two Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Rat Application R Fertility: NOA | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral EL: 100 mg/kg body weight |
| Suspe Comp Propy Effect Effect ment | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin: | Test Type: Two Species: Mou Application R Result: negation Test Type: En Species: Mou Application R Result: negation Test Type: Fe Species: Rat Application R Fertility: NOA | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral |
| Suspe Comp Propy Effect Effect ment Tulati | ected of damaging ferti <u>conents:</u> /lene glycol: s on fertility s on foetal develop- hromycin: | Test Type: Type: Type: Type: End Species: Mou Application R Result: negation Test Type: End Species: Mou Application R Result: negation Test Type: Fed Species: Rat Application R Fertility: NOA Result: No signature Test Type: End Species: End Species: Rat Application R Species: No Species: No Species: No Species: Rat Application R Species: No Species: No Species: Rat Application R Species: Rat Application R Species: Rat Application R Species: No Species: No Species: Rat Application R Species: No Species: No Species: Rat Application R Species: Rat Application R Species: Rat Application R Species: No Species: Rat Application R Species: Rat Application R | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral EL: 100 mg/kg body weight |
| Suspe Comp Propy Effect Effect ment Tulati | ected of damaging ferti <u>conents:</u> ylene glycol: s on fertility s on foetal develop- hromycin: s on fertility | Test Type: Type: Type: Type: Experies: Mou Application R Result: negation Test Type: Experies: Mou Application R Result: negation Test Type: Fe Species: Rat Application R Fertility: NOA Result: No signal | wo-generation reproduction toxicity study use oute: Ingestion ive mbryo-foetal development use oute: Ingestion ive ertility/early embryonic development oute: Oral EL: 100 mg/kg body weight gnificant adverse effects were reported mbryo-foetal development |



| ersion) | Revision Date: 2023/09/30 | SDS Number: 5297463-00010 | Date of last issue: 2023/04/04 Date of first issue: 2019/11/13 |
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| | | | |
| | | | r: NOAEL: 15 mg/kg body weight aplantation loss. |
| | | Application Ro General Toxic Teratogenicity | nbryo-foetal development bute: Oral ity Maternal: NOAEL: 15 mg/kg body weight r: NOAEL: 15 mg/kg body weight nal toxicity observed. |
| Repro sessn | oductive toxicity - As- nent | | e of adverse effects on sexual function and on development, based on animal experiment |
| Citric | acid: | | |
| Effect ment | ts on foetal develop- | Species: Rat | e-generation reproduction toxicity study oute: Ingestion ve |
| II STOT | - single exposure | | |
| | lassified based on avai | lable information. | |
| Com | oonents: | | |
| Tulat | hromycin: | | |
| | ssment | | e or mixture is not classified as specific target , single exposure. |
| Hydro | ochloric acid: | | |
| Asses | ssment | : May cause res | spiratory irritation. |
| Citric | acid: | | |
| Asses | ssment | : May cause res | spiratory irritation. |
| STOT | - repeated exposure | | |
| | | | prolonged or repeated exposure if swallowed. |
| Com | oonents: | | |
| | hromycin: | | |
| Expos | sure routes | : Oral | |
| | et Organs ssment | | duce significant health effects in animals at cor 10 mg/kg bw or less. |
| _ | ated dose toxicity | | |
| Repe | | | |
| - | oonents: | | |



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| | | | | | |
| | | | | | |
| I | Specie | S | : | Rat, male | |
| | NOAEI | | : | >= 1,700 mg/kg | |
| | | ation Route | ÷ | Ingestion | |
| | Exposi | ure time | | 2 yr | |
| | Tulath | romycin: | | | |
| | Specie | | : | Rat | |
| | NOAEI | | : | 5 mg/kg | |
| | Applica | ation Route | : | Oral 3 Months | |
| | Exposit | ure time Organs | : | Liver | |
| | Sympto | | : | Liver disorders | |
| I | Specie | <i>د</i> | | Dog | |
| | NOAEL | | ÷ | 5 mg/kg | |
| | | ation Route | : | Oral | |
| | | ure time | : | 3 Months | |
| | | Organs | : | Liver, Eye | |
| l | Sympto | oms | : | Liver disorders, E | ye disease |
| | Citric a | acid: | | | |
| | Specie | s | : | Rat | |
| | NOAEI | | : | 4,000 mg/kg | |
| | LOAEL | | : | 8,000 mg/kg | |
| | | ation Route ure time | ÷ | Ingestion 10 Days | |
| Į | Lypost | | · | TO Days | |
| | Aspira | tion toxicity | | | |
| | | ssified based on availa | | | |
| | Experi | ence with human exp | osu | ire | |
| | Compo | onents: | | | |
| | Tulath | romycin: | | | |
| | Ingesti | on | : | Symptoms: Diarrh | noea, Nausea, Abdominal pain, Vomiting |
| 12 6 | | GICAL INFORMATION | J | | |
| 12.1 | -0010 | | | | |
| | Ecoto | cicity | | | |
| | Compo | onents: | | | |
| | Propyl | ene glycol: | | | |
| | Toxicity | y to fish | : | | hus mykiss (rainbow trout)): 40,613 mg/l |
| | | | | Exposure time: 96 | δh |
| | Tavisit | to double and attern | | | |
| | | y to daphnia and other c invertebrates | : | EC50 (Ceriodaph Exposure time: 48 | nia dubia (water flea)): 18,340 mg/l |
| | aquall | | | | |
| | • | | | | |

SAFETY DATA SHEET



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|-----------------|---|---|--|--|
| | | | | |
| Toxic plants | ity to algae/aquatic s | : | Exposure time: | nema costatum (marine diatom)): 19,300 mg/ 72 h Test Guideline 201 |
| | ity to daphnia and other tic invertebrates (Chron- icity) | : | NOEC (Cerioda Exposure time: | aphnia dubia (water flea)): 13,020 mg/l 7 d |
| | ity to microorganisms | : | NOEC (Pseudo Exposure time: | monas putida): > 20,000 mg/l 18 h |
| Tulat | hromycin: | | | |
| | ity to fish | : | Exposure time: | ales promelas (fathead minnow)): 4 mg/l 96 h Test Guideline 203 |
| | ity to daphnia and other tic invertebrates | : | Exposure time: | magna (Water flea)): > 100 mg/l 48 h Test Guideline 202 |
| Toxic plants | ity to algae/aquatic s | : | mg/l End point: Grov Exposure time: | |
| | | | mg/l End point: Grov Exposure time: | |
| | | | End point: Grov Exposure time: | |
| | | | End point: Grov Exposure time: | |
| | | | 0.0028 mg/l End point: Grov Exposure time: | |
| | | | 0.0012 mg/l End point: Grov Exposure time: | |

SAFETY DATA SHEET



| M-Factor (Acute aquatic tox- icity) 100 M-Factor (Chronic aquatic 100 toxicity) Toxicity to microorganisms EC50: 41.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 EC10: 0.667 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: Toxicity to fish E LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 36 h Toxicity to dish : LC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h 3-Mercaptopropane-1,2-diol: : Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability : Somponents: Propylene glycol: Biodegradability : Biodegradability : Result: Readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301B | Version 7.0 | Revision Date: 2023/09/30 | - | 97463-00010 | Date of last issue: 2023/04/04 Date of first issue: 2019/11/13 |
|---|----------------|------------------------------|----|--|---|
| icity) M-Factor (Chronic aquatic : 100 toxicity) Toxicity to microorganisms : EC50: 41.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 EC10: 0.667 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h 3-Mercaptopropane-1,2-diol: Ectotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B | | | | | |
| icity) M-Factor (Chronic aquatic : 100 toxicity) Toxicity to microorganisms : EC50: 41.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 EC10: 0.667 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h 3-Mercaptopropane-1,2-diol: Ectotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B | | | | | |
| M-Factor (Chronic aquatic : 100 toxicity) Toxicity to microorganisms : EC50: 41.1 mg/l Exposure time: 3 h : Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 EC10: 0.667 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: : . C50 (Pimephales promelas (fathead minnow)): > 100 mg/l Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h : Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l Toxicity to daphnia and other : : EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h 3-Mercaptopropane-1,2-diol: Ectoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Prosylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradability : Result: Not readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301B | | | : | 100 | |
| Toxicity to microorganisms EC50: 41.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 EC10: 0.667 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Toxicity to daphnia and other : aquatic invertebrates : S-Mercaptopropane-1,2-diol: Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradability Didegradability : Citric acid: Biodegradability : Citric acid: : Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: : Biodegradability : Biodegradability : Exposure time: 29 d Method: OECD Test Guideline 301B <td>M-Fa</td> <td>actor (Chronic aquatic</td> <td>:</td> <td>100</td> <td></td> | M-Fa | actor (Chronic aquatic | : | 100 | |
| Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209 Citric acid: Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Exposure time: 96 h Toxicity to daphnia and other : aquatic invertebrates : S-Mercaptopropane-1,2-diol: Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradability : Tulathromycin: Biodegradability : Citric acid: Biodegradability : Citric acid: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : | | | : | Exposure time: 3 Test Type: Respir | ation inhibition of activated sludge |
| Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l s-Mercaptopropane-1,2-diol: : Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradability : Result: Readily biodegradable. Tulathromycin: : Result: Not readily biodegradable. Exposure time: 28 d : Method: OECD Test Guideline 301F Citric acid: : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: : Result: Readily biodegradable. Biodegradability : Result: Readily biodegradable. Exposure time: 28 d : Biodegradabile. | | | | Exposure time: 3 Test Type: Respir | ation inhibition of activated sludge |
| Exposure time: 96 h Toxicity to daphnia and other aquatic invertebrates EC50 (Daphnia magna (Water flea)): 1,535 mg/l Exposure time: 24 h 3-Mercaptopropane-1,2-diol: Ecotoxicology Assessment Acute aquatic toxicity : Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradability : Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Exposure time: 28 d | Citrie | c acid: | | | |
| aquatic invertebrates Exposure time: 24 h 3-Mercaptopropane-1,2-diol: Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Persistence and degradability Components: Propylene glycol: Biodegradability Cercon Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability Citric acid: Biodegradability Citric acid: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability Biodegradability : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B | Τοχία | city to fish | : | | |
| Ecotoxicology Assessment Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability Citric acid: Biodegradability : Biodegradability : <td:< td=""> <td:< td=""></td:<></td:<> | | | : | | |
| Acute aquatic toxicity : Toxic effects cannot be excluded Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability Biodegradability Components: Propylene glycol: Biodegradability Biodegradability : Result: Readily biodegradable. Biodegradability : Result: Not readily biodegradable. Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : : Result: Readily biodegradable. Biodegradability : : Result: Readily biodegradable. Biodegradability : : Result: Readily biodegradable. Biodegradability : : Biodegradation: 97 % : | 3-Ме | ercaptopropane-1,2-diol | | | |
| Chronic aquatic toxicity : Toxic effects cannot be excluded Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Biodegradability : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B | Ecot | oxicology Assessment | | | |
| Persistence and degradability Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability Biodegradability : Result: Readily biodegradable. Biodegradability | Acut | e aquatic toxicity | : | Toxic effects canr | not be excluded |
| Components: Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Biodegradability Exposure time: 29 d Method: OECD Test Guideline 301B : Result: Readily biodegradable. Biodegradability Exposure time: 28 d : Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d | Chro | nic aquatic toxicity | : | Toxic effects can | not be excluded |
| Propylene glycol: Biodegradability : Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Biodegradability Exposure time: 29 d Method: OECD Test Guideline 301B : Result: Readily biodegradable. Biodegradability Exposure time: 28 d : Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d | Pers | istence and degradabili | ty | | |
| Biodegradability : Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability Biodegradability : Result: Readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability Biodegradability : Result: Readily biodegradable. Biodegradability Exposure time: 28 d : Result: Readily biodegradable. | Com | ponents: | | | |
| Tulathromycin: Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Biodegradability Exposure time: 28 d | | | : | Biodegradation: 9 Exposure time: 28 | 98.3 % 3 d |
| Biodegradability : Result: Not readily biodegradable. Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: : Biodegradability : Result: Readily biodegradable. Biodegradabile. Biodegradation: 97 % Exposure time: 28 d | | | | Method: OECD T | est Guideline 301F |
| Exposure time: 29 d Method: OECD Test Guideline 301B Citric acid: Biodegradability : Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d | Tula | thromycin: | | | |
| Biodegradability : Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d | Biode | egradability | : | Exposure time: 29 | d |
| Biodegradation: 97 % Exposure time: 28 d | Citri | c acid: | | | |
| | Biode | egradability | : | Biodegradation: 9 Exposure time: 28 | 97 % 3 d |



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| | | | | |
| II | | | | |
| Bioa | ccumulative potential | | | |
| <u>Com</u> | ponents: | | | |
| Partit | ylene glycol: ion coefficient: n- nol/water | : | log Pow: -1.07 Method: Regula | ion (EC) No. 440/2008, Annex, A.8 |
| Partit | t hromycin: ion coefficient: n- nol/water | : | log Pow: -1.41 pH: 7 | |
| Partit | c acid: ion coefficient: n- iol/water | : | log Pow: -1.72 | |
| Partit | rcaptopropane-1,2-dic ion coefficient: n- ol/water | bl: : | log Pow: -0.84 | |
| | lity in soil ata available | | | |
| | rdous to the ozone lay | yer | | |
| | r adverse effects ata available | | | |
| 13. DISPO | SAL CONSIDERATIO | NS | | |
| Wast | osal methods e from residues aminated packaging | : | Do not dispose of Empty container dling site for rec | cordance with local regulations. of waste into sewer. s should be taken to an approved waste han- /cling or disposal. specified: Dispose of as unused product. |
| 14. TRAN | SPORT INFORMATION | N | | |
| Inter | national Regulations | | | |
| | TDG umber er shipping name | : | UN 3082 ENVIRONMENT N.O.S. | ALLY HAZARDOUS SUBSTANCE, LIQUID, |

(Tulathromycin) 9

: : :

III

9

Class

Labels

Packing group





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| Envii | onmentally hazardous | : | yes | |
| UN/I | -DGR D No. er shipping name | : | UN 3082 Environmentally h (Tulathromycin) | azardous substance, liquid, n.o.s. |
| Labe | ing group ls ing instruction (cargo | : | 9 III Miscellaneous 964 | |
| ger a | ing instruction (passen- ircraft) ronmentally hazardous | : | 964 yes | |
| UN r | G-Code humber er shipping name | : | UN 3082 ENVIRONMENTA N.O.S. (Tulathromycin) | ALLY HAZARDOUS SUBSTANCE, LIQUID, |
| Labe EmS | ing group | : | 9 III 9 F-A, S-F yes | |

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

| Priority Assessment Chemical Substance | |
|--|--------|
| Chemical name | Number |
| Propane-1,2-diol | 106 |



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Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

| Chemical name | Concentration (%) | Remarks |
|-------------------|-------------------|----------------------|
| propane-1,2-diol | >=50 - <60 | From April 1st, 2025 |
| Hydrogen chloride | >=1 - <10 | - |
| Sodium hydroxide | >=1 - <10 | - |

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

| Chemical name | Remarks |
|-------------------|----------------------|
| propane-1,2-diol | From April 1st, 2025 |
| Hydrogen chloride | - |
| Sodium hydroxide | - |

Ordinance on Prevention of Hazards Due to Specified Chemical Substances - Group 3 Substance

| Chemical name | |
|-------------------|--|
| hydrogen chloride | |

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable



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Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission) Not applicable Specific Narcotic or Psychotropic Raw Material (Export / Import permission) Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

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

16. OTHER INFORMATION

Further information

| Sources of key data used to : | Internal technical data, data from raw material SDSs, OECD |
|-------------------------------|--|
| compile the Safety Data | eChem Portal search results and European Chemicals Agen- |
| Sheet | cy, http://echa.europa.eu/ |

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

Date format

yyyy/mm/dd

:



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Full text of other abbreviations

| ACGIH JP OEL JSOH | USA. ACGIH Threshold Limit Values (TLV) Japan. The Japan Society for Occupational Health. Recom- mendation of Occupational Exposure Limits |
|----------------------------------|--|
| ACGIH / C JP OEL JSOH / OEL-C | Ceiling limit Occupational Exposure Limit-Ceiling |

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.

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