

Doxycycline Formulation

| Version 5.0 | Revision Date: 28.09.2024 | | S Number: 05684-00011 | Date of last issue: 30.09.2023 Date of first issue: 06.07.2020 | | |
|---------------------------|-------------------------------|--------|--|---|--|--|
| SECTION 1. IDENTIFICATION | | | | | | |
| Product identifier | | : | Doxycycline For | Doxycycline Formulation | | |
| Manu | facturer or supplier's | s deta | ils | | | |
| Comp | Company | | MSD | MSD | | |
| Address | | : | Rua Coronel Bento Soares, 530 Cruzeiro - Sao Paulo - Brazil CEP 12730-340 | | | |
| Telep | Telephone | | 908-740-4000 | | | |
| Emer | Emergency telephone | | 1-908-423-6000 | | | |
| E-mail address | | : | EHSDATASTEWARD@msd.com | | | |
| Reco | mmended use of the | chem | ical and restriction | ons on use | | |
| | mmended use ictions on use | : | Veterinary produ Not applicable | ict | | |

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

| Acute toxicity (Oral) | : | Category 5 |
|---------------------------------------|---|------------|
| Skin corrosion | : | Category 1 |
| Serious eye damage | : | Category 1 |
| Short-term (acute) aquatic hazard | : | Category 1 |
| Long-term (chronic) aquatic hazard | : | Category 2 |

GHS label elements in accordance with ABNT NBR 14725 Standard

| Hazard pictograms | : | |
|-------------------|---|---|
| Signal Word | : | Danger |
| Hazard Statements | : | H303 May be harmful if swallowed. H314 Causes severe skin burns and eye damage. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects. |



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| Precautionary Statements | | | ease to the environment. tective gloves/ protective clothing/ eye protec- |
| | | tor if you feel u P301 + P330 + Do NOT induce CENTER/ doct P303 + P361 + immediately all shower. Immed P304 + P340 + and keep comf POISON CENT P305 + P351 + water for sever and easy to do CENTER/ doct | P331 + P310 IF SWALLOWED: Rinse mouth. vomiting. Immediately call a POISON P353 + P310 IF ON SKIN (or hair): Take off contaminated clothing. Rinse skin with water or diately call a POISON CENTER/ doctor. P310 IF INHALED: Remove person to fresh air ortable for breathing. Immediately call a TER/ doctor. P338 + P310 IF IN EYES: Rinse cautiously with al minutes. Remove contact lenses, if present Continue rinsing. Immediately call a POISON or. |
| | | Storage: P405 Store loc | ked up. |

Other hazards which do not result in classification

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|---------------------|---------|--|-----------------------|
| Doxycycline Hyclate | | Acute Tox. (Oral), 4 Aquatic Acute, 1 Aquatic Chronic, 2 | >= 50 -< 70 |

SECTION 4. FIRST AID MEASURES

| General advice | In the case of accident or if you feel unwell, seek in advice immediately. When symptoms persist or in all cases of doubt se advice. | |
|-------------------------|---|--------------|
| If inhaled | If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately. | |
| In case of skin contact | In case of contact, immediately flush skin with plen | nty of water |



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| In cas | se of eye contact | : | and shoes. Get medical atter Wash clothing be Thoroughly clean In case of contac for at least 15 min | n shoes before reuse. t, immediately flush eyes with plenty of wate |
| lf swa | If swallowed | | Get medical atter If swallowed, DO If vomiting occurs Call a physician of Rinse mouth thor | ntion immediately. NOT induce vomiting. s have person lean forward. or poison control center immediately. roughly with water. |
| | important symptoms effects, both acute and red | : | Never give anyth May be harmful if Causes serious e Causes severe b Causes digestive | eye damage. urns. |
| Prote | Protection of first-aiders | | First Aid respond and use the reco | lers should pay attention to self-protection, mmended personal protective equipment al for exposure exists (see section 8). |
| | Notes to physician | | • • | ically and supportively. |
| | | 430 | | |
| Suita | ble extinguishing media | : | Water spray Alcohol-resistant Carbon dioxide ((Dry chemical | |
| Unsu media | itable extinguishing a | : | None known. | |
| Spec fightir | ific hazards during fire ng | : | concentrations, a potential dust exp | dust; fine dust dispersed in air in sufficient and in the presence of an ignition source is a plosion hazard. bustion products may be a hazard to health. |
| Haza ucts | rdous combustion prod- | : | Carbon oxides | |
| Speci ods | ific extinguishing meth- | : | cumstances and Use water spray | g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to c |
| | ial protective equipment | : | | e, wear self-contained breathing apparatus. |

for fire-fighters Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.



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| tive equipment and emer- gency procedures | | | Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). | | |
| | Enviror | nmental precautions | : | Retain and dispos | akage or spillage if safe to do so. se of contaminated wash water. should be advised if significant spillages |
| Methods and materials for containment and cleaning up | | : | container for disper Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the a Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1 | dust in the air (i.e., clearing dust surfaces | |

SECTION 7. HANDLING AND STORAGE

| Technical measures | Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
|-------------------------|--|
| Local/Total ventilation | : If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | Do not get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in eyes. Wash skin thoroughly after handling. |
| | Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the |
| Hygiene measures | environment. If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working 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 engineering controls, proper personal protective equipment, |



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| | itions for safe storage ials to avoid | appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. Keep in properly labeled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations Do not store with the following product types: | |
| mater | | Strong oxidizing | agents ostances and mixtures |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

| Components | | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--|-----|--|--|--|-----------|
| Doxycycline Hyclate | | 24390-14-5 | TWA | OEL = 100 μg/m3 (OEB 2) | Internal |
| Engineering measures | : | compound. All engineerin design and op | g controls shou perated in accor | trols to minimize expo ld be implemented by dance with GMP prin d the environment. | facility |
| Personal protective equipm | ent | | | | |
| Respiratory protection Filter type Hand protection | : | exposure ass | essment demor d guidelines, us | itilation is not availabl istrates exposures ou e respiratory protectio | tside the |
| Material | : | Chemical-res | istant gloves | | |
| Eye protection | : | If the work en mists or aeros Wear a faces potential for d aerosols. | vironment or ac sols, wear the a hield or other fu irect contact to | e shields or goggles. tivity involves dusty c ppropriate goggles. Il face protection if the the face with dusts, m | ere is a |
| Skin and body protection | : | Work uniform | or laboratory co | pat. | |
| TION 9. PHYSICAL AND CH | EMI | CAL PROPER | TIES | | |
| Physical state | : | powder | | | |
| Color | : | light yellow | | | |
| | | | | | |

| Odor : | No data available |
|--------|-------------------|
|--------|-------------------|

Odor Threshold : No data available



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| | | | | | |
| | рН | | : | 1,5 - 3,5 | |
| | Melting | point/freezing point | : | No data available | 9 |
| | Initial boiling point and boiling range Flash point | | : | No data available | 9 |
| | | | : | Not applicable | |
| | Evapor | ration rate | : | Not applicable | |
| | Flammability (solid, gas) | | : | May form explosi handling or other | ive dust-air mixture during processing, means. |
| | Flamm | ability (liquids) | : | Not applicable | |
| | | explosion limit / Upper ability limit | : | No data available | 9 |
| | | explosion limit / Lower ability limit | : | No data available | 9 |
| | Vapor | pressure | : | Not applicable | |
| | Relativ | e vapor density | : | Not applicable | |
| | Relativ | e density | : | No data available | 9 |
| | Density | ý | : | No data available | 9 |
| | Solubility(ies) | | | | |
| | | ter solubility | : | No data available | 9 |
| | Partitio octano | n coefficient: n- I/water | : | Not applicable | |
| | Autoigr | nition temperature | : | No data available | 2 |
| | Decom | position temperature | : | No data available | 9 |
| | Viscosi Visc | ity cosity, kinematic | : | Not applicable | |
| | Explos | ive properties | : | Not explosive | |
| | Oxidizi | ng properties | : | The substance o | r mixture is not classified as oxidizing. |
| | Molecu | ılar weight | : | No data available | 9 |
| | Particle Particle | e characteristics e size | : | No data available | 9 |

SECTION 10. STABILITY AND REACTIVITY



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| | | vity cal stability ility of hazardous reac- | : | handling or other n | al conditions. e dust-air mixture during processing, |
| | Incom | ions to avoid patible materials dous decomposition cts | : | | |
| SEC | CTION 1 | 11. TOXICOLOGICAL I | NFC | ORMATION | |
| | Inform exposi | ation on likely routes of ure | : | Inhalation Skin contact Ingestion Eye contact | |
| | | toxicity | | | |
| | - | e harmful if swallowed. | | | |
| | Produ Acute | <u>ct:</u> oral toxicity | : | Acute toxicity estim Method: Calculation | |
| | Comp | onents: | | | |
| | Doxyc | cycline Hyclate: | | | |
| | - | oral toxicity | : | LD50 (Rat): 2.000 r | ng/kg |
| | | | | LD50 (Mouse): 1.87 | 70 mg/kg |
| | | | | LD50 (Dog): 500 m | g/kg |
| | | toxicity (other routes of istration) | : | LD50 (Rat): 222 mg Application Route: I | |
| • | | orrosion/irritation | | | |
| | <u>Comp</u> | onents: | | | |
| | Doxyc Remar | s ycline Hyclate: rks | : | No data available May irritate skin. | |
| | | is eye damage/eye irri s serious eye damage. | tati | on | |
| | <u>Comp</u> | onents: | | | |
| I | Doxyc Remar | e ycline Hyclate: rks | : | No data available | |
| | | | | | |

Symptoms Target Organs

Remarks



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| | | May irritate eye | S. |
| atory or skin sens | itizatio | n | |
| ensitization | - 1 - 1 - 1 - | | |
| | | information. | |
| - | | information. | |
| onents: | | | |
| ycline Hyclate: | | | |
| ks | : | May cause sen May cause sen | sitization by skin contact. sitization of susceptible persons by skin con- |
| cell mutagenicity ssified based on av | ailable | information. | |
| onents: | | | |
| ycline Hyclate: | | | |
| oxicity in vitro | : | Test system: Cl Result: Weakly | omosome aberration test in vitro ninese hamster cells positive d on data from similar materials |
| | | Test system: Cl Result: negative | |
| | | | d on data from similar materials |
| oxicity in vivo | : | Species: Mouse | te: Oral |
| | ensitization ssified based on av atory sensitization ssified based on av onents: ycline Hyclate: ks cell mutagenicity ssified based on av onents: ycline Hyclate: | ensitization ssified based on available atory sensitization ssified based on available onents: ycline Hyclate: ks : cell mutagenicity ssified based on available onents: ycline Hyclate: oxicity in vitro : | ssified based on available information. atory sensitization ssified based on available information. onents: ycline Hyclate: ks : No data available May cause sense May cause sense tact or by inhala cell mutagenicity ssified based on available information. onents: ycline Hyclate: pxicity in vitro : Test Type: Chroc Test system: Chroc Result: Weakly Remarks: Based Test Type: In vir Test system: Chroc Result: Weakly Remarks: Based pxicity in vivo : Test Type: In vir Species: Mouse Application Rou |

Uterus (including cervix)Benign tumor(s)

females

:



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| Not cl | oductive toxicity assified based on availa ponents: | able | information. | |
| Doxy | cycline Hyclate: | | | |
| Effect | s on fetal development | : | Species: Rat, fem Application Route General Toxicity Result: No advers Test Type: Fertilit Species: Rat, ma Application Route General Toxicity Symptoms: male | e: Oral Maternal: NOAEL: 250 mg/kg body weight se effects. ty/early embryonic development le e: Oral Maternal: NOAEL: 50 mg/kg body weight reproductive effects v and developmental toxicity tests did not |

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Doxycycline Hyclate:

| Species | : | Rat |
|--|---|-----------------|
| NOAEL | : | 25 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 28 d |
| Species NOAEL Application Route Exposure time Symptoms | : | Thyroid effects |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

| Doxycycline Hyclate: | | |
|----------------------|---|---|
| General Information | : | May cause Target Organs: Teeth Symptoms: Gastrointestinal disturbance |
| Skin contact | : | Remarks: May cause photosensitization. |
| Further information | | |
| Components: | | |
| Doxycycline Hyclate: | | |



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| Rema | arks | : Well to | lerated in | clinical use |
| SECTION | 12. ECOLOGICAL INI | ORMATION | | |
| Ecot | oxicity | | | |
| Com | ponents: | | | |
| Doxy | vcycline Hyclate: | | | |
| Toxic plants | ity to algae/aquatic s | End po | Anabaen bint: Grow ure time: | |
| Ecot | oxicology Assessmer | t | | |
| Acute | e aquatic toxicity | : Very to | oxic to aqu | uatic life. |
| Chro | nic aquatic toxicity | : Toxic to | o aquatic | life with long lasting effects. |
| | istence and degradab ata available | ility | | |
| Bioa | ccumulative potential | | | |
| <u>Com</u> | ponents: | | | |
| Partit | vcycline Hyclate: tion coefficient: n- nol/water | : log Pov | w: 0,02 | |
| | i lity in soil ata available | | | |
| | r adverse effects ata available | | | |
| SECTION | 13. DISPOSAL CONS | IDERATION | 5 | |
| Disp | osal methods | | | |
| - | e from residues | | | of waste into sewer. |
| Conta | aminated packaging | : Empty | containe | cordance with local regulations. rs should be taken to an approved waste |

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

| UN number Proper shipping name | | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
|-----------------------------------|--|--|
| | | (Doxycycline Hyclate) |
| | | |

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.



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| Labe | ing group | : | 9 III 9 yes | |
| UN/II Prope | er shipping name | : | UN 3077 Environmentally h (Doxycycline Hyd | nazardous substance, solid, n.o.s. Slate) |
| Labe | ing group ls ing instruction (cargo | : | 9 III Miscellaneous 956 | |
| ger a | ing instruction (passen- ircraft) onmentally hazardous | : | 956 yes | |
| UN n | 3-Code umber er shipping name | : | UN 3077 ENVIRONMENTA N.O.S. (Doxycycline Hyc | ALLY HAZARDOUS SUBSTANCE, SOLID, |
| Labe EmS | ing group | : | 9 III 9 F-A, S-F yes | |
| | sport in bulk according | | | OL 73/78 and the IBC Code |
| Dom | estic regulation | | | |
| | F umber er shipping name | : | N.O.S. | ALLY HAZARDOUS SUBSTANCE, SOLID, |
| Labe | ing group | : | (Doxycycline Hyd 9 III 9 90 | אמוכן |
| - | ial precautions for use | | vided herein ere fe | r informational purposes only, and solely |

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/legislation specific for the substance or mixture

National List of Carcinogenic Agents for Humans - : Not applicable (LINACH)



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| Brazil. Police | List of chemicals contr | rolled by the Federal | : Not applicable |
| The ir AICS | ngredients of this proc | duct are reported in : not determined | the following inventories: |
| DSL | | : not determined | |
| IECSC | 2 | : not determined | |
| | | | |

SECTION 16. OTHER INFORMATION

| Revision Date | : | 28.09.2024 |
|---------------|---|------------|
| Date format | : | dd.mm.yyyy |

Further information

| Sources of key data used to | : | Internal technical data, data from raw material SDSs, OECD |
|-----------------------------|---|--|
| compile the Material Safety | | eChem Portal search results and European Chemicals Agen- |
| Data 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.

Full text of other abbreviations

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 - Transporta-



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tion 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 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.

BR / Z8