

SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Doxycycline Formulation

Version
8.0

Revision Date:
14.04.2025

SDS Number:
6105694-00012

Date of last issue: 28.09.2024
Date of first issue: 06.07.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Doxycycline Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A
Çubuk Yolu 2. Km
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848 and subsequent amendments

Skin corrosion, Category 1	H314: Causes severe skin burns and eye damage.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling T.R. SEA No 28848 and subsequent amendments

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Hazard pictograms	:	 
Signal word	:	Danger
Hazard statements	:	H314 Causes severe skin burns and eye damage. H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements	:	<p>Prevention:</p> <p>P260 Do not breathe dust. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</p> <p>Response:</p> <p>P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor. P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor. P391 Collect spillage.</p>

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. KKDIK Registration No.	SEA Classification	Concentration (% w/w)
Doxycycline Hyclate	24390-14-5	Acute Tox. 4; H302 Aquatic Acute 1; H400 Aquatic Chronic 2; H411	>= 50 - < 70

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
Protection of first-aiders	: 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).
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 plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.
If swallowed	: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks	: Causes digestive tract burns. Causes serious eye damage. Causes severe burns.
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4.3 Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically and supportively.
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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
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Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.

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Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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 environment.
Hygiene measures	: 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, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives

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7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Dust	15 mg/m ³ Value type (Form of exposure): ZOAD/TWA (Total dust) Basis: TR OEL DU Further information: Allowable occupational exposure limit values of mineral dusts
	5 mg/m ³ Value type (Form of exposure): ZOAD/TWA (Respirable part) Basis: TR OEL DU Further information: Allowable occupational exposure limit values of mineral dusts

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Doxycycline Hy- clate	24390-14-5	TWA	OEL = 100 µg/m ³ (OEB 2)	Internal

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Doxycycline Hyclate	Water	0,0003 mg/l

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Personal protective equipment

Eye/face protection	: 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.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 143

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Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	powder
Colour	:	light yellow
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	1,5 - 3,5
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive

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Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight : No data available

Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg
Method: Calculation method

Components:

Doxycycline Hydrate:

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Acute oral toxicity	: LD50 (Rat): 2.000 mg/kg LD50 (Mouse): 1.870 mg/kg LD50 (Dog): 500 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 222 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Causes severe burns.

Components:

Doxycycline Hyclate:

Remarks	: No data available May irritate skin.
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Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Doxycycline Hyclate:

Remarks	: No data available May irritate eyes.
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Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Doxycycline Hyclate:

Remarks	: No data available May cause sensitisation by skin contact. May cause sensitisation of susceptible persons by skin contact or by inhalation of dust.
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Germ cell mutagenicity

Not classified based on available information.

Components:

Doxycycline Hyclate:

Genotoxicity in vitro	: Test Type: Chromosome aberration test in vitro Test system: Chinese hamster cells Result: Weakly positive
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Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster cells

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo

: Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Oral

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Doxycycline Hyclate:

Species

: Rat

Application Route

: Oral

Exposure time

: 2 Years

Symptoms

: 200 mg/kg body weight

Target Organs

: females

Remarks

: Uterus (including cervix)

: Benign tumor(s)

Reproductive toxicity

Not classified based on available information.

Components:

Doxycycline Hyclate:

Effects on foetal development

: Test Type: Fertility/early embryonic development

Species: Rat, females

Application Route: Oral

General Toxicity Maternal: NOAEL: 250 mg/kg body weight

Result: No adverse effects

Test Type: Fertility/early embryonic development

Species: Rat, male

Application Route: Oral

General Toxicity Maternal: NOAEL: 50 mg/kg body weight

Symptoms: male reproductive effects

Remarks: Fertility and developmental toxicity tests did not reveal any effect on reproduction.

STOT - single exposure

Not classified based on available information.

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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
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 photosensitisation.

Further information

Components:

Doxycycline Hyclate:

Remarks	:	Well tolerated in clinical use
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SECTION 12: Ecological information

12.1 Toxicity

Components:

Doxycycline Hyclate:

Toxicity to algae/aquatic plants	:	EC10 (Anabaena flos-aquae): 0,251 mg/l End point: Growth rate Exposure time: 72 h
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Ecotoxicology Assessment

Acute aquatic toxicity	:	Very toxic to aquatic life.
Chronic aquatic toxicity	:	Toxic to aquatic life with long lasting effects.

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12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

Components:

Doxycycline Hyclate:

Partition coefficient: n-octanol/water : log Pow: 0,02

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Do not dispose of waste into sewer. Dispose of in accordance with local regulations. Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN	: UN 3077
ADR	: UN 3077
RID	: UN 3077
IMDG	: UN 3077

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IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Doxycycline Hyclate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Doxycycline Hyclate)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Doxycycline Hyclate)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Doxycycline Hyclate)

IATA : Environmentally hazardous substance, solid, n.o.s.
(Doxycycline Hyclate)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III

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Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17)

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published)

Regulation on prevention of major industrial accidents. Reg number 30702

Quantity 1

Quantity 2

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E1	ENVIRONMENTAL HAZARDS	100 t	200 t
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Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on Import and Export of Certain Hazardous Chemicals, No. 32087, 2023 : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

Full text of H-Statements

H302 : Harmful if swallowed.
H400 : Very toxic to aquatic life.
H411 : Toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
TR OEL DU : Türkiye. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1)
TR OEL DU / ZOAD/TWA : Time Weighted Average Value

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

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ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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

Classification of the mixture:

Skin Corr. 1	H314
Eye Dam. 1	H318
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

Classification procedure:

Based on product data or assessment
Based on product data or assessment
Calculation method
Calculation method

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

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.

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Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



Doxycycline Formulation

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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.

TR / EN