



| Versic 3.8 | on | Revision Date: 28.09.2024 | | S Number: 31699-00015 | Date of last issue: 30.09.2023 Date of first issue: 05.06.2017 |
|---------------------|-------------------------|---|--|--|---|
| SECT | ION 1 | . IDENTIFICATION | | | |
| P | Produc | t identifier | : | Moxifloxacin Liqu | uid Formulation |
| | /lanufa Compa | acturer or supplier's o | deta : | ils MSD | |
| Address | | : | Avenue Comendador Antônio Loureiro Ramos, nº 1500 – Distrito Industrial Montes Claros – MG, Brazil 39404-620 | | |
| Т | eleph | one | : | +55 (38) 3229 70 | 000 |
| Emergency telephone | | : | +55 (38) 3201 56 | 370 | |
| E | -mail | address | : | EHSDATASTEW | /ARD@msd.com |
| R | Recom | mended use of the c mended use tions on use | | ical and restriction Pharmaceutical Not applicable | ons on use |

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

:

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Classification | Concentration (% w/w) |
|------------------|-------------|--|-----------------------|
| Moxifloxacin HCL | 186826-86-8 | Acute Tox. (Oral), 4 Eye Irrit., 2B Repr., 2 STOT RE, (Liver) , 2 | >= 0,1 -<= 0,2 |

SECTION 4. FIRST AID MEASURES

General advice

In the case of accident or if you feel unwell, seek medical advice immediately.



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| If | f inhale | ed | : | When symptoms advice. If inhaled, remove | persist or in all cases of doubt seek medical e to fresh air. |
| Ir | n case | of skin contact | : | of water. Remove contamir Get medical atten Wash clothing bet | , immediately flush skin with soap and plenty nated clothing and shoes. tion. |
| Ir | n case | of eye contact | : | Flush eyes with w | rater as a precaution. tion if irritation develops and persists. |
| lf | f swallo | owed | : | | NOT induce vomiting. tion. |
| а | | portant symptoms ects, both acute and | : | None known. | |
| | | on of first-aiders | : | and use the recor | ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8). |
| Ν | Notes to | o physician | : | | cally and supportively. |
| SECT | ION 5. | FIRE-FIGHTING ME | ASU | IRES | |
| S | Suitable | e extinguishing media | : | Water spray Alcohol-resistant t Carbon dioxide (C Dry chemical | |
| | Jnsuita nedia | ble extinguishing | : | None known. | |
| | Specific ighting | hazards during fire | : | Exposure to comb | oustion products may be a hazard to health. |
| | Hazardo ucts | ous combustion prod- | : | No hazardous cor | mbustion products are known |
| | Specific ods | extinguishing meth- | : | cumstances and t Use water spray t | measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do |
| | | protective equipment fighters | : | | e, wear self-contained breathing apparatus. tective equipment. |

SECTION 6. ACCIDENTAL RELEASE MEASURES

| Personal precautions, protec- | : | Use personal protective equipment. |
|-------------------------------|---|--|
| tive equipment and emer- | | Follow safe handling advice (see section 7) and personal |
| gency procedures | | protective equipment recommendations (see section 8). |

SAFETY DATA SHEET



Moxifloxacin Liquid Formulation

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| Er | nvironm | nental precautions | : | Prevent spreading oil barriers). Retain and dispos | akage or spillage if safe to do so. g over a wide area (e.g., by containment or be of contaminated wash water. should be advised if significant spillages |
| | | and materials for ent and cleaning up | : | For large spills, pr containment to ke can be pumped, s container. Clean up remainin absorbent. Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1 | absorbent material. ovide diking or other appropriate ep material from spreading. If diked material tore recovered material in appropriate ng materials from spill with suitable egulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements. |

SECTION 7. HANDLING AND STORAGE

| Technical measures | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. | |
|--|--|---|
| Local/Total ventilation Advice on safe handling | Use only with adequate ventilation. Avoid inhalation of vapor or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment | |
| | Take care to prevent spills, waste and minimize release to the environment. | 1 |
| 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. | 3 |
| Conditions for safe storage | Keep in properly labeled containers. | |
| Materials to avoid | Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents Gases | |



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| | | . | | | | | |
|----------------------------------|---|--|---|-----------------------------------|--|--|--|
| Components | CAS-No. | Value type (Form of | Control parame- ters / Permissible | Basis | | | |
| | | exposure) | concentration | | | | |
| Moxifloxacin HCL | 186826-86-8 | TWA | 1000 µg/m3 (OEB 1) | Internal | | | |
| Engineering measures : | technologies t less quick con All engineerin design and op protect produc | o control airborn nections). g controls should erated in accord ts, workers, and | controls and manufactie concentrations (e.g d be implemented by lance with GMP prince the environment. require special contai | ı., drip- facility iples to | | | |
| Personal protective equipmen | t | | | | | | |
| Respiratory protection : | exposure asse | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. | | | | | |
| Filter type : Hand protection | : Particulates type | | | | | | |
| Material : | Chemical-resi | Chemical-resistant gloves | | | | | |
| Eye 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. | | | | | | |
| Skin and body protection : | Work uniform | or laboratory co | at | | | | |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state | : | liquid |
|---|---|-------------------|
| Color | : | yellow |
| Odor | : | odorless |
| Odor Threshold | : | No data available |
| рН | : | 4,1 - 4,6 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |

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| | Flamma | ability (solid, gas) | : | Not applicable | |
| | Flamma | ability (liquids) | : | No data available | |
| | | explosion limit / Upper bility limit | : | No data available | |
| | Lower of flamma | explosion limit / Lower bility limit | : | No data available | |
| | Vapor p | pressure | : | No data available |) |
| | Relative | e vapor density | : | No data available | |
| | Relative | e density | : | No data available | 9 |
| | Density | 1 | : | 1,0044 g/cm ³ (20 | °C) |
| | Solubili Wat | ty(ies) er solubility | : | slightly soluble | |
| | Partitio octanol | n coefficient: n- | : | No data available | 9 |
| | | nition temperature | : | No data available | 9 |
| | Decom | position temperature | : | No data available | |
| | Viscosi Visc | ty cosity, kinematic | : | No data available |) |
| | Explosi | ve properties | : | Not explosive | |
| | Oxidizii | ng properties | : | The substance o | r mixture is not classified as oxidizing. |
| | Molecu | lar weight | : | No data available |) |
| | Particle Particle | e characteristics e size | : | No data available | 9 |

SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation



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| exposi | ure | | Skin contact Ingestion Eye contact | |
| | toxicity | | | |
| | assified based on ava | ailable | information. | |
| | onents: | | | |
| - | oxacin HCL: oral toxicity | : | LD50 (Rat): 1.3 | 20 ma/ka |
| | 0.0. (0) | | . , | |
| | | | LD50 (Mouse): : LD50 (Monkey): | |
| | | | | |
| | orrosion/irritation | ailable | information. | |
| Comp | onents: | - | | |
| Moxifl | oxacin HCL: | | | |
| Specie Result | | : | Rabbit No skin irritatior | 1 |
| Not cla | us eye damage/eye assified based on ava onents: | | | |
| Moxifl | oxacin HCL: | | | |
| Specie Result | | : | Rabbit Moderate eye ir | ritation |
| Respir | ratory or skin sensi | tizatio | n | |
| | ensitization assified based on ava | ailabla | information | |
| | ratory sensitization | | | |
| • | assified based on ava | | information. | |
| | cell mutagenicity assified based on ava | ailable | information. | |
| | onents: | - | | |
| Moxifl | oxacin HCL: | | | |
| Genote | oxicity in vitro | : | Test Type: Bact Result: positive | erial reverse mutation assay (AMES) |
| | | | Test Type: Chro Result: negative | omosome aberration test in vitro |
| | | | Test Turney In with | tro mammalian cell gene mutation test |



| ersion 3 | Revision Date: 28.09.2024 | - | 9S Number: 31699-00015 | Date of last issue: 30.09.2023 Date of first issue: 05.06.2017 | |
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| | | | Result: negative | | |
| | | | Test Type: in vitro Result: negative | o micronucleus test | |
| Genotoxicity in vivo | | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Application Route: Oral Result: negative | | |
| | nogenicity assified based on availa | ble | information. | | |
| - | oductive toxicity assified based on availa | ıble | information. | | |
| Comp | oonents: | | | | |
| Moxif | loxacin HCL: | | | | |
| Effect | s on fertility | : | Species: Rat Application Route | 500 mg/kg body weight | |
| Effects on fetal development | | : | Test Type: Embryo-fetal development Species: Monkey Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: negative | | |
| | | | Species: Rabbit Application Route Developmental To | vo-fetal development :: Intravenous injection oxicity: LOAEL: 20 mg/kg body weight tal malformations. | |
| Repro sessn | oductive toxicity - As- nent | : | Some evidence of adverse effects on development, based or animal experiments. | | |
| | -single exposure assified based on availa | ble | information. | | |
| sтот | -repeated exposure | | | | |
| | assified based on availa | ble | information. | | |

Components:

Moxifloxacin HCL:

| Target Organs | : | Liver |
|---------------|---|--|
| Assessment | : | May cause damage to organs through prolonged or repeated |
| | | exposure. |



| ersion 8 | Revision Date: 28.09.2024 | SDS Number: 1731699-00015 | Date of last issue: 30.09.2023 Date of first issue: 05.06.2017 |
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| Repe | ated dose toxicity | | |
| <u>Com</u> | oonents: | | |
| Moxif | floxacin HCL: | | |
| | | : Rat : 100 mg/kg : Oral : 4 Weeks | |
| Expos | EL cation Route sure time et Organs | : Rat : 100 mg/kg : Oral : 13 Weeks : Liver : Liver disorders | |
| Expos | EL cation Route sure time et Organs | : Rat : 20 mg/kg : Oral : 6 Months : Liver : Liver disorders | |
| | EL cation Route sure time | : Monkey : 50 mg/kg : Oral : 4 Weeks : No adverse effe | cts. |
| Expos | EL cation Route sure time et Organs | : Monkey : 15 mg/kg : Oral : 13 Weeks : Gastrointestinal : Vomiting | tract |
| Expos | cation Route sure time et Organs | : Monkey : Oral : 26 Weeks : Liver : Liver disorders | |
| Aspir Not cl | ations ration toxicity lassified based on ava rience with human e | ailable information. | |

Components:

Moxifloxacin HCL:

Ingestion

: Symptoms: Nausea, Abdominal pain, Headache, Dizziness, central nervous system effects, joint pain

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| SECTION | 12. ECOLOGICAL II | NFORMATION | |
| | oxicity ata available | | |
| | istence and degrada ata available | bility | |
| | ccumulative potenti a ata available | al | |
| | i lity in soil ata available | | |
| Othe | r adverse effects | | |

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

| Waste from residues | : | Do not dispose of waste into sewer. Dispose of in accordance with local regulations. |
|------------------------|---|--|
| 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. |

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

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



raw material SDSs, OECD European Chemicals Agen-

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| (LINA | CH) | | |
| Brazil Police | | trolled by the Federal | : Not applicable |
| The i AICS | ngredients of this pro | oduct are reported in : not determined | the following inventories: |
| DSL | | : not determined | |
| IECS | C | : 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 |
|-----------------------------|---|------------------------------------|
| compile the Material Safety | | eChem Portal search results and |
| Data Sheet | | cy, http://echa.europa.eu/ |

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 Svstem; 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 Sub-



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stances 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.

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