

Ribavirin Solid Formulation

| Version 5.0 | Revision Date: 28.09.2024 | | S Number: 2487-00021 | Date of last issue: 30.09.2023 Date of first issue: 11.12.2015 | | | | | |
|----------------|-------------------------------|--------|----------------------------------|---|--|--|--|--|--|
| SECTION | SECTION 1. IDENTIFICATION | | | | | | | | |
| Produ | uct identifier | : | : Ribavirin Solid Formulation | | | | | | |
| Manu | afacturer or supplier's | s deta | ils | | | | | | |
| Com | bany | : | MSD | | | | | | |
| Addre | ess | : | nº 1500 – Distrit | dador Antônio Loureiro Ramos, o Industrial - MG, Brazil 39404-620 | | | | | |
| Telep | bhone | : | +55 (38) 3229 7 | 000 | | | | | |
| Emer | gency telephone | : | +55 (38) 3201 5 | 670 | | | | | |
| E-ma | il address | : | EHSDATASTEV | VARD@msd.com | | | | | |
| Reco | mmended use of the | chem | ical and restricti | ons on use | | | | | |
| | mmended use ictions on use | : | Pharmaceutical Not applicable | | | | | | |

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

| Acute toxicity (Oral) | : | Category 5 |
|--|---|--------------------|
| Germ cell mutagenicity | : | Category 2 |
| Reproductive toxicity | : | Category 1B |
| Specific target organ toxicity - single exposure | : | Category 3 |
| Specific target organ toxicity - repeated exposure (Oral) | : | Category 1 (Blood) |

GHS label elements in accordance with ABNT NBR 14725 Standard

| Hazard pictograms | |
|-------------------|--|
| Signal Word | : Danger |
| Hazard Statements | H303 May be harmful if swallowed. H335 May cause respiratory irritation. H341 Suspected of causing genetic defects. H360Df May damage the unborn child. Suspected of damaging |



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| | | | damage to organs (Blood) through prolonged or osure if swallowed. |
| Preca | autionary Statements | P260 Do not l P264 Wash s P270 Do not e P271 Use onl | kin thoroughly after handling. eat, drink or smoke when using this product. y outdoors or in a well-ventilated area. rotective gloves/ protective clothing/ eye protec- |
| | | tor if you feel P304 + P340 and keep com doctor if you f | + P312 IF INHALED: Remove person to fresh air fortable for breathing. Call a POISON CENTER/ |
| | | Storage: P405 Store lo | cked up. |

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin. 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) |
| Ribavirin | 36791-04-5 | Acute Tox. (Oral), 4 Muta., 2 Repr., 1B STOT SE, 3 STOT RE, (Oral)(Blood) , 1 | >= 50 -< 70 |
| Cellulose | 9004-34-6 | | >= 10 -< 20 |
| Magnesium stearate | 557-04-0 | | >= 1 -< 5 |

SECTION 4. 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. |
|----------------|---|--|
| If inhaled | : | If inhaled, remove to fresh air. |



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| In ca | se of skin contact | : In case of of water. | al attention. contact, immediately flush skin with soap and plenty ontaminated clothing and shoes. |
| | | Wash clot | al attention. hing before reuse. y clean shoes before reuse. |
| In ca | se of eye contact | | rinse well with water. |
| If ew/ | allowed | | al attention if irritation develops and persists. ed, DO NOT induce vomiting. |
| 11 3 WG | allowed | | al attention. |
| | | | uth thoroughly with water. |
| Most | important symptoms | | rmful if swallowed. |
| | effects, both acute and | | e respiratory irritation. |
| delay | red | | of causing genetic defects. |
| | | May dama fertility. | ge the unborn child. Suspected of damaging |
| | | | amage to organs through prolonged or repeated if swallowed. |
| | | | ith dust can cause mechanical irritation or drying of |
| | | Dust conta | act with the eyes can lead to mechanical irritation. |
| Prote | ection of first-aiders | and use th | esponders should pay attention to self-protection, ne recommended personal protective equipment potential for exposure exists (see section 8). |
| Notes | s to physician | | ptomatically and supportively. |

SECTION 5. FIRE-FIGHTING MEASURES

| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical |
|--|---|---|
| Unsuitable extinguishing media | : | None known. |
| 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 prod- ucts | : | Carbon oxides Metal oxides |
| 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 fire-fighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |



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| SECTION | 6. ACCIDENTAL RELE | AS | E MEASURES | |
| tive e | onal precautions, protec- quipment and emer- / procedures | : | Follow safe ha | protective equipment. ndling advice (see section 7) and personal pment recommendations (see section 8). |
| Enviro | onmental precautions | : | Prevent furthe Retain and dis | to the environment. r leakage or spillage if safe to do so. pose of contaminated wash water. es should be advised if significant spillages tained. |
| | ods and materials for inment and cleaning up | : | over the area t Add excess liq Soak up with in Avoid dispersa with compress Dust deposits surfaces, as the released into the Clean up remain absorbent. Local or nation disposal of this employed in the determine white Sections 13 ar | with absorbents and place a damp covering o minimize entry of the material into the air. uid to allow the material to enter into solution. nert absorbent material. If of dust in the air (i.e., clearing dust surfaces ed air). should not be allowed to accumulate on lese may form an explosive mixture if they are he atmosphere in sufficient concentration. tining materials from spill with suitable al regulations may apply to releases and a material, as well as those materials and items the cleanup of releases. You will need to ch regulations are applicable. and 15 of this SDS provide information regarding reational requirements. |

| 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. |
| | | Avoid contact with 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. |
| | | Already sensitized individuals, and those susceptible |
| | | to asthma, allergies, chronic or recurrent respiratory disease, |
| | | should consult their physician regarding working with |
| | | respiratory irritants or sensitizers. |
| | | Minimize dust generation and accumulation. |
| | | Keep container closed when not in use. |
| | | |



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| Hygier | ne measures | Take precauti Do not eat, dr Take care to penvironment. If exposure to flushing systeplace. | om heat and sources of ignition. onary measures against static discharges. ink or smoke when using this product. orevent spills, waste and minimize release to the chemical is likely during typical use, provide eye ms and safety showers close to the working |
| Condi | tions for sofe storage | When using d Wash contam The effective engineering c appropriate d industrial hygi use of admini | o not eat, drink or smoke. inated clothing before re-use. operation of a facility should include review of ontrols, proper personal protective equipment, egowning and decontamination procedures, ene monitoring, medical surveillance and the strative controls. |
| Condi | tions for safe storage | Store locked Keep tightly c Keep in a coc | |
| Materi | als to avoid | : Do not store v Strong oxidizi | vith the following product types: ng agents substances and mixtures |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parame- ters / Permissible concentration | Basis |
|--------------------|------------|--|--|----------|
| Ribavirin | 36791-04-5 | Wipe limit | 400 µg/100 cm ² | Internal |
| | | TWA | 40 µg/m3 (OEB 3) | Internal |
| Cellulose | 9004-34-6 | TWA | 10 mg/m ³ | ACGIH |
| Magnesium stearate | 557-04-0 | TWA (Inhalable particulate matter) | 10 mg/m ³ | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m ³ | ACGIH |

Engineering measures

: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.



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| Pers | onal protective equipn | nent | | | | |
| Respiratory protection Filter type Hand protection | | exposure asso recommended | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type | | | |
| Material | | : Chemical-resi | Chemical-resistant gloves | | | |
| Remarks Eye protection Skin and body protection | | If the work en mists or aeros Wear a faces potential for d aerosols. Work uniform Additional boo task being per disposable su | lasses with side shields or goggles. vironment or activity involves dusty conditions, sols, wear the appropriate goggles. hield or other full face protection if there is a irect contact to the face with dusts, mists, or or laboratory coat. dy garments should be used based upon the rformed (e.g., sleevelets, apron, gauntlets, its) to avoid exposed skin surfaces. ate degowning techniques to remove potentially | | | |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| Physical state | : | powder |
|---|---|---|
| Color | : | white |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| рН | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | Not applicable |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |



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| Vapor pressure | : Not applicable |
| Relative vapor 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 |
| Autoignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Viscosity Viscosity, kinematic | : Not applicable |
| Explosive properties | : Not explosive |
| Oxidizing properties | : The substance or mixture is not classified as oxidizing. |
| Particle characteristics Particle size | : No data available |

SECTION 10. STABILITY AND REACTIVITY

| Reactivity Chemical stability Possibility of hazardous reac- tions | Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents. |
|---|---|
| Conditions to avoid | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | Oxidizing agents |
| Hazardous decomposition products | No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION

| Information on likely routes of exposure | : | Inhalation Skin contact Ingestion Eye contact |
|--|---|--|
| Acute toxicity May be harmful if swallowed. | | |
| Product: Acute oral toxicity | : | Acute toxicity estimate: 2.249 mg/kg Method: Calculation method |



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| Compon | onte | | | |
| <u>Compon</u> | | | | |
| Ribavirin Acute ora | | | LD50 (Rat): 4.116 | 5 5 94 ma/ka |
| Acute of a | | • | , , , , , , , , , , , , , , , , , , , | |
| | | | LD50 (Mouse): > | 10.000 mg/kg |
| | | | LD50 (Dog): >= 1 | .500 mg/kg |
| Acute inh | alation toxicity | : | Remarks: No data | a available |
| Acute de | rmal toxicity | : | Remarks: No data | a available |
| Acute tox administr | ticity (other routes of ation) | : | LD50 (Rat): 1.554 Application Route | |
| | | | LD50 (Mouse): 1 Application Route | |
| Cellulos | e: | | | |
| Acute ora | al toxicity | : | LD50 (Rat): > 5.0 | 00 mg/kg |
| Acute inh | alation toxicity | : | LC50 (Rat): > 5,8 Exposure time: 4 Test atmosphere: | h |
| Acute de | rmal toxicity | : | LD50 (Rabbit): > 2 | 2.000 mg/kg |
| Magnesi | um stearate: | | | |
| Acute ora | | : | icity | |
| Acute de | rmal toxicity | : | LD50 (Rabbit): > 2 Remarks: Based | 2.000 mg/kg on data from similar materials |
| Skin cor | rosion/irritation | | | |
| Not class | ified based on availa | ble | information. | |
| Compon | ents: | | | |
| Ribavirin | n: | | | |
| Remarks | | : | No data available May irritate skin. | |
| Magnesi | um stearate: | | | |
| Species | | : | Rabbit | |
| Result | | : | No skin irritation | |
| Remarks | | : | Based on data fro | m similar materials |



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| | | | |
| | us eye damage/eye lassified based on ava | | |
| Com | oonents: | | |
| Ribay | /irin: | | |
| Rema | arks | : No data avai May irritate e | |
| Magn | esium stearate: | | |
| Speci | | : Rabbit | |
| Resu Rema | | : No eye irritat : Based on da | ion ta from similar materials |
| Resp | iratory or skin sensi | tization | |
| • | sensitization | | |
| - | lassified based on av | ailable information. | |
| Resp | iratory sensitization | | |
| - | lassified based on av | | |
| Com | ponents: | | |
| Ribay | /irin: | | |
| Rema | arks | : No data avai | lable |
| Magn | esium stearate: | | |
| Test | | : Maximization | Test |
| Speci | es of exposure | : Skin contact : Guinea pig | |
| Metho | | | Guideline 406 |
| Resu | | : negative | |
| Rema | arks | : Based on da | ta from similar materials |
| Germ | cell mutagenicity | | |
| Suspe | ected of causing gene | etic defects. | |
| Com | ponents: | | |
| Ribay | /irin: | | |
| Geno | toxicity in vitro | : Test Type: B Result: nega | acterial reverse mutation assay (AMES) tive |
| | | | vitro mammalian cell gene mutation tes Rodent cell line |

Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative



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| Geno | toxicity in vivo | : Test Type: dominant lethal test Species: Rat Result: negative | | | | | |
| | | Test Type: N Species: Mo Result: posit | | | | | |
| | | Test Type: N Species: Mo Result: posit | | | | | |
| | cell mutagenicity - ssment | : Positive resumutagenicity | ult(s) from in vivo mammalian somatic cell v tests. | | | | |
| Cellu | lose: | | | | | | |
| Geno | toxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative | | | | | |
| | | Test Type: lı Result: nega | n vitro mammalian cell gene mutation test ative | | | | |
| Geno | toxicity in vivo | cytogenetic Species: Mo | use Route: Ingestion | | | | |
| Magn | esium stearate: | | | | | | |
| | toxicity in vitro | Result: nega | n vitro mammalian cell gene mutation test ttive ased on data from similar materials | | | | |
| | | Method: OE Result: nega | Chromosome aberration test in vitro CD Test Guideline 473 ative ased on data from similar materials | | | | |
| | | Result: nega | Bacterial reverse mutation assay (AMES) ative ased on data from similar materials | | | | |

Carcinogenicity

Not classified based on available information.

Components:

Ribavirin:

| : | Mouse |
|---|----------------------|
| : | Oral |
| : | 6 Months |
| : | 75 mg/kg body weight |
| : | negative |
| | :: |



| Target Organs :: Blood, Testes Remarks :: The mechanism or mode of action may not be relevant in humans. Species :: Rat Application Route :: Oral Exposure time :: 2 Years NQAEL :: I0 mg/kg body weight Result :: regative Remarks :: The mechanism or mode of action may not be relevant in humans. Species :: Mouse Application Route :: Oral Exposure time :: 18 Months Result :: regative Remarks :: The mechanism or mode of action may not be relevant in humans. Species :: Mouse Reposition Route :: Oral Exposure time :: 72 weeks Result :: ingestion Exposure time :: 72 weeks Result :: regative Application Route: : ingestion Exposure time :: ?eraility: Application Route: <th>Version 5.0</th> <th>Revision Date: 28.09.2024</th> <th>SDS Number:Date of last issue: 30.09.2023402487-00021Date of first issue: 11.12.2015</th> <th></th> | Version 5.0 | Revision Date: 28.09.2024 | SDS Number:Date of last issue: 30.09.2023402487-00021Date of first issue: 11.12.2015 | | | | |
|---|----------------------------------|--|--|--------|--|--|--|
| Application Route : Oral Exposure time : 2 Years NOAEL : 10 mg/kg body weight Result : regative Remarks : The mechanism or mode of action may not be relevant in humans. Species : Mouse Application Route : Oral Exposure time : 18 Months Result : regative Remarks : The mechanism or mode of action may not be relevant in humans. Cellulose: : Species Species : Rat Application Route : Ingestion Exposure time : 72 weeks Result : negative Reproductive toxicity May damage the unborn child. Suspected of damaging fertility. Components: : Test Type: Fertility Ribavirin: : Test Type: Fertility: Effects on fertility : Test Type: Fertility: Species: Rat, male Application Route: I: at mg/k body weight Symptoms: Reduced fertility Species: Rat, male | | | : The mechanism or mode of action may not be relevant in hu | | | | |
| Application Route : Oral Exposure time : 18 Months Result : negative Remarks : The mechanism or mode of action may not be relevant in humans. Cellulose: Species : Species : Rat Application Route : Ingestion Exposure time : 72 weeks Result : negative Reproductive toxicity May damage the unborn child. Suspected of damaging fertility. Components: Ribavirin: Effects on fertility : Test Type: Fertility Species: Rat, male Application Route: Intraperitoneal injection Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Ap | Applic Expos NOAE Resul | cation Route sure time EL t | Oral 2 Years 10 mg/kg body weight negative The mechanism or mode of action may not be relevant | in hu- | | | |
| Species : Rat Application Route : Ingestion Exposure time : 72 weeks Result : negative Reproductive toxicity May damage the unborn child. Suspected of damaging fertility. Components: Ribavirin: Effects on fertility : Test Type: Fertility Species: Rat, male Application Route: Intraperitoneal injection Application Route: Nature: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight | Applic Expos Resul | cation Route sure time t | Oral 18 Months negative The mechanism or mode of action may not be relevant | in hu- | | | |
| May damage the unborn child. Suspected of damaging fertility. Components: Ribavirin: Effects on fertility : Test Type: Fertility Species: Rat, male Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Application Route: Oral | Speci Applic Expos | es cation Route sure time | : Ingestion : 72 weeks | | | | |
| Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Application Route: Oral | May c <u>Com</u> r Ribav | lamage the unborn chil ponents: ririn: | : Test Type: Fertility | | | | |
| Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility Result: positive Test Type: Fertility Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Application Route: Oral | | | Application Route: Intraperitoneal injection Fertility: LOAEL: < 20 mg/kg body weight Symptoms: Reduced fertility Result: positive | | | | |
| Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight Result: Animal testing did not show any effects on fertility. Test Type: Fertility Species: Rat, male Application Route: Oral | | | Species: Mouse, male Application Route: Oral Fertility: LOAEL: 35 mg/kg body weight Symptoms: Reduced fertility | | | | |
| Species: Rat, male Application Route: Oral | | | Species: Rat, females Application Route: Oral Fertility: NOAEL: 10 mg/kg body weight | ity. | | | |
| 11/10 | | | Species: Rat, male | | | | |



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| | | Fertility: NOAEL: 160 mg/kg body weight Result: Animal testing did not show any effects on fertility. |
| Effect | s on fetal development | Test Type: Development Species: Rat, female Application Route: Oral Developmental Toxicity: LOAEL: <= 1 mg/kg body weight Symptoms: Reduced body weight, Reduced number of viable fetuses., Skeletal malformations. Result: Embryotoxic effects and adverse effects on the off- spring were detected. |
| | | Test Type: Development Species: Rabbit, female Application Route: Oral General Toxicity Maternal: LOAEL: 1 mg/kg body weight Developmental Toxicity: LOAEL: 1 mg/kg body weight Symptoms: Reduced body weight, Skeletal malformations. Result: Embryotoxic effects and adverse effects on the off- spring were detected. |
| | | Test Type: Development Species: Hamster Application Route: Oral Developmental Toxicity: LOAEL: 2,5 mg/kg body weight Symptoms: Skeletal and visceral variations ., Total Resorp- tions / resorption rate. Result: Embryotoxic effects and adverse effects on the off- spring were detected. |
| | | Test Type: Embryo-fetal development Species: Rat Application Route: Oral General Toxicity Maternal: NOAEL: 0,3 mg/kg body weight Embryo-fetal toxicity.: LOAEL: 1 mg/kg body weight Symptoms: Skeletal malformations. Result: positive |
| Repro sessn | oductive toxicity - As- nent | : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments. |
| II Cellu | lose: | |
| | s on fertility | : Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
| Effect | s on fetal development | : Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative |



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| Magne | esium stearate: | | | |
| | s on fertility | : | reproduction/dever Species: Rat Application Route Method: OECD Te Result: negative | |
| Effects | s on fetal development | : | Species: Rat Application Route Result: negative | o-fetal development : Ingestion on data from similar materials |
| | -single exposure ause respiratory irritatio | n. | | |
| <u>Comp</u> | onents: | | | |
| Ribav | irin: | | | |
| Asses | sment | : | May cause respire | atory irritation. |
| Cause | onents: | looc | I) through prolonge | d or repeated exposure if swallowed. |
| Target | s of exposure t Organs sment | : | Ingestion Blood Causes damage t exposure. | o organs through prolonged or repeated |
| Repea | ated dose toxicity | | | |
| <u>Comp</u> | onents: | | | |
| | es | : : : | Monkey 30 mg/kg 10 d Blood, Gastrointes | stinal tract |
| Expos | | : | Rat 7,6 mg/kg Inhalation 90 d Blood, Lungs | |
| | | : | Dog 5 mg/kg Oral 1 y | |



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| Targe | et Organs | : Blood, Gastrointestinal tract | |
| Species NOAEL Application Route Exposure time Target Organs | | Mouse 20 mg/kg Oral 18 Months Blood, Cardio-vascular system | |
| | es | : Rat : >= 9.000 mg/kg : Ingestion : 90 Days | |
| Speci NOAE Applic | EL cation Route sure time | Rat > 100 mg/kg Ingestion 90 Days Based on data from similar materials | |
| - | ration toxicity lassified based on av | lable information. | |
| Expe | rience with human e | posure | |
| Comp | ponents: | | |
| Ribav Inhala | | : Symptoms: Headache, Dizziness Remarks: Based on Human Evidence | |
| Skin d | contact | : Remarks: May cause eye irritation. | |
| | ontoot | Based on Human Evidence : Remarks: May cause eye irritation. Based on Human Evidence | |
| Eye c | onaci | | |

Ecotoxicity

Components:

| Ribavirin: Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 119 mg/l Exposure time: 96 h |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 117 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |



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|----------------------------------|--|---|--|---|
| Toxicity to algae/aquatic plants | | : | EC50 (Pseudokiro mg/l Exposure time: 96 Method: OECD To | |
| | | | NOEC (Pseudokin mg/l Exposure time: 96 Method: OECD Te | |
| Toxic | ity to microorganisms | : | EC50: > 1.000 mg Exposure time: 3 Test Type: Respir Method: OECD Te | h ration inhibition |
| Cellu | lose: | | | |
| | ity to fish | : | Exposure time: 48 | ipes (Japanese medaka)): > 100 mg/l 3 h on data from similar materials |
| Magn | esium stearate: | | | |
| Toxic | ity to fish | : | Exposure time: 48 Method: DIN 384 | |
| | ity to daphnia and other ic invertebrates | : | Exposure time: 47 Test substance: V Method: Directive | Vater Accommodated Fraction 67/548/EEC, Annex V, C.2. on data from similar materials |
| Toxic plants | ity to algae/aquatic | : | mg/l Exposure time: 72 Test substance: V Method: OECD To | Vater Accommodated Fraction est Guideline 201 on data from similar materials |
| | | | mg/l Exposure time: 72 Test substance: V Method: OECD To | Vater Accommodated Fraction |
| Toxic | ity to microorganisms | : | Exposure time: 16 Test substance: V | nas putida): > 100 mg/l 5 h Vater Accommodated Fraction on data from similar materials |



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|----------------|--------------------------------|---|--|---|--|--|--|--|--|
| Persis | Persistence and degradability | | | | | | | | |
| <u>Comp</u> | Components: | | | | | | | | |
| Cellul | ose: | | | | | | | | |
| Biodeg | gradability | : | Result: Readily biodegradable. | | | | | | |
| Magn | esium stearate: | | | | | | | | |
| Biode | Biodegradability : | | Result: Not biodegradable Remarks: Based on data from similar materials | | | | | | |
| Bioac | cumulative potential | | | | | | | | |
| Comp | onents: | | | | | | | | |
| Ribav | irin: | | | | | | | | |
| | on coefficient: n- bl/water | : | log Pow: 0,971 | | | | | | |
| Magne | esium stearate: | | | | | | | | |
| | on coefficient: n- bl/water | : | log Pow: > 4 | | | | | | |
| Mobili | ity in soil | | | | | | | | |
| No da | ta available | | | | | | | | |
| Other | adverse effects | | | | | | | | |
| No da | ta available | | | | | | | | |
| SECTION | | | PATIONS | | | | | | |

SECTION 13. DISPOSAL CONSIDERATIONS

| Disposal methods | | |
|------------------------|---|--|
| 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



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|---------------------|--|-----------------------------|---|--|--|--|--|--|
| ANT Not i | T regulated as a dangero | ous good | | | | | | |
| | cial precautions for u applicable | ser | | | | | | |
| SECTION | 15. REGULATORY I | NFORMATION | | | | | | |
| | Safety, health and environmental regulations/legislation specific for the substance or mixture | | | | | | | |
| | National List of Carcinogenic Agents for Humans - : Not applicable (LINACH) | | | | | | | |
| | Brazil. List of chemicals controlled by the Federal : Not applicable Police | | | | | | | |
| The | ingredients of this pr | oduct are reported i | n the following inventories: | | | | | |
| AICS | 3 | : not determined | d | | | | | |
| DSL | | : not determined | d | | | | | |
| IECS | SC | : not determined | d | | | | | |

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

| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
|-------|---|---|
| | | |

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory con-



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|---------|----------------|--------------|---------------------------------|
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centration; 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 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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