



|) | Revision Date: 06.04.2024 | | S Number: 2653-00021 | Date of last issue: 30.09.2023 Date of first issue: 11.12.2015 |
|--|---|-------|---|---|
| | | | | |
| ction 1: | Identification | | | |
| Produ | uct identifier | : | Ribavirin Solid | Formulation |
| Reco | mmended use of the ch | nem | ical and restric | tions on use |
| | nmended use | : | Pharmaceutica | |
| Restri | ctions on use | : | Not applicable | |
| Manu | facturer or supplier's d | letai | ls | |
| Comp | any | : | MSD | |
| Addre | SS | : | 50 Tuas West Singapore - S | Drive ingapore 638408 |
| Telepl | hone | : | +1-908-740-40 | 000 |
| Emerç | gency telephone number | • : | 65 6697 2111 | (24/7/365) |
| E-mai | l address | : | EHSDATASTE | EWARD@msd.com |
| | | | | |
| | Hazard identification | nce | or mixture | |
| Class | | | or mixture Category 2 | |
| Class Germ | ification of the substar | : | | |
| Class Germ Repro Specit | ification of the substar cell mutagenicity | : | Category 2 Category 1B | |
| Class Germ Repro Specif single | ification of the substar cell mutagenicity ductive toxicity fic target organ toxicity - | : | Category 2 Category 1B Category 3 | ood) |
| Class Germ Repro Specif single Specif repea | ification of the substar cell mutagenicity ductive toxicity fic target organ toxicity - exposure fic target organ toxicity - | :: | Category 2 Category 1B Category 3 Category 1 (Bl | |
| Class Germ Repro Specifi single Specifi repear | ification of the substar cell mutagenicity ductive toxicity fic target organ toxicity - exposure fic target organ toxicity - ted exposure (Oral) | :: | Category 2 Category 1B Category 3 Category 1 (Bl | |
| Class Germ Repro Specifi single Specifi repear | ification of the substar cell mutagenicity ductive toxicity fic target organ toxicity - exposure fic target organ toxicity - ted exposure (Oral) Label elements, includi d pictograms | :: | Category 2 Category 1B Category 3 Category 1 (Bl | |



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| Precautionary statements | | P202 Do not I and understod P260 Do not I P264 Wash s P270 Do not e P271 Use onI P280 Wear pi | | | | |
| | | and keep com doctor if you f | + P312 IF INHALED: Remove person to fresh air fortable for breathing. Call a POISON CENTER/ eel unwell. IF exposed or concerned: Get medical advice/ | | | |
| | | Storage: P405 Store locked up. | | | | |
| | | Disposal: P501 Dispose disposal plant | of contents/ container to an approved waste | | | |
| II Othe | r hazards which do r | not result in classific | ation | | | |

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. | Concentration (% w/w) |
| Ribavirin | | | 36791-04-5 | >= 50 -< 70 |
| Cellulose | | | 9004-34-6 | >= 10 -< 20 |
| Magnesium stearate | | | 557-04-0 | >= 1 -< 10 |

Section 4: First-aid measures

| General advice | : | In the case of accident or if you feel unwell, seek medical ad- vice immediately. |
|----------------|---|--|
| | | When symptoms persist or in all cases of doubt seek medical advice. |
| If inhaled | : | If inhaled, remove to fresh air. Get medical attention. |



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| | | | | | | |
| In cas | e of skin contact | : | In case of contact, immediately flush skin with soap and plent of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. | | | |
| In case of eye contact | | | Thoroughly clean shoes before reuse. If in eyes, rinse well with water. Get medical attention if irritation develops and persists. | | | |
| lf swa | llowed | : | If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. | | | |
| Most | important symptoms a | and | l effects, both acute and delayed | | | |
| Risks | | : | May cause respiratory irritation. Suspected of causing genetic defects. May damage the unborn child. Suspected of damaging fertili- ty. Causes damage to organs through prolonged or repeated exposure if swallowed. Contact with dust can cause mechanical irritation or drying of the skin. | | | |
| Protection of first-aiders | | Dust contact with the eyes can lead to mechanical irritation. 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). | | | | |
| | ation of any immediate | me | edical attention and special treatment needed | | | |
| | - | , | - | | | |
| Treatr | ment | : | Treat symptomatically and supportively. | | | |
| Treatr | - | : | - | | | |
| Treatr | ment | : | - | | | |
| Treatr ection 5: Exting | ment Fire-fighting measure | : | - | | | |
| Treatr Section 5: Exting Suitat | ment Fire-fighting measure guishing media ble extinguishing media | : | Treat symptomatically and supportively. Water spray Alcohol-resistant foam Carbon dioxide (CO2) | | | |
| Treatr Eection 5: Exting Suitat Unsui media | ment Fire-fighting measure guishing media ble extinguishing media itable extinguishing | : : : | Treat symptomatically and supportively. Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical | | | |
| Treatr Fection 5: Exting Suitat Unsui media Speci | ment Fire-fighting measure guishing media ble extinguishing media table extinguishing a ial hazards arising fror fic hazards during fire- | : : : | Treat symptomatically and supportively. Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known. he substance or mixture 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. | | | |
| Treatr Ection 5: Exting Suitat Unsui media Speci fightin | ment Fire-fighting measure guishing media ble extinguishing media table extinguishing a ial hazards arising fror fic hazards during fire- | : : : | Treat symptomatically and supportively. Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known. he substance or mixture 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. | | | |
| Treatr Fection 5: Exting Suitat Unsui media Speci fightin Hazar ucts | ment Fire-fighting measure guishing media ble extinguishing media table extinguishing a ial hazards arising from fic hazards during fire- | : : : : : : | Treat symptomatically and supportively. Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical None known. he substance or mixture 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. Carbon oxides Metal oxides | | | |





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| ods | | Use water spra | nd the surrounding environment. ay to cool unopened containers. maged containers from fire area if it is safe to d a. |
| Section 6 | : Accidental release r | neasures | |
| | precautions, protection onal precautions | : Use personal Follow safe ha | emergency procedures protective equipment. andling advice (see section 7) and personal pro- nent recommendations (see section 8). |
| | ental precautions onmental precautions | Prevent furthe Retain and dis | to the environment. r leakage or spillage if safe to do so. spose of contaminated wash water. es should be advised if significant spillages tained. |
| | and materials for con ods for cleaning up | : Surround spill over the area to Add excess lice Soak up with in Avoid dispersa with compress Dust deposits es, as these m leased into the Clean up rema bent. Local or nation posal of this m employed in th mine which rep Sections 13 ar | with absorbents and place a damp covering to minimise entry of the material into the air. quid to allow the material to enter into solution. nert absorbent material. al of dust in the air (i.e., clearing dust surfaces |

| Precautions for safe handling | ng | |
|-------------------------------|----|--|
| 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. |



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| Hygi | | | adle in accorda ctice, based o sment ep container tig ady sensitise sthma, allergi uld consult the irritants or se imize dust gen p container cl p away from l e precautiona not eat, drink e care to prev ironment. cposure to che hing systems ce. en using do no sh contaminat effective ope ineering contr ropriate dego | ghly after handling. ance with good industrial hygiene and safety in the results of the workplace exposure as- ghtly closed. d individuals, and those susceptible es, chronic or recurrent respiratory disease, eir physician regarding working with respira- nsitisers. heration and accumulation. osed when not in use. heat and sources of ignition. ry measures against static discharges. or smoke when using this product. rent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working of eat, drink or smoke. ed clothing before re-use. ration of a facility should include review of ols, proper personal protective equipment, wning and decontamination procedures, e monitoring, medical surveillance and the |
| | Conditions for safe storage, including an Conditions for safe storage : Keep in p | | | abelled containers. |
| | erials to avoid | Stor Kee Kee Stor : Do | re locked up. p tightly close p in a cool, w re in accordar | ed. ell-ventilated place. Ice with the particular national regulations. the following product types: |
| | | 000 | | зусть |

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

| 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 | PEL (long term) | 10 mg/m3 | SG OEL |
| | | TWA | 10 mg/m3 | ACGIH |



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

| Magnesium stearate | 557-04-0 | PEL (long | 10 mg/m3 | SG OEL |
|--------------------|----------|---------------|----------|--------|
| | | term) | | |
| | | TWA (Inhal- | 10 mg/m3 | ACGIH |
| | | able particu- | | |
| | | late matter) | | |
| | | TWA (Res- | 3 mg/m3 | ACGIH |
| | | pirable par- | - | |
| | | ticulate mat- | | |
| | | ter) | | |

| Appropriate engineering control 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 con- tainment devices). Minimize open handling. |
|---|------|--|
| Individual protection measu | ures | s, such as personal protective equipment (PPE) |
| 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. |
| Skin protection | : | Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis- posable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. |
| Respiratory protection | : | |
| Filter type Hand protection | : | Particulates type |
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |

Section 9: Physical and chemical properties

| Appearance | : | powder |
|-----------------|---|-------------------|
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |



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| | | | | |
| pl | Н | : | No data available | e |
| М | lelting point/freezing poi | nt : | No data available | e |
| | itial boiling point and bo ange | iling : | No data available | e |
| FI | lash point | : | No data available | e |
| E, | vaporation rate | : | Not applicable | |
| FI | lammability (solid, gas) | : | May form explos dling or other me | ive dust-air mixture during processing, han- eans. |
| FI | lammability (liquids) | : | No data available | e |
| | pper explosion limit / Up ammability limit | per : | No data available | e |
| | ower explosion limit / Lo ammability limit | wer : | No data available | e |
| V | apour pressure | : | Not applicable | |
| R | elative vapour density | : | Not applicable | |
| R | elative density | : | No data available | e |
| D | ensity | : | No data available | e |
| S | olubility(ies) Water solubility | : | No data available | e |
| | artition coefficient: n- | : | Not applicable | |
| | ctanol/water uto-ignition temperature | : | No data available | e |
| D | ecomposition temperatu | re : | No data available | e |
| Vi | iscosity Viscosity, kinematic | : | Not applicable | |
| E | xplosive properties | : | Not explosive | |
| 0 | xidizing properties | : | The substance o | or mixture is not classified as oxidizing. |
| | article characteristics article size | : | No data available | e |



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| | tivity hical stability bility of hazardous reac- | : | Stable under n May form exp dling or other | |
| Incom | itions to avoid npatible materials rdous decomposition icts | : | Can react with strong oxidizing agents. Heat, flames and sparks. Avoid dust formation. Oxidizing agents No hazardous decomposition products are known. | |
| ection 1 | 1: Toxicological inform | atic | on | |
| Inforn expos | nation on likely routes of sure | : | Inhalation Skin contact Ingestion Eye contact | |
| | e toxicity lassified based on availa | ble | information. | |
| <u>Produ</u> Acute | uct: oral toxicity | : | Acute toxicity e Method: Calcu | estimate: > 2,000 mg/kg lation method |
| Com | oonents: | | | |
| Ribay | | | | |
| | oral toxicity | : | LD50 (Rat): 4, | 116 - 5,584 mg/kg |
| | | | LD50 (Mouse): | > 10,000 mg/kg |
| | | | LD50 (Dog): >: | |
| Acute | inhalation toxicity | : | Remarks: No c | |
| | | | Remarks: No c | |
| | e dermal toxicity | • | | |
| | e toxicity (other routes of histration) | : | | 554 - 1,758 mg/kg ute: Intraperitoneal |
| | | | LD50 (Mouse): Application Ro | 1,268 mg/kg ute: Intraperitoneal |
| Cellu | lose: | | | |
| Acute | oral toxicity | : | LD50 (Rat): > \$ | 5,000 mg/kg |
| Acute | inhalation toxicity | : | LC50 (Rat): > 5 Exposure time Test atmosphe | : 4 h |



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| | | | | |
| Acute | e dermal toxicity | : LD | 950 (Rabbit): > | > 2,000 mg/kg |
| | esium stearate: | | | |
| Acute | oral toxicity | Me As icit | sessment: Th | 000 mg/kg Test Guideline 423 e substance or mixture has no acute oral to d on data from similar materials |
| Acute | e dermal toxicity | | 950 (Rabbit): > emarks: Basec | 2,000 mg/kg I on data from similar materials |
| - | corrosion/irritation | - 11 - 1 - 1 - 1 | | |
| | lassified based on ava | aliable into | rmation. | |
| | oonents: | | | |
| Riba Rema | | · No | data availabl | 6 |
| i torric | | | ay irritate skin. | |
| Magn | esium stearate: | | | |
| Speci | | | ibbit | |
| Resu Rema | | | skin irritation sed on data fr | rom similar materials |
| Serio | us eye damage/eye | irritation | | |
| Not c | assified based on ava | ailable info | rmation. | |
| <u>Com</u> | oonents: | | | |
| Ribay | /irin: | | | |
| Rema | arks | | o data availabl ay irritate eyes | |
| Magn | esium stearate: | | | |
| Speci | | | ibbit | |
| Resu Rema | | | eye irritation sed on data fr | rom similar materials |
| Poen | iratory or skin sensi | tisation | | |
| - | - | isation | | |
| - | sensitisation lassified based on ava | ailable info | rmation. | |
| - | iratory sensitisation | | | |
| Not c | assified based on ava | ailable info | rmation. | |



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|---------------|-------------------------------|--|---|
| Com | oonents: | | |
| Ribav | /irin· | | |
| Rema | | : No data av | vailable |
| Magn | esium stearate: | | |
| Test | | : Maximisat | ion Test |
| Expos | sure routes | : Skin conta | ct |
| Speci | | : Guinea pig | |
| Metho Resu | | : OECD Tes | st Guideline 406 |
| Rema | | | data from similar materials |
| Germ | cell mutagenicity | | |
| | ected of causing gene | tic defects. | |
| | oonents: | | |
| Riba | | T = 1 T = 1 | |
| Geno | toxicity in vitro | : Test Type: Result: ne | : Bacterial reverse mutation assay (AMES) gative |
| | | | : In vitro mammalian cell gene mutation test m: Rodent cell line sitive |
| | | | : Chromosomal aberration m: Human lymphocytes gative |
| Geno | toxicity in vivo | · Test Type | dominant lethal test |
| Conc | | Species: F | Rat |
| | | Result: ne | gative |
| | | Test Type Species: N Result: po | |
| | | Test Type: Species: N Result: po | |
| | cell mutagenicity - ssment | : Positive re genicity te | sult(s) from in vivo mammalian somatic cell mutas |
| Cellu | lose: | | |
| Geno | toxicity in vitro | : Test Type: Result: ne | : Bacterial reverse mutation assay (AMES) gative |
| | | | : In vitro mammalian cell gene mutation test gative |



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| Geno | toxicity in vivo | : Test Type: Ma cytogenetic as Species: Mous Application Ro | se |
| | | Result: negativ | /e |
| Magr | nesium stearate: | | |
| Geno | toxicity in vitro | Result: negativ | vitro mammalian cell gene mutation test ve ed on data from similar materials |
| | | Method: OECI Result: negativ | romosome aberration test in vitro D Test Guideline 473 /e ed on data from similar materials |
| | | Test Type: Ba Result: negativ | cterial reverse mutation assay (AMES) |
| | i nogenicity lassified based on av | ailable information. | |
| Not c <u>Com</u> Ribay | lassified based on ava ponents: virin: | | |
| Not c <u>Com</u> Riba Spec | lassified based on ava ponents: virin: ies | : Mouse | |
| Not c <u>Com</u> Riba Spec Appli | lassified based on ava ponents: virin: ies cation Route | : Mouse : Oral | |
| Not c <u>Com</u> Riba Spec Appli | lassified based on ava ponents: virin: ies cation Route sure time | : Mouse | ∕ weight |
| Not c Com Ribar Spec Appli Expo LOAE Resu | lassified based on ava ponents: virin: ies cation Route sure time EL It | : Mouse : Oral : 6 Months : 75 mg/kg body : negative | v weight |
| Not c Com Ribar Spec Appli Expo LOAE Resu | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs | : Mouse : Oral : 6 Months : 75 mg/kg body : negative : Blood, Testes | |
| Not c Com Ribar Spec Appli Expo LOAE Resu Targe | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks | : Mouse : Oral : 6 Months : 75 mg/kg body : negative : Blood, Testes : The mechanis | |
| Not c <u>Com</u> Riba Spec Applie Expo LOAE Resu Targe Rema Spec Applie | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral | |
| Not c <u>Com</u> Ribay Spec Applie Expo LOAE Resu Targe Rema Spec Applie Expo | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route sure time | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral 2 Years | m or mode of action may not be relevant in h |
| Not c <u>Com</u> Riba Spec Appli Expo LOAE Resu Targe Rema Spec Appli Expo NOAI | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route sure time EL | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral 2 Years 10 mg/kg body | m or mode of action may not be relevant in h |
| Not c <u>Com</u> Ribay Spec Applie Expo LOAE Resu Targe Rema Spec Applie Expo | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route sure time EL It | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral 2 Years 10 mg/kg body negative | m or mode of action may not be relevant in h |
| Not c <u>Com</u> Riba Spec Applie Expo LOAE Resu Targe Rema Spec Applie Expo NOAI Resu Rema | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route sure time EL It arks ies | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral 2 Years 10 mg/kg body negative The mechanis | m or mode of action may not be relevant in h |
| Not c <u>Com</u> Ribay Spec Appli Expo LOAE Resu Targe Rema Spec Appli Resu Rema Spec Appli | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route sure time EL It arks ies | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral 2 Years 10 mg/kg body negative The mechanis mans. | m or mode of action may not be relevant in h |
| Not c <u>Com</u> Ribay Spec Appli Expo LOAE Resu Targe Rema Spec Appli Resu Rema Spec Appli | lassified based on ava ponents: virin: ies cation Route sure time EL It et Organs arks ies cation Route sure time EL It arks ies cation Route sure time Sure time | Mouse Oral 6 Months 75 mg/kg body negative Blood, Testes The mechanis mans. Rat Oral 2 Years 10 mg/kg body negative The mechanis mans. | m or mode of action may not be relevant in h |



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| | ies cation Route sure time | : Rat : Ingestion : 72 weeks : negative | |
| May | oductive toxicity damage the unborn ch ponents: | ild. Suspected of dam | naging fertility. |
| Ribay | virin: ts on fertility | Fertility: LOAE Symptoms: Re Result: positiv Test Type: Fer Species: Mous Application Ro Fertility: LOAE Symptoms: Re Result: positiv Test Type: Fer Species: Rat, Application Ro Fertility: NOAE Result: Anima Test Type: Fer Species: Rat, Application Ro Fertility: NOAE | male pute: Intraperitoneal injection EL: < 20 mg/kg body weight educed fertility e rtility se, male pute: Oral EL: 35 mg/kg body weight educed fertility e rtility females pute: Oral EL: 10 mg/kg body weight I testing did not show any effects on fertility. rtility male |
| Effect | ts on foetal develop- | : Test Type: De Species: Rat, Application Ro Developmenta Symptoms: Re fetuses, Skele Result: Embry spring were de Test Type: De Species: Rabb Application Ro General Toxic | velopment female bute: Oral Il Toxicity: LOAEL: <= 1 mg/kg body weight educed body weight, Reduced number of viable tal malformations otoxic effects and adverse effects on the off- etected. velopment bit, female |



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| | | | |
| | | Species: Ham Application Ro Developmenta Symptoms: Sk / resorption ra | ster bute: Oral al Toxicity: LOAEL: 2.5 mg/kg body weight keletal and visceral variations, Total Resorptior te otoxic effects and adverse effects on the off- |
| | | Species: Rat Application Ro General Toxic Embryo-foetal | ity Maternal: NOAEL: 0.3 mg/kg body weight toxicity: LOAEL: 1 mg/kg body weight keletal malformations |
| Repro sessn | oductive toxicity - As- nent | fertility, based | e of adverse effects on sexual function and on animal experiments., Clear evidence of ad- on development, based on animal experiments |
| Cellu | lose: | | |
| Effect | s on fertility | : Test Type: On Species: Rat Application Rc Result: negativ | |
| Effect ment | s on foetal develop- | : Test Type: Fe Species: Rat Application Ro Result: negativ | |
| Magn | esium stearate: | | |
| Effect | s on fertility | reproduction/c Species: Rat Application Rc Method: OECI Result: negativ | D Test Guideline 422 |
| Effect ment | s on foetal develop- | Species: Rat Application Ro Result: negation | |



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| May o <u>Com</u> Ribay | F - single exposure cause respiratory irrita ponents: virin: ssment | | e respiratory irritation. |
| Caus <u>Com</u> | ponents: | | rolonged or repeated exposure if swallowed. |
| Targe | virin: sure routes et Organs ssment | : Ingestion : Blood : Causes da exposure. | amage to organs through prolonged or repeated |
| - | eated dose toxicity | | |
| Riba Spec LOAE Expo | virin: ies | : Monkey : 30 mg/kg : 10 d : Blood, Ga | strointestinal tract |
| Expo | ies EL cation Route sure time et Organs | : Rat : 7.6 mg/kg : Inhalation : 90 d : Blood, Lur | ngs |
| Expo | | : Dog : 5 mg/kg : Oral : 1 yr : Blood, Ga | strointestinal tract |
| Expo | | : Mouse : 20 mg/kg : Oral : 18 Months : Blood, Ca | s rdio-vascular system |
| Spec NOA | | : Rat : >= 9,000 r : Ingestion | ng/kg |



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| | | | | |
| Expo | sure time | : | 90 Days | |
| | nesium stearate: | | | |
| Spec NOA Appli Expo Rema | EL cation Route sure time | | Rat > 100 mg/kg Ingestion 90 Days Based on data fro | om similar materials |
| - | ration toxicity classified based on availa | able | information. | |
| Expe | erience with human exp | osi | ıre | |
| Com | ponents: | | | |
| Riba | | | | |
| Inhala | ation | : | Symptoms: Head Remarks: Based | ache, Dizziness on Human Evidence |
| Skin | contact | : | Remarks: May ca | use eye irritation. |
| Eye o | contact | : | Based on Human Remarks: May ca | use eye irritation. |
| Inges | stion | : | Dizziness, insomi | Evidence effects, immune system effects, anorexia, nia, Fatigue, Headache, Itching, Rash, liver Gastrointestinal disturbance |
| Section 1 | 2: Ecological informati | on | | |
| Toxic | city | | | |
| Com | ponents: | | | |
| Riba | virin: | | | |
| Toxic | to fish | : | LC50 (Oncorhync Exposure time: 96 | chus mykiss (rainbow trout)): > 119 mg/l 6 h |
| | tity to daphnia and other tic invertebrates | : | Exposure time: 48 | nagna (Water flea)): > 117 mg/l 3 h est Guideline 202 |
| Toxic plants | sity to algae/aquatic s | : | EC50 (Pseudoking mg/l Exposure time: 96 Method: OECD T | |
| | | | NOEC (Pseudoki mg/l Exposure time: 90 Method: OECD T | |



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| | | | | |
| Toxic | ity to microorganisms | : | EC50: > 1,000 m Exposure time: 3 Test Type: Resp Method: OECD 1 | 5 ĥ |
| Cellu | lose: | | | |
| Toxic | ity to fish | : | Exposure time: 4 | tipes (Japanese medaka)): > 100 mg/l 8 h on data from similar materials |
| Magn | nesium stearate: | | | |
| Toxic | ity to fish | : | Exposure time: 4 Method: DIN 384 | |
| | ity to daphnia and other tic invertebrates | : | Exposure time: 4 Test substance: Method: Directive | Water Accommodated Fraction e 67/548/EEC, Annex V, C.2. on data from similar materials |
| Toxic plants | ity to algae/aquatic s | : | mg/l Exposure time: 7 Test substance: Method: OECD 1 | Water Accommodated Fraction Fest Guideline 201 on data from similar materials |
| | | | mg/l Exposure time: 7 Test substance: Method: OECD 1 | kirchneriella subcapitata (green algae)): > 2 h Water Accommodated Fraction Fest Guideline 201 on data from similar materials |
| Toxic | ity to microorganisms | : | Exposure time: 1 Test substance: | onas putida): > 100 mg/l 6 h Water Accommodated Fraction on data from similar materials |
| Persi | stence and degradabili | ty | | |
| Com | ponents: | | | |
| Cellu Biode | l ose: egradability | : | Result: Readily b | viodegradable. |



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| | nesium stearate: egradability | | sult: Not biode narks: Based | gradable on data from similar materials |
| Bioa | ccumulative potential | | | |
| Com | ponents: | | | |
| | virin: ion coefficient: n- ol/water | : log | Pow: 0.971 | |
| | nesium stearate: | | | |
| Partit | ion coefficient: n- ol/water | : log | Pow: > 4 | |
| | lity in soil ata available | | | |
| | r adverse effects ata available | | | |

| Section | 13: Dis | posal cor | nsiderations |
|---------|---------|-----------|--------------|
|---------|---------|-----------|--------------|

| 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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |

Section 14: Transport information

International Regulations

UNRTDG

| UN number UN proper shipping name Transport hazard class(es) Subsidiary risk Packing group Labels Environmentally hazardous | Not applicable no |
|---|--|
| IATA-DGR UN/ID No. UN proper shipping name Class Subsidiary risk Packing group Labels Packing instruction (cargo | Not applicable |



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| aircra Packii ger ai | ng instruction (passen- | : Not applicable | |
| UN nu UN pr Class Subsi Packin Labels EmS (Marine | oper shipping name diary risk ng group s Code e pollutant | Not applicable | |
| | port in bulk according | | 3 |
| - | al precautions for use | r | |
| | : Regulatory informat | | pecific for the product in question |
| Workp tions: | blace Safety and Health | Act and Workplace S | afety and Health (General Provisions) Regula- g, PEL and other requirements in the |
| Enviro | onmental Protection and onmental Protection and ubstances) Regulations | Management (Hazai | |
| Fire S Regul | afety (Petroleum and Fl ations | ammable Materials) | : Not applicable |

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

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

Section 16: Other information

| Revision Date | : | 06.04.2024 |
|---|---|--|
| 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 Agen- 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.



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| Date format | : | dd.mm.yyyy |
|---|----|--|
| Full text of other abbreviation | ns | |
| ACGIH SG OEL | : | USA. ACGIH Threshold Limit Values (TLV) Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances. |
| ACGIH / TWA SG OEL / PEL (long term) | : | 8-hour, time-weighted average Permissible Exposure Level (PEL) Long Term |

AIIC - Australian Inventory of Industrial Chemicals: ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China: IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.



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