

| Version | Revision Date: | SDS Number: | Date of last issue: 06.04.2024 |
|---------|----------------|---------------|---------------------------------|
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

| 1.1 | Product identifier Trade name | : | Interferon Alfa-2b Liquid Formulation |
|-----|--|------|--|
| 1.2 | Relevant identified uses of th | ne s | substance or mixture and uses advised against |
| | Use of the Sub- stance/Mixture | | Pharmaceutical |
| | Recommended restrictions on use | : | Not applicable |
| 1.3 | Details of the supplier of the | saf | ety data sheet |
| | Company | : | MSD 120 Moorgate EC2M 6UR London, United Kingdom |
| | Telephone | : | +44 (0) 2081548000 |
| | E-mail address of person responsible for the SDS | : | EHSDATASTEWARD@msd.com |

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 2

H360FD: May damage fertility. May damage the unborn child. H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms



According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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|----------------|---------------------------|---|-----------------------------------|--|
| Signa | al word | : | Danger | |
| Haza | rd statements | : | H360FD H373 | May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. |
| Preca | autionary statements | : | Prevention P201 P280 | : Obtain special instructions before use. Wear protective gloves/ protective clothing/ eye protection/ face protection. |
| | | | Response: P308 + P31 | |
| | | | Storage: P405 | Store locked up. |

Hazardous components which must be listed on the label:

Interferon alfa-2b

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|--------------------|---|--|--------------------------|
| m-Cresol | 108-39-4 203-577-9 604-004-00-9 | Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 | >= 0.1 - < 0.25 |
| Interferon alfa-2b | 98530-12-2 | Skin Irrit. 2; H315 Repr. 1B; H360FD STOT RE 2; H373 (Blood, Bone mar- row) specific concentra- tion limit Repr. 1B; H360FD | >= 0.001 - < 0.1 |

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| | | | >= 0.001 % STOT RE 2; H373 >= 0.001 % Repr. 1B; H360FD >= 0.001 % STOT RE 2; H373 >= 0.001 % |

For explanation of abbreviations see section 16.

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 ad- vice 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. Get medical attention. |
| In case of skin contact : | In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact : | Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. |
| If swallowed : | If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. |
| 4.2 Most important symptoms and Risks : | effects, both acute and delayed May damage fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. |
| 4.3 Indication of any immediate me Treatment : | dical attention and special treatment needed 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 (CO2) Dry chemical |
|-----|---|-----|---|
| | Unsuitable extinguishing media | : | None known. |
| 5.2 | Special hazards arising from | the | e substance or mixture |
| | Specific hazards during fire- fighting | : | Exposure to combustion products may be a hazard to health. |
| | Hazardous combustion prod- ucts | : | No hazardous combustion products are known |
| 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 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. |

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 pro- tective 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. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. If spillage enters rivers or watercourses, inform the Environ- ment Agency (emergency telephone number 0800 807060). |

6.3 Methods and material for containment and cleaning up

| Methods for cleaning up | : | Soak up with inert absorbent material. |
|-------------------------|---|--|
| | | For large spills, provide dyking or other appropriate contain- |



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| | | be pumped, sto Clean up remain bent. Local or nationa posal of this ma employed in the mine which regu Sections 13 and | aterial from spreading. If dyked material can re recovered material in appropriate container. hing materials from spill with suitable absor- Il regulations may apply to releases and dis- terial, as well as those materials and items cleanup of releases. You will need to deter- ulations are applicable. I 15 of this SDS provide information regarding hational 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 | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
|---|------|---|
| 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 mist or vapours. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as- sessment Keep container tightly closed. 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 contami- nated 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, | incl | luding 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 Gases |

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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

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--------------------|------------|-------------------------------|--------------------------|----------|
| Interferon alfa-2b | 98530-12-2 | TWA | 0.2 μg/m3 (OEB 5) | Internal |
| | | Wipe limit | 2 µg/100 cm ² | Internal |

Derived No Effect Level (DNEL)

| | · · · | | | |
|----------------|-----------|-----------------|-------------------------------|----------------------|
| Substance name | End Use | Exposure routes | Potential health ef- fects | Value |
| m-Cresol | Workers | Inhalation | Long-term systemic effects | 3.5 mg/m3 |
| | Workers | Inhalation | Acute systemic ef- fects | 343 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 0.5 mg/kg bw/day |
| | Workers | Skin contact | Acute systemic ef- fects | 1.47 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 0.75 mg/m3 |
| | Consumers | Inhalation | Acute systemic ef- fects | 222 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 0.25 mg/kg bw/day |
| | Consumers | Skin contact | Acute systemic ef- fects | 0.74 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0.25 mg/kg bw/day |
| | Consumers | Ingestion | Acute systemic ef- fects | 0.74 mg/kg bw/day |

Predicted No Effect Concentration (PNEC)

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|--------------|
| m-Cresol | Fresh water | 0.1 mg/l |
| | Marine water | |
| | Intermittent use/release | |
| | Sewage treatment plant | 1.14 mg/l |
| | Fresh water sediment | 0.71 mg/kg |
| | Marine sediment | 0.071 mg/kg |
| | Soil | 0.0831 mg/kg |

SAFETY DATA SHEET According to REACH Regulation (EC) No 1907/2006, as amended by



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8.2 Exposure controls

Engineering measures

Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.

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

No open handling permitted.

Totally enclosed processes and materials transport systems are required.

Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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 | |
| Remarks Skin and body protection | : | Consider double gloving. Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing. | |
| Respiratory protection | : | No personal respiratory protective equipment normally re- quired. | |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Appearance Colour Odour Odour Threshold | : | liquid colourless No data available No data available |
|--|---|--|
| рН | : | 6.5 - 8 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling | : | No data available |
| range Flash point | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |

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|------------|---|-------------------------------------|---|--|---|
| | Upper explosion limit / Upper flammability limit | | : | No data available | 9 |
| | Lower explosion limit / Lower flammability limit | | : | No data available | 9 |
| | Vapou | rpressure | : | No data available | 9 |
| | Relativ | e vapour density | : | No data available | 9 |
| | Relativ | e density | : | No data available | 9 |
| | Density | / | : | No data available | 9 |
| | Partitio octano | ter solubility n coefficient: n- | : | No data available Not applicable No data available | |
| | Decomposition temperature | | : | No data available | 9 |
| | | cosity, kinematic | : | No data available | 9 |
| | | ive properties ng properties | : | Not explosive The substance o | r mixture is not classified as oxidizing. |
| 9.2 | Other ir | nformation | | | |
| | Flamm | ability (liquids) | : | No data available | 9 |
| | Molecu | ılar weight | : | Not applicable | |
| | Particle | e size | : | Not applicable | |

SECTION 10: Stability and reactivity

| 10.1 | Reactivity Not classified as a reactivity haza | irc | d. |
|------|--|-----|---|
| 10.2 | Chemical stability Stable under normal conditions. | | |
| 10.3 | Possibility of hazardous reaction | or | ns |
| | Hazardous reactions : | | Can react with strong oxidizing agents. |
| 10.4 | Conditions to avoid | | |
| | Conditions to avoid : | | None known. |

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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 toxicologica | 11.1 Information on toxicological effects | | | | | | | | |
|--|---|---|--|--|--|--|--|--|--|
| Information on likely routes of exposure | : | Inhalation Skin contact Ingestion Eye contact | | | | | | | |
| Acute toxicity | | | | | | | | | |
| Not classified based on availa | ble | information. | | | | | | | |
| Product: | | | | | | | | | |
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method | | | | | | | |
| Acute dermal toxicity | : | Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method | | | | | | | |
| Components: | | | | | | | | | |
| m-Cresol: | | | | | | | | | |
| Acute oral toxicity | : | LD50 (Rat): 121 mg/kg Remarks: Based on data from similar materials | | | | | | | |
| Acute inhalation toxicity | : | Assessment: Corrosive to the respiratory tract. | | | | | | | |
| Acute dermal toxicity | : | LD50 (Rabbit): 301 mg/kg Remarks: Based on data from similar materials | | | | | | | |
| Skin corrosion/irritation | | | | | | | | | |
| Not classified based on availa | ble | information. | | | | | | | |
| Components: | | | | | | | | | |
| m-Cresol: | | | | | | | | | |
| Species Result | : | Rabbit Corrosive after 3 minutes to 1 hour of exposure | | | | | | | |
| Interferon alfa-2b: | | | | | | | | | |
| | | Det | | | | | | | |

| Species | : | Rat |
|---------|---|-----------------|
| Result | : | Skin irritation |

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|----------------|---|---------|--|--|--|--|--|--|
| | Serious eye damage/eye irritation Not classified based on available information. | | | | | | | |
| Com | ponents: | | | | | | | |
| m-C | resol: | | | | | | | |
| Spec Rest | | : | Rabbit Irreversible effect | s on the eye | | | | |
| Inter | feron alfa-2b: | | | | | | | |
| Spec Rem | | : | Rabbit slight irritation | | | | | |
| Res | piratory or skin sensit | tisatio | n | | | | | |
| ••••• | sensitisation classified based on ava | ilable | information. | | | | | |
| - | piratory sensitisation classified based on ava | ilable | information. | | | | | |
| | n cell mutagenicity classified based on ava | ilable | information. | | | | | |
| Com | ponents: | | | | | | | |
| m-C | resol: | | | | | | | |
| Gen | otoxicity in vitro | : | | nosome aberration test in vitro Test Guideline 473 | | | | |
| | | | | rial reverse mutation assay (AMES) est Guideline 471 | | | | |
| Gene | otoxicity in vivo | : | cytogenetic test, Species: Mouse Application Route | genicity (in vivo mammalian bone-marrow chromosomal analysis) e: Ingestion fest Guideline 475 | | | | |
| Inter | feron alfa-2b: | | | | | | | |
| Gene | otoxicity in vitro | : | Test Type: Chror Result: negative | nosome aberration test in vitro | | | | |
| | | | Test Type: Bacte Result: negative | rial reverse mutation assay (AMES) | | | | |
| Gen | otoxicity in vivo | : | Test Type: Micro Species: Mouse Result: negative | nucleus test | | | | |

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| - | | | |

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

| m-Cresol: |
|-----------|
|-----------|

| Species Application Route Exposure time Result Remarks | : | Mouse, males Ingestion 105 weeks equivocal Based on data from similar materials |
|--|---|---|
| Species Application Route Exposure time Result Remarks | : | Mouse, female Ingestion 106 - 107 weeks positive Based on data from similar materials |
| Carcinogenicity - Assess- ment | : | Weight of evidence does not support classification as a car- cinogen |

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

| m-Cresol: Effects on fertility | : | Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative |
|-----------------------------------|---|---|
| Effects on foetal develop- | : | Test Type: Prenatal development toxicity study (teratogenicity) Species: Rat Application Route: Ingestion Result: negative |
| Interferon alfa-2b: | | |
| Effects on fertility | : | Test Type: Fertility/early embryonic development Species: Monkey Fertility: LOAEL: 3.8 μg/kg Result: menstrual irregularities Remarks: Abortion |
| Effects on foetal develop- | : | Test Type: Fertility/early embryonic development Species: Monkey Developmental Toxicity: LOAEL: 3.8 μg/kg body weight Result: Embryolethal effects |
| Reproductive toxicity - As- | : | May damage fertility. May damage the unborn child. |

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repeated

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sessment

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

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| Target Organs Assessment | Blood, Bone marrow May cause damage to organs through prolonged or exposure. |
|-----------------------------|---|
| | expectate: |

Repeated dose toxicity

Components:

m-Cresol:

| Species | : | Rat |
|-------------------|---|-------------------------|
| NOAEL | : | 150 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 13 Weeks |
| Method | : | OECD Test Guideline 408 |

Interferon alfa-2b:

| Species NOAEL Application Route Exposure time Remarks | : | Monkey 0.095 mg/kg Intramuscular 1 Months No significant adverse effects were reported |
|--|---|---|
| Species NOAEL Application Route Exposure time Remarks | | Rat 0.38 mg/kg Subcutaneous 3 Months No significant adverse effects were reported |
| Species NOAEL Application Route Exposure time Remarks | : | Mouse 0.076 mg/kg Intraperitoneal 9 d No significant adverse effects were reported |
| Species LOAEL Application Route Exposure time Target Organs Remarks | | Monkey 0.38 mg/kg Intramuscular 3 Months Blood, Bone marrow Significant toxicity observed in testing |

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| - | ration toxicity lassified based on availa | able | information. | | |
| Expe | erience with human exp | osi | ıre | | |
| <u>Com</u> | ponents: | | | | |
| Inter | feron alfa-2b: | | | | |
| Skin | contact | : | : Symptoms: The most common side effects are:, flu-like syr toms, Fever, chills, Fatigue | | |
| SECTIO | N 12: Ecological infor | rma | ition | | |
| 12.1 Toxi | city | | | | |
| <u>Com</u> | ponents: | | | | |
| m-Cr | esol: | | | | |
| Toxic | sity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l Exposure time: 96 h | | |
| | ity to daphnia and other tic invertebrates | : | EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l Exposure time: 48 h | | |
| Toxic icity) | ity to fish (Chronic tox- | : | NOEC: 1.35 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Remarks: Based on data from similar materials | | |
| | city to daphnia and other tic invertebrates (Chron- cicity) | | NOEC: 1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials | | |
| 12.2 Pers | istence and degradabil | lity | | | |
| Com | ponents: | | | | |
| m-Cr | esol: | | | | |
| Biode | egradability | : | Result: Readily biodegradable. Biodegradation: 90 % Exposure time: 28 d Method: OECD Test Guideline 301D | | |
| 12.3 Bioa | ccumulative potential | | | | |
| <u>Com</u> | ponents: | | | | |
| m-Cr | esol: | | | | |
| Б. | 1. 2 | | . | | |

| Bioaccumulation | : | Species: Leuciscus idus (Golden orfe) Bioconcentration factor (BCF): 17 - 20 |
|---------------------------|---|---|
| Partition coefficient: n- | : | log Pow: 1.96 |



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| octar | nol/water | | | | |
| | ility in soil ata available | | | | |
| 12.5 Resu | Its of PBT and vPvB | assessment | | | |
| <u>Prod</u> Asse | <u>uct:</u> ssment | to be either pe very persisten | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. | | |
| 12.6 Othe | r adverse effects | | | | |
| <u>Prod</u> Endo tial | uct: crine disrupting poten- | ered to have e | e/mixture does not contain components consid- endocrine disrupting properties for environment JK REACH Article 57(f). | | |
| SECTION | N 13: Disposal cons | iderations | | | |
| 13.1 Was t Produ | te treatment methods uct | : Dispose of in | accordance with local regulations. | | |

| Product | 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. | - |

SECTION 14: Transport information

14.1 UN number

| ADN | : | Not regulated as a dangerous good |
|------------------------------|---|-----------------------------------|
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| ΙΑΤΑ | : | Not regulated as a dangerous good |
| 14.2 UN proper shipping name | | |
| ADN | : | Not regulated as a dangerous good |
| ADR | : | Not regulated as a dangerous good |
| RID | : | Not regulated as a dangerous good |

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|----------------|--|------------------------------|---|
| IMDO | 3 | · Not regulate | d as a dangerous good |
| IATA | | 6 | d as a dangerous good |
| | Isport hazard class(e | - | |
| ADN | - | - | d as a dangerous good |
| ADR | | - | d as a dangerous good |
| RID | | 6 | d as a dangerous good |
| IMDO | 3 | 6 | d as a dangerous good |
| IATA | | - | d as a dangerous good |
| | king group | | |
| ADN | | · Not regulate | d as a dangerous good |
| ADR | | - | d as a dangerous good |
| RID | | C C | d as a dangerous good |
| IMDO | 3 | - | d as a dangerous good |
| | (Cargo) | 6 | d as a dangerous good |
| | (Passenger) | - | d as a dangerous good |
| | ronmental hazards | . Hot regulates | |
| - | egulated as a danger | ous good | |
| - | c <mark>ial precautions for ι</mark> applicable | Iser | |
| 14.7 Tran | sport in bulk accord | ing to Annex II of N | larpol and the IBC Code |
| Rem | arks | : Not applicab | le for product as supplied. |
| SECTIO | N 15: Regulatory in | formation | |
| ture | | - | s/legislation specific for the substance or mix- |
| Relevant | EU provisions transpo | sed through retained | d EU law |
| UK R | EACH List of restriction | ons (Annex 17) | : Conditions of restriction for the fol- lowing entries should be considered: Number on list 3 |
| | | | Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the condi- tions in corresponding Regulation to determine whether an entry is appli- cable to the placing on the market or not. |
| | EACH Candidate list | of substances of ver | v high · Not applicable |

UK REACH Candidate list of substances of very high : Not applicable

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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|--------------------------|---------------------------|---|--------|----|---|
| The Pe | 5 | ation ants Regulations (retai s amended for Great B | | : | Not applicable |
| Regula | tion (EC) on substance | es that deplete the ozo | ne | : | Not applicable |
| layer UK RE (Annex | | s subject to authorisati | on | : | Not applicable |
| ĠB Ex | / | ardous chemicals - Prio | or | : | Not applicable |
| | | zards Regulations 2015 Not applicable | 5 (CON | ЛA | H) |

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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. |
|--------------------------------|-----|--|
| Full text of H-Statements | | |
| H301 | : | Toxic if swallowed. |
| H311 | : | Toxic in contact with skin. |
| H314 | : | Causes severe skin burns and eye damage. |
| H315 | : | Causes skin irritation. |
| H318 | : | Causes serious eye damage. |
| H360FD | : | May damage fertility. May damage the unborn child. |
| H373 | : | May cause damage to organs through prolonged or repeated exposure. |
| H412 | : | Harmful to aquatic life with long lasting effects. |
| Full text of other abbreviatio | ons | |
| Acute Tox. | : | Acute toxicity |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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|---|---------------------------|--|---------------------------------|
| 3.4 | | 9825501-00008 | Date of first issue: 12.10.2021 |
| Eye D Repr. Skin C Skin Ir STOT | Corr. rrit. | : Serious eye d : Reproductive : Skin corrosior : Skin irritation : Specific targe | toxicity |

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 Testing 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

STOT RE 2

Sources of key data used to compile the Safety Data : 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: | | |
|--------------------------------|--------|--|
| Repr. 1B | H360FD | |

H373

Classification procedure: Calculation method Calculation method

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



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