Commission Regulation (EU) 2020/878



Omarigliptin Formulation

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

| 1.1 | Product identifier Trade name | : | Omarigliptin Formulation |
|-----|--|------|---|
| 1.2 | Relevant identified uses of th | e s | ubstance 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 | safe | ety data sheet |
| | Company | : | MSD Piercetown A86 HD21 Dunboyne, Ireland |
| | Telephone | : | 908-740-4000 |
| | 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 127 | 2/2008) |
|---|---|
| Specific target organ toxicity - repeated | H373: May cause damage to organs through pro- |

Specific target organ toxicity - repeated exposure, Category 2

longed or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

2

Hazard pictograms

| Signal word | : | Warning |
|-------------------|---|---------|
| Hazard statements | : | H373 |

May cause damage to organs through prolonged or repeated exposure.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

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| Precautio | onary statements : | Prevention: P260 Response: P314 | Do not breathe dust. Get medical advice/ attention if you feel unwell. |

Hazardous components which must be listed on the label:

Omarigliptin

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

3.2 Mixtures

Components

| Chemical name | CAS-No. | Classification | Concentration |
|---------------|---------------------|------------------|---------------|
| | EC-No. | | (% w/w) |
| | Index-No. | | |
| | Registration number | | |
| Omarigliptin | 1226781-44-7 | STOT RE 2; H373 | >= 10 - < 20 |
| | | (Stomach, Blood, | |
| | | Kidney) | |

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 |



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| | | | when the potentia | al for exposure exists (see section 8). | | |
| lf ir | haled | : | If inhaled, remove Get medical atter | e to fresh air. tion if symptoms occur. | | |
| In c | case of skin contact | : | Wash with water Get medical atter | and soap. ition if symptoms occur. | | |
| In c | case of eye contact | : | If in eyes, rinse w Get medical atter | ell with water. ation if irritation develops and persists. | | |
| If swallowed | | : | Get medical atter | NOT induce vomiting. ntion if symptoms occur. oughly with water. | | |
| 4.2 Mos | 4.2 Most important symptoms and effects, both acute and delayed | | | | | |
| Risks | | : | May cause dama exposure. | ge to organs through prolonged or repeated | | |
| | | | Contact with dust the skin. | can cause mechanical irritation or drying of | | |
| | | | Dust contact with | the eyes can lead to mechanical irritation. | | |
| 4.3 Indi | cation of any immediate | me | dical attention and | d special treatment needed | | |
| Tre | atment | : | Treat symptomati | cally and supportively. | | |
| SECTIO | ON 5: Firefighting meas | sur | es | | | |
| 5.1 Exti | nguishing media | | | | | |
| Sui | table extinguishing media | : | Water spray Alcohol-resistant Carbon dioxide (C Dry chemical | | | |
| Un: me | suitable extinguishing dia | : | None known. | | | |
| 5.2 Spe | cial hazards arising from | n the | e substance or mi | xture | | |
| | ecific hazards during fire- | : | | dust; fine dust dispersed in air in sufficient | | |

| 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 |

5.3 Advice for firefighters

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



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| for fire | fighters | Use personal pro | ptective equipment. |
| Specific extinguishing meth- ods | | cumstances and Use water spray | g measures that are appropriate to local cir- the surrounding environment. to cool unopened containers. aged containers from fire area if it is safe to do |

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. |

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

| 6.3 Methods and material for containment and cleaning up | | | | |
|--|---|--|--|--|
| Methods for cleaning up | : | Sweep up or vacuum up spillage and collect in suitable con- tainer for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfac- es, as these may form an explosive mixture if they are re- leased into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and dis- posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter- mine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. | | |

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

| Technical measures | : Static electricity may accumulate and ignite suspended dust causing an explosion. |
|-------------------------|---|
| | Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : Use only with adequate ventilation. |

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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| Handle in accordance practice, based on the sessment Minimize dust generat Keep container closed Keep away from heat Take precautionary m Take care to prevent s environment. Hygiene measures : If exposure to chemica flushing systems and | | n eyes. or repeated contact with skin. ance with good industrial hygiene and safety in the results of the workplace exposure as- neration and accumulation. osed when not in use. neat and sources of ignition. ry measures against static discharges. ent spills, waste and minimize release to the emical is likely during typical use, provide eye and safety showers close to the working g do not eat, drink or smoke. Wash contami- | | | |
| 7.2 C | Conditi | ons for safe storage, | inc | luding any incom | patibilities |
| | • | ements for storage and containers | : | Keep in properly the particular nati | labelled containers. Store in accordance with onal regulations. |
| | Advice | on common storage | : | Do not store with Strong oxidizing a | the following product types: agents |
| | • | c end use(s) c use(s) | : | No data available | |

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

dusts non-specific

Occupational Exposure Limits

4 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust) Basis: IE OEL

10 mg/m3 Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust) Basis: IE OEL

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--------------|------------------|-------------------------------|--------------------|----------|
| Cellulose | 9004-34-6 | OELV - 8 hrs (TWA) | 10 mg/m3 | IE OEL |
| Omarigliptin | 1226781- 44-7 | TWA | 10 µg/m3 | Internal |
| | | Wipe limit | 100 μg/100 cm² | Internal |



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8.2 Exposure controls

Engineering measures

Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

| Personal protective equipment | | | | |
|--|---|--|--|--|
| Eye/face protection | : | Wear the following personal protective equipment: Safety goggles | | |
| Hand protection | | Equipment should conform to I.S. EN 166 | | |
| Material | : | Chemical-resistant gloves | | |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous sub- stance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. | | |
| Skin and body protection Respiratory protection | : | Skin should be washed after contact. If adequate local exhaust ventilation is not available or expo- sure assessment demonstrates exposures outside the rec- ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143 | | |
| Filter type | : | Particulates type (P) | | |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| Physical state | : | tablet |
|---|---|--|
| Colour | : | yellow |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, han- dling or other means. |

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| | Flamma | ability (liquids) | : | No data available | |
| | Upper e | explosion limit / Upper bility limit | : | No data available | |
| | | explosion limit / Lower bility limit | : | No data available | |
| | Flash p | oint | : | No data available | 9 |
| | Auto-ig | nition temperature | : | No data available | 9 |
| | Decom | position temperature | : | No data available | 9 |
| | pН | | : | No data available | 9 |
| | Viscosi Visc | ty :osity, dynamic | : | No data available | 9 |
| | Visc | osity, kinematic | : | No data available |) |
| | Solubili Wat | ty(ies) er solubility | : | No data available | 9 |
| | Partitio octanol | n coefficient: n- /water | : | No data available | |
| | Vapour | pressure | : | No data available |) |
| | Density | , | : | No data available |) |
| | Relative | e vapour density | : | No data available |) |
| | | characteristics icle size | : | No data available | |
| 9.2 C | Other in | formation | | | |
| | Explosi | ves | : | Not explosive | |
| | Oxidizir | ng properties | : | The substance of | r mixture is not classified as oxidizing. |
| | Evapor | ation rate | : | No data available |) |
| | Molecu | lar weight | : | No data available | 9 |



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SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

| Hazardous reactions | May form explosive dust-air mixture during processing, han- dling or other means. Can react with strong oxidizing agents. |
|--------------------------|--|
| 10.4 Conditions to avoid | |
| Conditions to avoid | : Heat, flames and sparks. |

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

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

| Information on likely routes of | : | Inhalation |
|---------------------------------|---|--------------|
| exposure | | Skin contact |
| | | Ingestion |
| | | Eve contact |

Acute toxicity

Not classified based on available information.

Components:

Omarigliptin:

Acute oral toxicity : LD50 (Rat): 750 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Omarigliptin:

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.



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|-------------|--|--------------------------------------|---|
| Com | ponents: | | |
| Omai | rigliptin: | | |
| Speci | | : Bovine cornea | |
| Resu | lt | : No eye irritatior | 1 |
| Resp | iratory or skin sens | itisation | |
| Skin | sensitisation | | |
| Not c | lassified based on av | ailable information. | |
| Resp | iratory sensitisatior | 1 | |
| Not c | lassified based on av | ailable information. | |
| <u>Com</u> | ponents: | | |
| Omai | rigliptin: | | |
| Test | | | de assay (LLNA) |
| Speci | ies ssment | : Mouse | e skin sensitisation. |
| Resu | | : negative | SKIT SETSIISAUOT. |
| Not c | n cell mutagenicity lassified based on av ponents: | ailable information. | |
| Omai | rigliptin: | | |
| | toxicity in vitro | : Test Type: Bac Result: negative | terial reverse mutation assay (AMES) e |
| | | Test Type: Chr | omosome aberration test in vitro |
| | | Test system: C | hinese hamster ovary cells |
| | | Result: negative | 9 |
| Geno | toxicity in vivo | | agenicity (in vivo mammalian bone-marrow |
| | | | t, chromosomal analysis) |
| | | Species: Rat Application Rou | ite: Intraperitoneal injection |
| | | Result: negative | |
| • | | | |
| | inogenicity | - United in the second second | |
| INOT C | lassified based on av | allable information. | |

Components:

Omarigliptin:

| Species | : | Rat |
|-------------------|---|----------------------|
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| | : | 20 mg/kg body weight |
| Result | : | negative |

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|---------------|---|------|--|---|
| Ar Ex | pecies oplication Route kposure time esult | | Mouse Oral 2 Years 20 mg/kg body we negative | eight |
| | eproductive toxicity | able | information | |
| | omponents: | | information. | |
| Ο | marigliptin: | | | |
| Ef | fects on fertility | : | Species: Rat Application Route | y/early embryonic development :: Oral 100 mg/kg body weight |
| | fects on foetal develop- ent | : | Species: Rabbit Developmental To | vo-foetal development oxicity: NOAEL: > 50 mg/kg body weight s on foetal development |
| | | | Species: Rat Application Route Developmental To Result: Reduced food consumption | vo-foetal development :: Oral oxicity: LOAEL: 100 mg/kg body weight offspring weight gain, Reduced maternal n, Skeletal malformations ects were seen only at maternally toxic dos- |

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

| Omarigliptin: | |
|-----------------|--|
| Exposure routes | : Ingestion |
| Target Organs | : Stomach, Blood, Kidney |
| Assessment | : May cause damage to organs through prolonged or repeated |
| | exposure. |

Repeated dose toxicity

Components:

Omarigliptin:

| Species | : | Rat |
|---------|---|-----|
|---------|---|-----|

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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|----------------|---------------------------------|---|---|--|
| | cation Route sure time | : 100 mg/kg : Oral : 90 Days : No significant | t adverse effects were reported | |
| Expo | EL | : Rat : 10 mg/kg : 100 mg/kg : Oral : 180 Days : Blood, Kidney | / | |
| Expo | EL | : Dog : 10 mg/kg : 75 mg/kg : Oral : 40 Days : Stomach | | |
| Expo | EL | : Dog : 10 mg/kg : 75 mg/kg : Oral : 270 Days : Stomach | | |
| | EL cation Route sure time | : Monkey : 9 mg/kg : Oral : 90 Days : No significant | t adverse effects were reported | |

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Omarigliptin:

Ingestion

: Symptoms: Headache, stomach discomfort, Dizziness, Tiredness, Diarrhoea, flu-like symptoms, Back pain, Vomiting, chills



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SECTION 12: Ecological information

12.1 Toxicity

| Omarigliptin: Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
|--|---|---|
| | | EC50 (Americamysis): > 100 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| | | NOEC (Pseudokirchneriella subcapitata (green algae)): 25 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 |
| Toxicity to microorganisms | : | EC50 : > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| | | NOEC : 0.1 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic tox- icity) | : | NOEC: 11 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity) | : | NOEC: 11 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 |

12.2 Persistence and degradability

Components:

Omarigliptin:

| Biodegradability | : | Result: Not readily biodegradable. |
|------------------|---|------------------------------------|
| | | Biodegradation: 50 % |

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| | | Exposure time Method: OEC | : 11 d D Test Guideline 314 |
| 12.3 Bioad | ccumulative potentia | I | |
| Comp | oonents: | | |
| Partiti | igliptin: on coefficient: n- ol/water | : log Pow: 0.52 | 5 |
| 12.4 Mobi | lity in soil | | |
| <u>Com</u> | oonents: | | |
| Distrik | igliptin: oution among environ- al compartments | 5 | D Test Guideline 106 |
| 12.5 Resu | Its of PBT and vPvB | assessment | |
| Produ | uct: | | |
| Asses | ssment | to be either pe | e/mixture contains no components considered prsistent, bioaccumulative and toxic (PBT), or t and very bioaccumulative (vPvB) at levels of r. |
| 12.6 Endo | crine disrupting pro | perties | |
| Produ | | - | |

| Assessment | : The substance/mixture does not contain components consid- ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at |
|------------|--|
| | levels of 0.1% or higher. |

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

| 13.1 Waste treatment methods | |
|------------------------------|---|
| 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 han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. |



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SECTION 14: Transport information

14.1 UN number or ID 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 | 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 |
| | IMDG | : | Not regulated as a dangerous good |
| | ΙΑΤΑ | : | Not regulated as a dangerous good |
| 14.3 | 3 Transport hazard class(es) | | |
| | 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 |
| 14.4 Packing group | | | |
| | 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 |
| | IATA (Cargo) | : | Not regulated as a dangerous good |
| | IATA (Passenger) | : | Not regulated as a dangerous good |
| 14. | 5 Environmental hazards | | |
| | | | |

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.



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SECTION 15: Regulatory information

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

| REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) | : | Not applicable |
|--|-----|--------------------------|
| REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). | : | Not applicable |
| Regulation (EC) on substances that deplete the ozone layer | : | Not applicable |
| Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast) | : | Not applicable |
| Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals | : | Not applicable |
| REACH - List of substances subject to authorisation (Annex XIV) | : | Not applicable |
| Seveso III: Directive 2012/18/EU of the European Parliam | ent | and of the Council on th |

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

| SE | 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 | | | | | |
| | H373 : | May cause damage to organs through prolonged or repeated exposure if swallowed. | | | | |
| Full text of other abbreviations | | | | | | |
| | STOT RE : IE OEL : | Specific target organ toxicity - repeated exposure Ireland. List of Chemical Agents and Carcinogens with Occu- pational Exposure Limit Values - Code of Practice, Schedule 1 | | | | |



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and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

H373

Classification of the mixture:

STOT RE 2

Classification procedure:

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 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



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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.

IE / EN