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

1.1 Product identifier

Trade name : Fidaxomicin Solid Formulation

1.2 Relevant identified uses of the 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 safety 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)

Acute toxicity, Category 4 H302: Harmful if swallowed.

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 :

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

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Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this prod-

uct.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

Hazardous components which must be listed on the label:

Fidaxomicin

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.

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 | | | |
| Fidaxomicin | 873857-62-6 | Acute Tox. 4; H302 | >= 50 - < 70 | |
| Sodium benzoate | 532-32-1 | Eye Irrit. 2; H319 | >= 1 - < 10 | |
| | 208-534-8 | | | |
| Citric acid | 77-92-9 | Eye Irrit. 2; H319 | >= 1 - < 10 | |
| | 201-069-1 | STOT SE 3; H335 | | |
| | 607-750-00-3 | | | |
| Substances with a workplace exposure limit : | | | | |
| Cellulose | 9004-34-6 | | >= 20 - < 30 | |
| | 232-674-9 | | | |

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

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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 if symptoms occur.

In case of skin contact : Wash with water and soap.

Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting unless directed to do

> so by medical personnel. Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks Harmful if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

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 substance or mixture

fighting

Specific hazards during fire- : Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Chlorine compounds

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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. Retain and dispose of contaminated wash water.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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 surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal 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.

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Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Use only with adequate ventilation. Local/Total ventilation

Do not breathe dust. Advice on safe handling Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

> 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, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store in accordance with

the particular national regulations.

Advice on common storage Do not store with the following product types:

Strong oxidizing agents

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 |
|-------------|-----------------|-------------------------------|--------------------|----------|
| Fidaxomicin | 873857-62- 6 | TWA | 200 μg/m3 (OEB 2) | Internal |
| Cellulose | 9004-34-6 | TWA (inhalable dust) | 10 mg/m3 | GB EH40 |
| | | TWA (Respirable dust) | 4 mg/m3 | GB EH40 |

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|----------------|---------------------------|------------------------------|--|---------|
| | | STEL (inhala | ble 20 mg/m3 | GB EH40 |

Derived No Effect Level (DNEL)

| Delived No Elicot Level (DNEL) | | | | |
|--------------------------------|-----------|-----------------|------------------------------|-----------------------|
| Substance name | End Use | Exposure routes | Potential health effects | Value |
| Sodium benzoate | Workers | Inhalation | Long-term systemic effects | 3 mg/m3 |
| | Workers | Inhalation | Long-term local effects | 0.1 mg/m3 |
| | Workers | Skin contact | Long-term systemic effects | 62.5 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 1.5 mg/m3 |
| | Consumers | Inhalation | Long-term local ef- fects | 0.06 mg/m3 |
| | Consumers | Skin contact | Long-term systemic effects | 31.25 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 16.6 mg/kg bw/day |

Predicted No Effect Concentration (PNEC)

| Substance name | Environmental Compartment | Value |
|-----------------|---------------------------|----------------------------------|
| Citric acid | Fresh water | 0.44 mg/l |
| | Marine water | 0.044 mg/l |
| | Sewage treatment plant | 1000 mg/l |
| | Fresh water sediment | 34.6 mg/kg dry weight (d.w.) |
| | Marine sediment | 3.46 mg/kg dry weight (d.w.) |
| | Soil | 33.1 mg/kg dry weight (d.w.) |
| Sodium citrate | Fresh water | 0.44 mg/l |
| | Marine water | 0.044 mg/l |
| | Sewage treatment plant | 1000 mg/l |
| | Fresh water sediment | 34.6 mg/kg dry weight (d.w.) |
| | Marine water | 3.46 mg/kg dry weight (d.w.) |
| | Soil | 31.1 mg/kg dry weight (d.w.) |
| Sodium benzoate | Fresh water | 0.13 mg/l |
| | Freshwater - intermittent | 0.305 mg/l |
| | Marine water | 0.013 mg/l |
| | Sewage treatment plant | 10 mg/l |
| | Fresh water sediment | 1.76 mg/kg dry weight (d.w.) |
| | Marine sediment | 0.176 mg/kg dry weight (d.w.) |
| | Soil | 0.276 mg/kg dry weight (d.w.) |

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Oral (Secondary Poisoning) 300 mg/kg food

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.

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

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

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : 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 BS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : granules

Colour : White to light yellow Odour : No data available Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

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Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : No data available

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.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 875.04 mg/kg

Method: Calculation method

Components:

Fidaxomicin:

Acute oral toxicity : LD50 (Rat): > 1,000 mg/kg

LD50 (Dog): > 120 mg/kg

Acute toxicity (other routes of:

administration)

LD50 (Rat): 200 mg/kg

Application Route: Intravenous

Sodium benzoate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Assessment: The substance or mixture has no acute oral tox-

icity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Remarks: Based on data from similar materials

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Sodium benzoate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Remarks : Based on data from similar materials

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Germ cell mutagenicity

Not classified based on available information.

Components:

Fidaxomicin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster ovary cells

Result: positive

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Intravenous

Result: negative

Test Type: comet assay

Species: Rat Result: negative

Sodium benzoate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

Citric acid:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

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Cellulose:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Sodium benzoate:

Species : Rat
Application Route : Ingestion
Exposure time : 24 month(s)
Result : negative

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Fidaxomicin:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Intravenous injection Fertility: NOAEL: 6.3 mg/kg body weight

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 12.6 mg/kg body weight Remarks: No significant adverse effects were reported

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Intravenous injection

Developmental Toxicity: NOAEL: 7 mg/kg body weight

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Remarks: No significant adverse effects were reported

Sodium benzoate:

Effects on fertility : Test Type: Four-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Citric acid:

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

Not classified based on available information.

Components:

Citric acid:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Fidaxomicin:

Species : Rat
NOAEL : 90 mg/kg
Application Route : Oral

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Exposure time 28 D

Remarks No significant adverse effects were reported

Species Rat

NOAEL 62.5 mg/kg Intravenous Application Route 14 D

Exposure time

Species Dog

NOAEL 9,600 mg/kg

Application Route Oral Exposure time 3 M Vomiting **Symptoms**

Remarks No significant adverse effects were reported

Species Monkey 90 mg/kg **NOAEL** Oral Application Route Exposure time 28 D

Remarks No significant adverse effects were reported

Species Juvenile rat NOAEL 200 mg/kg Application Route Oral Exposure time 28 D

Remarks No significant adverse effects were reported

Sodium benzoate:

Species Rat

NOAEL 1,000 mg/kg Application Route : Ingestion Exposure time 24 Months

Citric acid:

Species Rat

NOAEL : 4,000 mg/kg LOAEL : 8,000 mg/kg : Application Route Ingestion Exposure time 10 Days

Cellulose:

Species Rat

NOAEL >= 9,000 mg/kg: : Application Route Ingestion Exposure time 90 Days

Aspiration toxicity

Not classified based on available information.

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Experience with human exposure

Components:

Fidaxomicin:

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, constipation

SECTION 12: Ecological information

12.1 Toxicity

Components:

Fidaxomicin:

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae (cyanobacterium)): > 18.4 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

NOEC (Anabaena flos-aquae (cyanobacterium)): 5.8 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms : EC50 : > 50 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 5.9 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 8.91 mg/l Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 19.6 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Sodium benzoate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 484 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 96 h

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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)): 32

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,535 mg/l

Exposure time: 24 h

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Sodium benzoate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 75 % Exposure time: 28 d

Citric acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Cellulose:

Biodegradability : Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Fidaxomicin:

Partition coefficient: n-

: log Pow: 4.4

octanol/water

Sodium benzoate:

Partition coefficient: n- : log Pow: 1.88

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octanol/water

Citric acid:

Partition coefficient: n-

octanol/water

log Pow: -1.72

12.4 Mobility in soil

Components:

Fidaxomicin:

Distribution among environmental compartments

: log Koc: 0.80

12.5 Results of PBT and vPvB assessment

Product:

Assessment : 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 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

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.

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

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



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IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : 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 : Not regulated as a dangerous good

14.3 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
IATA : 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 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

Brit-

Not applicable

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



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ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

aver

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not 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.

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

H302 : Harmful if swallowed.

H319 : Causes serious eye irritation. H335 : May cause respiratory irritation.

Full text of other abbreviations

Acute Tox. : Acute toxicity Eye Irrit. : Eye irritation

STOT SE : Specific target organ toxicity - single exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute 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

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



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tional 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

Sources of key data used to compile the Safety Data

eChem Portal search results and European Chemicals Agen-

Sheet

cy, http://echa.europa.eu/

Classification of the mixture:

Classification procedure:

Acute Tox. 4

H302

Calculation method

Internal technical data, data from raw material SDSs, OECD

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.

GB / EN