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

1.1 Product identifier

Trade name : Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or

breathing difficulties if inhaled.

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

Specific target organ toxicity - repeated H372: Causes damage to organs through pro-

exposure, Category 1 longed 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)

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Hazard pictograms

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breath-

ing difficulties if inhaled.

H372 Causes damage to organs through prolonged or

repeated exposure.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P362 + P364 Take off contaminated clothing and wash it

before reuse.

Hazardous components which must be listed on the label:

Dihydrostreptomycin sulphate

Benzylpenicillin

### 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.	Classification	Concentration (% w/w)
	Registration number		
Dihydrostreptomycin sulphate	5490-27-7	STOT RE 1; H372	>= 20 - < 30
	226-823-7	(ear, Kidney, inner	
		ear)	
Benzylpenicillin	61-33-6	Resp. Sens. 1A;	>= 20 - < 25
	200-506-3	H334	
		Skin Sens. 1B;	

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		H317 Aquatic Acute 1; H400 Aquatic Chronic 3; H412 M-Factor (Acute aquatic toxicity): 1	
Sodium hydroxymethanesulphinate	149-44-0	Muta. 2; H341	>= 0.1 - < 1
	205-739-4	Repr. 2; H361d	

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.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

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 effects, both acute and delayed

Risks : May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Causes damage to organs through prolonged or repeated

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exposure.

Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

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

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

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).

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#### 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 Environment 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 containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate 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.

Wash skin thoroughly after handling.

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

sessment

Keep container tightly closed.

Already sensitised individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory irritants or sensitisers.

Do not eat, drink or smoke when using this product.

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

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flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated 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. 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

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
Dihydrostreptomy- cin sulphate	5490-27-7	TWA	0.4 mg/m3 (OEB 2)	
	Further information: OTO			
		Wipe limit	Not required	
Benzylpenicillin	61-33-6	TWA	600 µg/m3 (OEB 2)	Internal
	Further information: RSEN, DSEN			
		Wipe limit	100 μg/100 cm2	Internal

#### **Derived No Effect Level (DNEL)**

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium hy- droxymethanesulphi- nate	Workers	Inhalation	Long-term systemic effects	21 mg/m3
	Workers	Inhalation	Acute systemic effects	140 mg/m3
	Workers	Skin contact	Long-term systemic	6 mg/kg

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		effects	bw/day
Workers	Skin contact	Acute systemic ef-	40 mg/kg
		fects	bw/day
Workers	Skin contact	Acute local effects	0.225 mg/cm2

#### **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Benzylpenicillin	Water	0.014 mg/l
Sodium hydroxymethanesulphi-	Fresh water	0.056 mg/l
nate		
	Marine water	0.006 mg/l
	Freshwater - intermittent	0.056 mg/l
	Sewage treatment plant	1 mg/l
	Fresh water sediment	0.046 mg/kg dry weight (d.w.)
	Marine sediment	0.005 mg/kg dry weight (d.w.)
	Soil	0.011 mg/kg dry weight (d.w.)

#### 8.2 Exposure controls

#### **Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

#### 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 : suspension Colour : off-white, white

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Odour No data available Odour Threshold No data available

рΗ 5.0 - 7.2

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

No data available Flash point

Evaporation rate No data available

Flammability (solid, gas) Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

No data available Vapour pressure

Relative vapour density No data available

Relative density No data available

Density 1.14 - 1.18 g/cm<sup>3</sup>

Solubility(ies)

Water solubility No data available Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature No data available

No data available Decomposition temperature

Viscosity

No data available Viscosity, kinematic

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

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Particle Size Distribution :  $D50 = 15 \mu m$ 

 $D90 = 30 \mu m$ 

### **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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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 toxicological effects

Information on likely routes of : Inhalation exposure Skin contact

Ingestion
Eve contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Dihydrostreptomycin sulphate:

Acute oral toxicity : LD50 (Rat): 9,000 - 25,000 mg/kg

LD50 Oral (Mouse): 30,000 mg/kg

Benzylpenicillin:

Acute oral toxicity : LD50 (Rat): 8,000 mg/kg

LD50 (Mouse): > 5,000 mg/kg

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Acute toxicity (other routes of :

administration)

LD50 (Mouse): 3,500 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 329 mg/kg Application Route: Intravenous

#### Sodium hydroxymethanesulphinate:

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

Method: OECD Test Guideline 423

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

icity

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

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

## Sodium hydroxymethanesulphinate:

Species : Rat

Result : No skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

#### Sodium hydroxymethanesulphinate:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

#### Respiratory or skin sensitisation

### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### **Components:**

#### Benzylpenicillin:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Dermal

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Species : Mouse

Result : Weak sensitizer

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig Result : positive

Remarks : Based on data from similar materials

Result : Strong sensitizer

Remarks : Based on human experience.

#### Sodium hydroxymethanesulphinate:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

#### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

### Dihydrostreptomycin sulphate:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Test system: Human lymphocytes

Result: negative

Benzylpenicillin:

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

#### Sodium hydroxymethanesulphinate:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: positive

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Method: OECD Test Guideline 474

Result: positive

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Germ cell mutagenicity- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

## Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Dihydrostreptomycin sulphate:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 5 mg/kg body weight

Result : negative

### Reproductive toxicity

Not classified based on available information.

#### **Components:**

#### Dihydrostreptomycin sulphate:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Oral

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-foetal development

Species: Guinea pig

Application Route: Intramuscular

General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body

weight

Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: Maternal toxicity observed., Embryotoxic effects and

adverse effects on the offspring were detected.

## Benzylpenicillin:

Effects on fertility : Test Type: Fertility

Species: Mouse

Result: No effects on fertility

Test Type: Fertility Species: Rat

Result: No effects on fertility

Test Type: Fertility Species: Rabbit

Result: No effects on fertility

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

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Result: No effects on foetal development

Test Type: Development

Species: Rat

Result: No effects on foetal development

Test Type: Development

Species: Rabbit

Result: No effects on foetal development

#### Sodium hydroxymethanesulphinate:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

#### **Components:**

#### Dihydrostreptomycin sulphate:

Assessment : Causes damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

### **Components:**

### Dihydrostreptomycin sulphate:

Species : Guinea pig
LOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 90 d
Target Organs : ear

Symptoms : hearing loss

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Species : Cat

LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 60 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

Species : Cat

LOAEL : 300 mg/kg
Application Route : Oral
Exposure time : 21 d
Target Organs : ear

Symptoms : ataxia, hearing loss, Reduced body weight

## Sodium hydroxymethanesulphinate:

Species : Rat

NOAEL : 600 mg/kg Application Route : Ingestion Exposure time : 13 Weeks

Method : OECD Test Guideline 408

#### **Aspiration toxicity**

Not classified based on available information.

#### Experience with human exposure

#### **Components:**

#### Dihydrostreptomycin sulphate:

General Information : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting,

Headache, hypotension

Benzylpenicillin:

Inhalation : Symptoms: Allergic reactions, Abdominal pain, bron-

chospasm, skin rash

### **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **Components:**

#### Benzylpenicillin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 3.6 mg/l

Exposure time: 48 hrs

Method: OECD Test Guideline 202

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Toxicity to algae/aquatic

plants

: EC50 (Raphidocelis subcapitata (freshwater green alga)): >

100 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50

mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

EC50 (blue-green algae): 0.74 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

NOEC (blue-green algae): 0.14 mg/l

Exposure time: 72 hrs

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

. '

Toxicity to microorganisms : EC50 : > 500 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 5 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

: ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC : 10 mg/l

Exposure time: 4 h

Toxicity to fish (Chronic tox- : NOEC: 13.5 mg/l

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icity) Exposure time: 35 d

Species: Danio rerio (zebra fish) Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

EC10: 8 mg/l Exposure time: 21 d

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

#### 12.2 Persistence and degradability

#### Components:

Benzylpenicillin:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 70.10 % Exposure time: 28 d

Method: OECD Test Guideline 301B

#### Sodium hydroxymethanesulphinate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 77 % Exposure time: 28 d

Method: OECD Test Guideline 301B

#### 12.3 Bioaccumulative potential

#### **Components:**

#### Sodium hydroxymethanesulphinate:

Partition coefficient: n-

octanol/water

: log Pow: < 0.3

### 12.4 Mobility in soil

No data available

#### 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).

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### **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
IATA : 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
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

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



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**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) 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 conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone

layer UK REACH List of substances subject to authorisation

(Annex XIV)

GB Export and import of hazardous chemicals - Prior

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

#### 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

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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**

H317 : May cause an allergic skin reaction.

H334 : May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

H341 : Suspected of causing genetic defects.
H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H412 : Harmful to aquatic life with long lasting effects.

#### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Muta.: Germ cell mutagenicityRepr.: Reproductive toxicityResp. Sens.: Respiratory sensitisationSkin Sens.: Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure

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 La-

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



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boratory 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**

Sources of key data used to compile the Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

#### Classification of the mixture:

#### Classification procedure:

Resp. Sens. 1 H334 Calculation method Skin Sens. 1 H317 Calculation method STOT RE 1 H372 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 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