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# Desionated in Pseudoephedrine Formulation

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

1.1 Product identifier

Trade name Desloratadine / Pseudoephedrine 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 Organon & Co.

**Shotton Lane** 

NE23 3JU Cramlington NU - Great Britain

Telephone +44 1 670 59 32 05

E-mail address of person

responsible for the SDS

: EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

### **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)

Specific target organ toxicity - repeated

exposure, Category 1

H372: Causes damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

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

Hazard pictograms

Signal word Danger

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Hazard statements : H372 Causes damage to organs through prolonged or

repeated exposure.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

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

uct.

Response:

P314 Get medical advice/ attention if you feel unwell.

Hazardous components which must be listed on the label:

Bis[[S-(R\*,R\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate

#### 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)	
D:=UC (D* D*)1 (0 hl	Registration number	A	00 00	
Bis[[S-(R*,R*)]-(β-hydroxy-α-methylphenethyl)methylammonium] sulphate	7460-12-0 231-243-2	Acute Tox. 4; H302 Acute Tox. 4; H332 STOT RE 1; H372 (Central nervous system) STOT RE 1; H372 (Cardio-vascular system)	>= 20 - < 30	
Disodium EDTA, dihydrate	6381-92-6	Acute Tox. 4; H332 STOT RE 2; H373 (Respiratory Tract)	>= 1 - < 10	
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10	
Desloratadine	100643-71-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Repr. 2; H361fd Aquatic Chronic 2; H411	>= 0.25 - < 1	
Substances with a workplace exposure limit :				
Cellulose	9004-34-6 232-674-9		>= 30 - < 50	
Starch, oxidized	65996-62-5		>= 1 - < 10	

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Silicon dioxide	7631-86-9	>= 1 - < 10
1	231-545-4	

For explanation of abbreviations see section 16.

#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention.

Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

# 4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes damage to organs through prolonged or repeated

exposure.

#### 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)

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Dry chemical

Unsuitable extinguishing

media

: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

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

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.

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.

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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 breathe dust, fume, gas, mist, vapours or spray.

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-

sessment

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

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

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	Control parameters	Basis

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	1			
		of exposure)		
Cellulose	9004-34-6	TWA (inhalable	10 mg/m3	GB EH40
		dust)	_	
		TWA (Respirable	4 mg/m3	GB EH40
		dust)	_	
		STEL (inhalable	20 mg/m3	GB EH40
		dust)		
Bis[[S-(R*,R*)]-(β-	7460-12-0	TWA	50 μg/m3 (OEB 3)	Internal
hydroxy-α-				
methylphenethyl)m				
ethylammonium]				
sulphate				
		Wipe limit	500 μg/100 cm <sup>2</sup>	Internal
Starch, oxidized	65996-62-5	TWA (inhalable	10 mg/m3	GB EH40
		dust)	_	
	Further information: Capable of causing occupational asthma.			
		STEL (inhalable	30 mg/m3	GB EH40
		dust)	_	
	Further information: Capable of causing occupational asthma.			
Silicon dioxide	7631-86-9	TWA (inhalable	6 mg/m3	GB EH40
		dust)	(Silica)	
		TWA (Respirable	2.4 mg/m3	GB EH40
		dust)	(Silica)	
Desloratadine	100643-71-	TWA	20 μg/m3 (OEB 3)	Internal
	8		,	
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Silicon dioxide	Workers	Inhalation	Long-term systemic effects	4 mg/m3
Disodium EDTA, di- hydrate	Workers	Inhalation	Long-term systemic effects	1.5 mg/m3
	Workers	Inhalation	Acute systemic effects	3 mg/m3
	Workers	Inhalation	Long-term local ef- fects	1.5 mg/m3
	Workers	Inhalation	Acute local effects	3 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	0.6 mg/m3
	Consumers	Inhalation	Acute local effects	1.2 mg/m3
	Consumers	Ingestion	Long-term systemic effects	25 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Disodium EDTA, dihydrate	Fresh water	2.5 mg/l
	Marine water	0.25 mg/l
	Sewage treatment plant	50 mg/l
	Soil	1.1 mg/kg dry

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		weight (d.w.)
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.)

#### 8.2 Exposure controls

#### **Engineering measures**

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

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : 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 : solid
Colour : white, blue
Odour : No data available
Odour Threshold : No data available

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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) : Not classified as a flammability hazard

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility
Partition coefficient: n-

octanol/water

No data available

Not applicable

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

Particle size : No data available

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

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#### 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 : Skin contact

exposure Ingestion

Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

#### **Components:**

#### Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Acute oral toxicity : LD50 (Rat): 660 mg/kg

LD50 (Mouse): 371 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 2.37 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Remarks: Information given is based on data obtained from

similar substances.

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Disodium EDTA, dihydrate:

Acute oral toxicity : LD50 (Rat): 2,800 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): > 1 mg/l

Exposure time: 6 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 412

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

**Desloratadine:** 

Acute oral toxicity : LD50 (Rat): > 549 mg/kg

LD50 (Mouse): 353 mg/kg

LD50 (Monkey): > 250 mg/kg

Symptoms: Vomiting

Remarks: No mortality observed at this dose.

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

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

Silicon dioxide:

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

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

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#### **Components:**

Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Species : Rabbit

Result : No skin irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

**Desloratadine:** 

Species : Rabbit

Result : No skin irritation

Silicon dioxide:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Species : Rabbit

Result : No eye irritation

Disodium EDTA, dihydrate:

Species : Rabbit

Result : No eye irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

**Desloratadine:** 

Species : Rabbit

Remarks : Severe eye irritation

Silicon dioxide:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

### Bis[[S-(R\*,R\*)]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Remarks : No data available

#### **Disodium EDTA, dihydrate:**

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

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

#### **Desloratadine:**

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig Result : negative

### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

#### Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

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

Result: negative

Remarks: Information given is based on data obtained from

similar substances.

Test Type: Chromosomal aberration

Result: negative

Remarks: Information given is based on data obtained from

similar substances.

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat

Application Route: Oral

Result: negative

Remarks: Based on data from similar materials

#### Disodium EDTA, dihydrate:

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

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Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Remarks: Based on data from similar materials

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion Method: OECD Test Guideline 474

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

**Desloratadine:** 

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

Result: negative

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral

Result: negative

Cellulose:

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

Result: negative

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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

Silicon dioxide:

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

Method: OECD Test Guideline 471

Result: negative

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

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

#### Carcinogenicity

Not classified based on available information.

#### **Components:**

# $Bis[[S-(R^*,R^*)]-(\beta-hydroxy-\alpha-methylphenethyl)methylammonium] \ sulphate:$

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

Remarks : Based on data from similar materials

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

Remarks : Based on data from similar materials

# Disodium EDTA, dihydrate:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Remarks : Based on data from similar materials

### **Desloratadine:**

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : negative

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Species : Rat Application Route : Oral

LOAEL : 10 mg/kg body weight

Result : equivocal Target Organs : Liver

Remarks : Based on data from similar materials

The mechanism or mode of action may not be relevant in hu-

mans.

Cellulose:

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

Silicon dioxide:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

#### Reproductive toxicity

Not classified based on available information.

#### **Components:**

#### Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: LOAEL: 80 mg/kg body weight Symptoms: male reproductive effects

Effects on foetal development Test Type: Embryo-foetal development Species: Rabbit

Application Route: Oral

Result: No teratogenic effects

Test Type: Embryo-foetal development

Application Route: Oral

Developmental Toxicity: LOAEL: 27 mg/kg body weight Result: No embryotoxic effects have been observed in animal

tests., No teratogenic effects

Remarks: Maternal toxicity observed.

Disodium EDTA, dihydrate:

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

Species: Rat

Application Route: Ingestion

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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

**Desloratadine:** 

Effects on fertility : Test Type: Fertility

Species: Rat, male Application Route: Oral

Fertility: LOAEL: 12 mg/kg body weight

Symptoms: Reduced fertility

Result: positive

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Fertility Species: Rat, female

Fertility: NOAEL: 3 mg/kg body weight Symptoms: No effects on fertility

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 30 mg/kg body weight

Result: No teratogenic effects

Test Type: Embryo-foetal development

Species: Rat

**Application Route: Oral** 

Developmental Toxicity: LOAEL: 9 mg/kg body weight Symptoms: Preimplantation loss, Reduced body weight

Result: Specific developmental abnormalities

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Two-generation study

Species: Rat

**Application Route: Oral** 

Developmental Toxicity: LOAEL: 18 mg/kg body weight

Result: No adverse effects

Reproductive toxicity - As- : Some evidence of adverse effects on sexual function and

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



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sessment fertility, based on animal experiments., Some evidence of

adverse effects on development, based on animal experi-

ments.

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

Silicon dioxide:

ment

Effects on foetal develop-

Test Type: Embryo-foetal 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

Causes damage to organs through prolonged or repeated exposure.

Components:

Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Exposure routes : Ingestion, Inhalation

Target Organs : Central nervous system, Cardio-vascular system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Disodium EDTA, dihydrate:

Exposure routes : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : May cause damage to organs through prolonged or repeated

exposure.

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#### Repeated dose toxicity

#### **Components:**

### Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Remarks : No data available

#### Disodium EDTA, dihydrate:

Species: RatNOAEL: 500 mg/kgApplication Route: IngestionExposure time: 13 Weeks

Species : Rat LOAEL : 0.03 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 4 Weeks

Method : OECD Test Guideline 412

#### Citric acid:

Species : Rat

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

#### **Desloratadine:**

Species : Rat
LOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Kidney

Remarks : Significant toxicity observed in testing

The mechanism or mode of action may not be relevant in hu-

mans.

Species: MonkeyNOAEL: 6 mg/kgLOAEL: 12 mg/kgApplication Route: OralExposure time: 3 Months

Target Organs : Central nervous system
Symptoms : Gastrointestinal disturbance

Species : Monkey
NOAEL : 40 mg/kg
Application Route : Oral
Exposure time : 17 Months

Remarks : No significant adverse effects were reported

Species : Monkey

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NOAEL : 6 mg/kg
Application Route : Oral
Exposure time : 3 Months

Symptoms : Gastrointestinal disturbance, Fatigue

Cellulose:

Species : Rat

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

Starch, oxidized:

Species : Rat

NOAEL : 22,500 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Silicon dioxide:

Species : Rat NOAEL : 1.3 mg/m3

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

Components:

 $Bis[[S-(R^*,R^*)]-(\beta-hydroxy-\alpha-methylphenethyl)methylammonium]$  sulphate:

Inhalation : Remarks: May cause irritation of respiratory tract.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: central nervous system effects, tachycardia, Palpi-

tation

**Desloratadine:** 

Inhalation : Remarks: May cause respiratory tract irritation.

Eye contact : Symptoms: Eye irritation

Ingestion : Symptoms: dry mouth, muscle pain, Fatigue, Drowsiness,

sore throat, painful menstration

**SECTION 12: Ecological information** 

12.1 Toxicity

**Components:** 

Disodium EDTA, dihydrate:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l

Exposure time: 96 h

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Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 140 mg/l

Exposure time: 48 h Method: DIN 38412

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms EC10 (activated sludge): > 500 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC: 25 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

Citric acid:

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

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,535 mg/l

Exposure time: 24 h

**Desloratadine:** 

Toxicity to fish LC50 (Lepomis macrochirus (Bluegill sunfish)): 9.2 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 9.6 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

Method: FDA 4.08

: EC50 (Pseudokirchneriella subcapitata (green algae)): 1.6

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.36

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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Toxicity to microorganisms : EC50 (Natural microorganism): 53.7 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC (Natural microorganism): 12 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.12 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: 0.48 mg/l Exposure time: 21 d

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

Cellulose:

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

Exposure time: 48 h

Remarks: Based on data from similar materials

Silicon dioxide:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

Exposure time: 24 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): > 10,000

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

#### 12.2 Persistence and degradability

#### **Components:**

Disodium EDTA, dihydrate:

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Biodegradability Result: Not readily biodegradable.

> Biodegradation: 2 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Citric acid:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

**Desloratadine:** 

Biodegradability Result: Not readily biodegradable.

Biodegradation: 67.4 % Exposure time: 28 d

Method: OECD Test Guideline 314

Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d Method: FDA 3.11

: Hydrolysis: < 10 % at 50 °C(5 d) Stability in water

Method: FDA 3.09

Cellulose:

Biodegradability Result: Readily biodegradable.

12.3 Bioaccumulative potential

Components:

Bis[[S-( $R^*$ , $R^*$ )]-( $\beta$ -hydroxy- $\alpha$ -methylphenethyl)methylammonium] sulphate:

Partition coefficient: n-: log Pow: 0.89

octanol/water

Disodium EDTA, dihydrate:

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): < 500

Remarks: Based on data from similar materials

Partition coefficient: n-

octanol/water

: log Pow: -4.3

Citric acid:

Partition coefficient: n-

log Pow: -1.72

log Pow: 1.24

octanol/water

Desloratadine:

Partition coefficient: n-

octanol/water Method: OECD Test Guideline 107

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12.4 Mobility in soil

**Components:** 

**Desloratadine:** 

Distribution among environ- : log Koc: 3.00

mental compartments

Method: OECD Test Guideline 106

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.

Empty containers should be taken to an approved waste han-Contaminated packaging

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

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



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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
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 : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained

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

alli) Damilatian (EO) N

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

UK REACH List of substances subject to authorisation

: Not applicable

Not applicable

: Not applicable

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(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

#### Other regulations:

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

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H302 : Harmful if swallowed.

H318 : Causes serious eye damage. H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H335 : May cause respiratory irritation.

H361fd : Suspected of damaging fertility. Suspected of damaging the

unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure if inhaled.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H373 : May cause damage to organs through prolonged or repeated

exposure.

H411 : Toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Dam. : Serious eye damage

Eye Irrit. : Eye irritation

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Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure 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 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

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

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

Classification of the mixture: Classification procedure:

STOT RE 1 H372 Calculation method

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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