

according to Regulation UK SI 2019/758 and UK SI 2020/1577 as amended

Revision Date 25-Sep-2023 Revision Number 6

# SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1. Product identifier

Product Description: Oxytetracycline dihydrate

Cat No. : 123840000; 123840100; 123841000

Molecular Formula C22 H24 N2 O9 . 2 H2 O

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

Recommended Use Laboratory chemicals.
Uses advised against No Information available

#### 1.3. Details of the supplier of the safety data sheet

Company

UK entity/business name

Fisher Scientific UK Bishop Meadow Road,

Loughborough, Leicestershire LE11 5RG, United Kingdom

**EU entity/business name** Thermo Fisher Scientific

Janssen Pharmaceuticalaan 3a, 2440 Geel, Belgium

**E-mail address** begel.sdsdesk@thermofisher.com

1.4. Emergency telephone number

For information **US** call: 001-800-227-6701 / **Europe** call: +32 14 57 52 11 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99 **CHEMTREC** Tel. No. **US**:001-800-424-9300 / **Europe**:001-703-527-3887

## **SECTION 2: HAZARDS IDENTIFICATION**

#### 2.1. Classification of the substance or mixture

#### CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567

#### **Physical hazards**

Based on available data, the classification criteria are not met

#### **Health hazards**

Serious Eye Damage/Eye Irritation Category 2 (H319)
Reproductive Toxicity Category 2 (H361d)

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#### **Environmental hazards**

Based on available data, the classification criteria are not met

Full text of Hazard Statements: see section 16

2.2. Label elements



Signal Word

Warning

#### **Hazard Statements**

H319 - Causes serious eye irritation

H361d - Suspected of damaging the unborn child

### **Precautionary Statements**

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P308 + P313 - IF exposed or concerned: Get medical advice/attention

#### 2.3. Other hazards

No information available

This product does not contain any known or suspected endocrine disruptors

## **SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

#### 3.1. Substances

Component	CAS No	EC No	Weight %	CLP Classification - According to GB-CLP Regulations UK SI 2019/720 and UK SI 2020/1567
<ol><li>Naphthacenecarboxamide,</li></ol>	6153-64-6		95	Eye Irrit. 2 (H319)
4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-oct				Repr. 2 (H361d)
ahydro-3,5,6,10,12,12a				
-hexahydroxy-6-methyl-1,11-dioxo-,				
dihydrate,				
[4S-(4.alpha.,4a.alpha.,5.alpha.,5a.alpha.,6				
.beta.,12a.alpha.)]				

Full text of Hazard Statements: see section 16

## **SECTION 4: FIRST AID MEASURES**

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#### 4.1. Description of first aid measures

**General Advice** If symptoms persist, call a physician.

Eye Contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get

medical attention.

**Skin Contact** Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

**Ingestion** Clean mouth with water and drink afterwards plenty of water. Get medical attention if

symptoms occur.

**Inhalation** Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Self-Protection of the First Aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination.

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

None reasonably foreseeable.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

## **SECTION 5: FIREFIGHTING MEASURES**

#### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Water spray. Carbon dioxide (CO2). Dry chemical. Chemical foam.

## Extinguishing media which must not be used for safety reasons

No information available.

#### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### **Hazardous Combustion Products**

Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>).

#### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

#### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

### 6.2. Environmental precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

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#### 6.3. Methods and material for containment and cleaning up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

#### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## **SECTION 7: HANDLING AND STORAGE**

#### 7.1. Precautions for safe handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

#### 7.2. Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place. Keep container tightly closed. Protect from direct sunlight. Store contents under argon.

Class 11

Technical Rules for Hazardous Substances (TRGS) 510 Storage Class (LGK) (Germany)

#### 7.3. Specific end use(s)

Use in laboratories

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

#### 8.1. Control parameters

#### **Exposure limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

## **Biological limit values**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

#### Derived No Effect Level (DNEL) / Derived Minimum Effect Level (DMEL)

No information available

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

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No information available.

#### 8.2. Exposure controls

#### **Engineering Measures**

Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

Personal protective equipment

**Eye Protection** Goggles (European standard - EN 166)

Hand Protection Protective gloves

Glove material Nitrile rubber Neoprene Natural rubber	Breakthrough time See manufacturers recommendations	Glove thickness	EU standard EN 374	Glove comments (minimum requirement)
PVC				

Skin and body protection

Wear appropriate protective gloves and clothing to prevent skin exposure.

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatability, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

**Respiratory Protection** When workers are facing concentrations above the exposure limit they must use

appropriate certified respirators.

To protect the wearer, respiratory protective equipment must be the correct fit and be used

and maintained properly

Large scale/emergency use Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits

are exceeded or if irritation or other symptoms are experienced **Recommended Filter type:** Particulates filter conforming to EN 143

Small scale/Laboratory use Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

limits are exceeded or if irritation or other symptoms are experienced.

**Recommended half mask:-** Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted

**Environmental exposure controls** No information available.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

## 9.1. Information on basic physical and chemical properties

Physical State Powder Solid

Appearance Yellow Odorless

Odor Threshold No data available

Melting Point/Range 181 - 182 °C / 357.8 - 359.6 °F

Softening Point No data available
Boiling Point/Range No information available

Flammability (liquid) Not applicable Solid

Flammability (solid,gas) No information available

Explosion Limits No data available

Flash Point No information available Method - No information available

Autoignition Temperature Not applicable

Decomposition Temperature No data available

**pH** 4.5-7.5

Viscosity Not applicable Solid

Water Solubility slightly soluble

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

Vapor Pressure

Density / Specific Gravity

Bulk Density

No data available
No data available
No data available
No data available

Vapor Density Not applicable Solid

Particle characteristics No data available

9.2. Other information

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Molecular Formula C22 H24 N2 O9 . 2 H2 O

Molecular Weight 496.46

Evaporation Rate Not applicable - Solid

## **SECTION 10: STABILITY AND REACTIVITY**

10.1. Reactivity

None known, based on information available

10.2. Chemical stability

Air sensitive. Light sensitive.

10.3. Possibility of hazardous reactions

Hazardous Polymerization Hazardous polymerization does not occur.

Hazardous Reactions None under normal processing.

10.4. Conditions to avoid

Exposure to air. Exposure to light. Incompatible products. Exposure to moist air or water.

10.5. Incompatible materials

Bases. Strong oxidizing agents.

10.6. Hazardous decomposition products

Nitrogen oxides (NOx). Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

### **SECTION 11: TOXICOLOGICAL INFORMATION**

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

**Product Information**No acute toxicity information is available for this product

(a) acute toxicity;

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No data available Oral **Dermal** No data available Inhalation No data available

No data available (b) skin corrosion/irritation;

(c) serious eye damage/irritation; Category 2

(d) respiratory or skin sensitization;

Respiratory No data available No data available Skin

No data available (e) germ cell mutagenicity;

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; Category 2

Teratogenicity Teratogenic effects have occurred in experimental animals.

No data available (h) STOT-single exposure;

(i) STOT-repeated exposure; No data available

None known. **Target Organs** 

(j) aspiration hazard; Not applicable

Solid

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects,both acute and No information available.

delayed

11.2. Information on other hazards

**Endocrine Disrupting Properties** Assess endocrine disrupting properties for human health. This product does not contain any

known or suspected endocrine disruptors.

## **SECTION 12: ECOLOGICAL INFORMATION**

12.1. Toxicity

Do not empty into drains. **Ecotoxicity effects** 

12.2. Persistence and degradability

Soluble in water, Persistence is unlikely, based on information available. **Persistence** 

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12.3. Bioaccumulative potential Bioaccumulation is unlikely

**12.4. Mobility in soil**The product is water soluble, and may spread in water systems. Will likely be mobile in the

environment due to its water solubility. Highly mobile in soils

12.5. Results of PBT and vPvB

assessment

No data available for assessment.

12.6. Endocrine disrupting

properties

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

12.7. Other adverse effects

Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected substance This product does not contain any known or suspected substance

## **SECTION 13: DISPOSAL CONSIDERATIONS**

13.1. Waste treatment methods

Waste from Residues/Unused

**Products** 

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

Contaminated Packaging Dispose of this container to hazardous or special waste collection point.

European Waste Catalogue (EWC) According to the European Waste Catalog, Waste Codes are not product specific, but

application specific.

Other Information Waste codes should be assigned by the user based on the application for which the product

was used. Do not empty into drains.

## **SECTION 14: TRANSPORT INFORMATION**

IMDG/IMO Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

ADR Not regulated

14.1. UN number

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

IATA Not regulated

14.1. UN number

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14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards No hazards identified

14.6. Special precautions for user No special precautions required.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable, packaged goods

## **SECTION 15: REGULATORY INFORMATION**

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

#### **International Inventories**

Europe (EINECS/ELINCS/NLP), China (IECSC), Taiwan (TCSI), Korea (KECL), Japan (ENCS), Japan (ISHL), Canada (DSL/NDSL), Australia (AICS), New Zealand (NZIoC), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	EINECS	ELINCS	NLP	IECSC	TCSI	KECL	ENCS	ISHL
2-Naphthacenecarboxamide,	6153-64-6	-	-	-	-	X	-	ı	
4-(dimethylamino)-1,4,4a,5,5a,6,1									
1,12a-octahydro-3,5,6,10,12,12a									
-hexahydroxy-6-methyl-1,11-dioxo									
-, dihydrate,									
[4S-(4.alpha.,4a.alpha.,5.alpha.,5a									
.alpha.,6.beta.,12a.alpha.)]									

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	AICS	NZIoC	PICCS
2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,1 1,12a-octahydro-3,5,6,10,12,12a -hexahydroxy-6-methyl-1,11-dioxo -, dihydrate, [4S-(4.alpha.,4a.alpha.,5.alpha.,5a .alpha.,6.beta.,12a.alpha.)]		-		-	-	-	Х	

Legend: X - Listed '-' - Not Listed KECL - NIER number or KE number (http://ncis.nier.go.kr/en/main.do)

## Authorisation/Restrictions according to EU REACH

Component	CAS No	REACH (1907/2006) - Annex XIV - Substances Subject to Authorization	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous Substances	REACH Regulation (EC 1907/2006) article 59 - Candidate List of Substances of Very High Concern (SVHC)
2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11, 12a-octahydro-3,5,6,10,12,12a -hexahydroxy-6-methyl-1,11-dioxo-, dihydrate, [4S-(4.alpha.,4a.alpha.,5.alpha.,5a. alpha.,6.beta.,12a.alpha.)]	6153-64-6	-	-	-

Not applicable

#### Seveso III Directive (2012/18/EC)

Component	CAS No	Seveso III Directive (2012/18/EC) -	Seveso III Directive (2012/18/EC) -		
-		Qualifying Quantities for Major Accident	<b>Qualifying Quantities for Safety Report</b>		
		Notification	Requirements		

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2-Naphthacenecarboxamide 6153-64-6 Not applicable Not applicable 4-(dimethylamino)-1,4,4a,5,5 a,6,11,12a-octahydro-3,5,6,1 0,12,12a -hexahydroxy-6-methyl-1,11dioxo-, dihydrate, [4S-(4.alpha.,4a.alpha.,5.alp ha.,5a.alpha.,6.beta.,12a.alp ha.)]

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of dangerous chemicals

Not applicable

Contains component(s) that meet a 'definition' of per & poly fluoroalkyl substance (PFAS)?

Not applicable

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work .

Take note of Directive 94/33/EC on the protection of young people at work

Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work

#### **National Regulations**

UK - Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment

**WGK Classification** 

Water endangering class = 3 (self classification)

#### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

#### **SECTION 16: OTHER INFORMATION**

#### Full text of H-Statements referred to under sections 2 and 3

H319 - Causes serious eye irritation

H361d - Suspected of damaging the unborn child

#### Legend

**CAS** - Chemical Abstracts Service

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

Substances/EU List of Notified Chemical Substances

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances IECSC - Chinese Inventory of Existing Chemical Substances **KECL** - Korean Existing and Evaluated Chemical Substances

**ENCS** - Japanese Existing and New Chemical Substances AICS - Australian Inventory of Chemical Substances NZIoC - New Zealand Inventory of Chemicals

WEL - Workplace Exposure Limit

TWA - Time Weighted Average

**ACGIH** - American Conference of Governmental Industrial Hygienists

IARC - International Agency for Research on Cancer

**DNEL** - Derived No Effect Level

Predicted No Effect Concentration (PNEC)

RPE - Respiratory Protective Equipment

LD50 - Lethal Dose 50%

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LC50 - Lethal Concentration 50%

NOEC - No Observed Effect Concentration

PBT - Persistent, Bioaccumulative, Toxic

PBT - VPVB - very Persistent, very Bioaccumulative

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

ICAO/IATA - International Civil Aviation Organization/International Air Transport Association

MARPOL - International Convention for the Prevention of Pollution from

Ships **ATE** - Acute Toxicity Estimate

VOC - (Volatile Organic Compound)

## Key literature references and sources for data

https://echa.europa.eu/information-on-chemicals

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

#### **Training Advice**

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

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**Revision Summary** SDS sections updated.

# This safety data sheet complies with Regulation UK SI 2019/758 and UK SI 2020/1577 as amended.

#### **Disclaimer**

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

## **End of Safety Data Sheet**