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



# Florfenicol Solid Formulation

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

1.1 Product identifier

Trade name : Florfenicol Solid 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** 

Kilsheelan

Clonmel Tipperary, IE

Telephone 353-51-601000

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)

Reproductive toxicity, Category 2 H361fd: Suspected of damaging fertility. Suspected

of damaging the unborn child.

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

exposure, Category 1

longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-

H410: Very toxic to aquatic life with long lasting effects.

egory 1

## 2.2 Label elements

## Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms

\*

Signal word : Danger

Hazard statements : H361fd Suspected of damaging fertility. Suspected of

damaging the unborn child.

H372 Causes damage to organs through prolonged or

repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

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

attention.

P391 Collect spillage.

## Hazardous components which must be listed on the label:

Florfenicol

## 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

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

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

## **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

Components

Componente			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		

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



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	Registration number		
Florfenicol	73231-34-2	Repr. 2; H361fd STOT RE 1; H372 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10	>= 50 - < 70
	l l	1	

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 : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

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 : Suspected of damaging fertility. Suspected of damaging the

unborn child.

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



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Causes damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

# **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

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

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

## 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).

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



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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. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

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

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

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

### **SECTION 7: Handling and storage**

# 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.

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

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

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

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

environment.

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-

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



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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 locked up. 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**

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Florfenicol	73231-34-2	TWA	100 μg/m3 (OEB 2)	Internal

## 8.2 Exposure controls

#### **Engineering measures**

Use feasible engineering controls to minimize exposure to compound.

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

## Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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



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> 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 I.S. EN 143

Particulates type (P) Filter type

# **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Physical state powder

Colour white

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

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

dling or other means.

Flammability (liquids) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point Not applicable

Auto-ignition temperature No data available

Decomposition temperature No data available

No data available pН

Viscosity

Viscosity, kinematic Not applicable

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



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Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

# **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

Not classified as a reactivity hazard.

## 10.2 Chemical stability

Stable under normal conditions.

# 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

## 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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



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## **SECTION 11: Toxicological information**

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

Information on likely routes of : Inhalation

exposure Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Florfenicol:

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

LD50 (Mouse): > 2,000 mg/kg

LD50 (Dog): > 1,280 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.28 mg/l

Exposure time: 4 h

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of :

administration)

LD50 (Rat): 1,913 - 2,253 mg/kg

Application Route: Intraperitoneal

LD50 (Mouse): 100 mg/kg Application Route: Intravenous

## Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Florfenicol:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Florfenicol:

Species : Rabbit

Result : Mild 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:**

#### Florfenicol:

Test Type : Maximisation Test
Species : Guinea pig
Result : negative

## Germ cell mutagenicity

Not classified based on available information.

## **Components:**

#### Florfenicol:

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

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro) Test system: rat hepatocytes

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Result: negative

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

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow Application Route: Oral Result: negative

## Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Florfenicol:

Species : Rat

Application Route : oral (gavage)
Exposure time : 2 Years
Result : negative

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



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Target Organs : Liver, Testes

Species : Mouse
Application Route : oral (gavage)
Exposure time : 2 Years
Result : negative
Target Organs : Testes, Blood

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:** 

Florfenicol:

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

Species: Rat

Application Route: Oral

Fertility: LOAEL: 12 mg/kg body weight

Result: decreased pup survival, reduced lactation

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

General Toxicity Maternal: NOAEL: 4 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight

Result: No teratogenic effects, Fetotoxicity

Remarks: The effects were seen only at maternally toxic dos-

es.

Test Type: Embryo-foetal development

Species: Mouse

Application Route: oral (gavage)

General Toxicity Maternal: NOAEL: 120 mg/kg body weight Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight

Result: Fetotoxicity

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on sexual function and

fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experi-

ments.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Components:

Florfenicol:

Target Organs : Liver, Brain, Testis, Spinal cord, Blood, gallbladder

Assessment : Causes damage to organs through prolonged or repeated

exposure.

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



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## Repeated dose toxicity

## **Components:**

#### Florfenicol:

Species : Dog NOAEL : 3 mg/kg Exposure time : 13 Weeks

Target Organs : Liver, Testis, Brain, Spinal cord

Species : Mouse
NOAEL : 200 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis

Species : Rat
NOAEL : 30 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis

Species: DogNOAEL: 3 mg/kgLOAEL: 12 mg/kgExposure time: 52 Weeks

Target Organs : Liver, gallbladder

Species : Rat
NOAEL : 1 mg/kg
LOAEL : 3 mg/kg
Exposure time : 52 Weeks
Target Organs : Testis

## **Aspiration toxicity**

Not classified based on available information.

## 11.2 Information on other hazards

## **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

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## **SECTION 12: Ecological information**

## 12.1 Toxicity

### **Components:**

Florfenicol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l

Exposure time: 96 h Method: FDA 4.11

LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l

Exposure time: 96 h Method: FDA 4.11

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 330 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9

mg/l

Exposure time: 14 d Method: FDA 4.01

NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9

mg/l

Exposure time: 14 d Method: FDA 4.01

IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l

Exposure time: 72 h Method: ISO 10253

NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l

Exposure time: 72 h Method: ISO 10253

EC50 (Lemna gibba (gibbous duckweed)): 0.76 mg/l

Exposure time: 7 d

Method: OECD Test Guideline 221

NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l

Exposure time: 7 d

Method: OECD Test Guideline 221

EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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



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EC50 (Anabaena flos-aquae): 0.066 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.051 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

: 10

Toxicity to fish (Chronic tox-

icity)

NOEC: 5.5 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: 1.5 mg/l Exposure time: 21 d

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

M-Factor (Chronic aquatic : 10

toxicity)

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

**Components:** 

Florfenicol:

Partition coefficient: n- : log Pow: 0.373

octanol/water pH: 7

12.4 Mobility in soil

Components:

Florfenicol:

Distribution among environ: Koc: 52

mental compartments Method: FDA 3.08

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.

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



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## 12.6 Endocrine disrupting properties

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

#### 12.7 Other adverse effects

No data available

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

## **SECTION 14: Transport information**

### 14.1 UN number or ID number

ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

# 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Florfenicol)

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Florfenicol)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Florfenicol)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

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



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(Florfenicol)

IATA : Environmentally hazardous substance, solid, n.o.s.

(Florfenicol)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

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



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**ADN** 

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

**RID** 

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

## 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## 14.7 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

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

layer

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia-

ment and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

E1

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

Quantity 1

ENVIRONMENTAL 100 t 200 t

Not applicable

Not applicable

Quantity 2

**HAZARDS** 

#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations,

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



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 SDS Number:
 Date of last issue: 06.04.2024

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 28.09.2024
 444133-00021
 Date of first issue: 07.01.2016

where applicable.

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## **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** 

H361fd : Suspected of damaging fertility. Suspected of damaging the

unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H400 : Very toxic to aquatic life.

H410 : Very toxic 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

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China;

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



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IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD compile the Safety Data

eChem Portal search results and European Chemicals Agen-Sheet cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Repr. 2	H361fd	Calculation method
STOT RE 1	H372	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	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.

IE / EN