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



## Dexamethasone (0.28%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 5.0
 14.04.2025
 5498612-00015
 Date of first issue: 10.03.2020

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

1.1 Product identifier

Trade name : Dexamethasone (0.28%) Formulation

Other means of identification : Dexadreson (A001421)

**DEXADRESON INJECTION (52298)** 

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

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Skin sensitisation, Category 1 Long-term (chronic) aquatic hazard, CatH317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting ef-

f€

fects.

#### 2.2 Label elements

egory 3

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

Hazard pictograms

Signal word : Warning

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

Hazard statements : H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P272 Contaminated work clothing should not be allowed

out of the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves.

Response:

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

advice/ attention.

P362 + P364 Take off contaminated clothing and wash it

before reuse.

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

Benzyl alcohol

#### 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.

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

#### 3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Benzyl alcohol	100-51-6 202-859-9 603-057-00-5	Acute Tox. 4; H302 Eye Irrit. 2; H319 Skin Sens. 1B; H317  Acute toxicity estimate  Acute oral toxicity: 1,200 mg/kg	>= 1 - < 10
dexamethasone	50-02-2 200-003-9	Repr. 1B; H360D STOT RE 2; H373	>= 0.25 - < 0.3

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



## Dexamethasone (0.28%) Formulation

Version	Revision Date:	SDS Number: 5498612-00015	Date of last issue: 19.02.2025
5.0	14.04.2025		Date of first issue: 10.03.2020
			(Adrenal gland, Immune system, thymus gland) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 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 : Flush eyes with water as a precaution.

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 : May cause an allergic skin reaction.

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

Treatment : Treat symptomatically and supportively.

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

### **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

: Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

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.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

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 : Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate contain-

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

ment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

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

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

### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Avoid breathing mist or vapours.

Do not swallow.

Avoid contact with eyes.

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

sessment

Keep container tightly closed.

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. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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

Requirements for storage areas and containers

: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

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



## Dexamethasone (0.28%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 5.0
 14.04.2025
 5498612-00015
 Date of first issue: 10.03.2020

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
		of exposure)		
dexamethasone	50-02-2	TWA	10 μg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal

## Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Benzyl alcohol	Workers	Inhalation	Long-term systemic effects	22 mg/m3
	Workers	Inhalation	Acute systemic effects	110 mg/m3
	Workers	Skin contact	Long-term systemic effects	8 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	40 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	5.4 mg/m3
	Consumers	Inhalation	Acute systemic effects	27 mg/m3
	Consumers	Skin contact	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	20 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	4 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	20 mg/kg bw/day

## Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Benzyl alcohol	Fresh water	1 mg/l
	Marine water	0.1 mg/l
	Intermittent use/release	2.3 mg/l
	Sewage treatment plant	39 mg/l
	Fresh water sediment	5.27 mg/kg
	Marine sediment	0.527 mg/kg
	Soil	0.456 mg/kg

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



## Dexamethasone (0.28%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 5.0
 14.04.2025
 5498612-00015
 Date of first issue: 10.03.2020

### 8.2 Exposure controls

#### **Engineering measures**

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

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

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, dis-

posable 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.

Filter should conform to I.S. EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

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

#### 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : clear

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) : Not applicable

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



## Dexamethasone (0.28%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 5.0
 14.04.2025
 5498612-00015
 Date of first issue: 10.03.2020

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 : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

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 : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5498612-00015 Date of first issue: 10.03.2020

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

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### **SECTION 11: Toxicological information**

## 11.1 Information on 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.

### **Product:**

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

Method: Calculation method

### **Components:**

## Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

#### dexamethasone:

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

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

LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of : LD50 (Rat): 14 mg/kg

administration) Application Route: Subcutaneous

### Skin corrosion/irritation

Not classified based on available information.

### **Components:**

### Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

#### dexamethasone:

Species : Rabbit

Result : Mild skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

## Benzyl alcohol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

#### dexamethasone:

Species : Rabbit

Result : Mild eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

## Respiratory sensitisation

Not classified based on available information.

## **Components:**

### Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact
Species : Humans
Result : positive

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



## Dexamethasone (0.28%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 5.0
 14.04.2025
 5498612-00015
 Date of first issue: 10.03.2020

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Benzyl alcohol:

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

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

dexamethasone:

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

Result: negative

Test Type: in vitro assay

Test system: mouse lymphoma cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Benzyl alcohol:

Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Benzyl alcohol:

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

Species: Rat

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

**Application Route: Ingestion** 

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

dexamethasone:

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: NOAEL: 0.025 mg/kg body weight

Result: Specific developmental abnormalities

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: >= 0.062 mg/kg body weight

Result: Specific developmental abnormalities

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: >= 0.02 mg/kg body weight Result: Skeletal and visceral variations, Fetal growth retarda-

tion

Reproductive toxicity - As-

sessment

May damage the unborn child.

### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

Not classified based on available information.

## Components:

#### dexamethasone:

Exposure routes : Oral

Target Organs : Adrenal gland, Immune system, thymus gland

Assessment : May cause damage to organs through prolonged or repeated

exposure.

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

### Repeated dose toxicity

### **Components:**

### Benzyl alcohol:

Species Rat NOAEL 1.072 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 28 Days

Method : OECD Test Guideline 412

#### dexamethasone:

Species Rat

NOAEL 0.0015 mg/kg

Application Route Oral Exposure time 7 d Target Organs Liver

Remarks Significant toxicity observed in testing

Species Rat

LOAEL 0.003 mg/kg

Application Route : Oral Exposure time : 90 d

Target Organs Blood, Adrenal gland, thymus gland Significant toxicity observed in testing Remarks

Species Dog

LOAEL : 0.125 mg/kg Application Route Oral Exposure time 6 Weeks : Adrenal gland Target Organs

Remarks Significant toxicity observed in testing

Species Rat LOAEL 0.4 mg/kg Application Route Oral Exposure time 3 Months

Target Organs Immune system

Remarks Significant toxicity observed in testing

Species Dog LÖAEL 8 mg/kg Application Route : Oral Exposure time : 3 Months Target Organs : Immune system

Remarks : Significant toxicity observed in testing

### **Aspiration toxicity**

Not classified based on available information.

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5498612-00015 Date of first issue: 10.03.2020

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

Not classified based on available information.

**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.

#### **Experience with human exposure**

### **Components:**

#### dexamethasone:

Ingestion : Target Organs: Immune system

Target Organs: Adrenal gland

Target Organs: Bone

Symptoms: muscle weakness

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

## 12.1 Toxicity

## **Components:**

### Benzyl alcohol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l

Exposure time: 96 h

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 230 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): 770

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 51 mg/l Exposure time: 21 d

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

### dexamethasone:

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 56 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2

mg/I

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 1,000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Toxicity to fish (Chronic tox-

icity)

NOEC: 0.033 mg/l

Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

M-Factor (Chronic aquatic

toxicity)

: 1

### 12.2 Persistence and degradability

### **Components:**

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 - 96 %

Exposure time: 14 d

dexamethasone:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 3.54 d

Method: OECD Test Guideline 314

### 12.3 Bioaccumulative potential

## **Components:**

Benzyl alcohol:

Partition coefficient: n- : log Pow: 1.05

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5498612-00015 Date of first issue: 10.03.2020

octanol/water

dexamethasone:

Partition coefficient: n-

octanol/water

: log Pow: 1.83

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 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.

Not regulated as a dangerous good

If not otherwise specified: Dispose of as unused product.

**SECTION 14: Transport information** 

14.1 UN number or ID number

RID

ADN : Not regulated as a dangerous good

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

16/20

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



## Dexamethasone (0.28%) Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 5.0
 14.04.2025
 5498612-00015
 Date of first issue: 10.03.2020

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
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 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) : Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 75: If you intend to

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



## Dexamethasone (0.28%) Formulation

Version Revision Date: SDS Number: Date of last issue: 19.02.2025 5.0 14.04.2025 5498612-00015 Date of first issue: 10.03.2020

use this product as tattoo ink, please

contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not. Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EU) No 2024/590 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

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

Not applicable

#### Other regulations:

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** 

H302 : Harmful if swallowed.

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H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. May damage the unborn child. H360D

H373 May cause damage to organs through prolonged or repeated

exposure if swallowed.

H410 Very 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 Irrit. Eve irritation

Reproductive toxicity Repr. Skin Sens. Skin sensitisation

STOT RE Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### **Further information**

compile the Safety Data Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

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 5.0
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Classification of the mixture: Classification procedure:

Skin Sens. 1 H317 Calculation method Aquatic Chronic 3 H412 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.

IE / EN