

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

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

#### 1.1 Product identifier

Trade name : Gentamicin / Betamethasone Cream Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

+1-215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 1B

Specific target organ toxicity - repeated exposure, Category 1

Long-term (chronic) aquatic hazard, Category 1

H360D: May damage the unborn child.

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

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

#### 2.2 Label elements

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

Hazard pictograms :



Signal word : Danger

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Commission Regulation (EU) 2020/878



ORGANON

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Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
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Hazard statements : H360D May damage the unborn child.  
H372 Causes damage to organs through prolonged or re-  
peated exposure.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P264 Wash skin thoroughly after handling.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protec-  
tion/ 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:

betamethasone

EUH208 Contains 4-Chloro-3-methylphenol. May produce an allergic reaction.

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumula-  
tive 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 regu-  
lation (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)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 2,5 - < 10
4-Chloro-3-methylphenol	59-50-7 200-431-6	Acute Tox. 4; H302 Skin Corr. 1C;	>= 0,1 - < 0,25

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



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Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
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	604-014-00-3	H314 Eye Dam. 1; H318 Skin Sens. 1B; H317 STOT SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 3; H412  M-Factor (Acute aquatic toxicity): 1  Acute toxicity esti- mate  Acute oral toxicity: 600 mg/kg	
Gentamicin	1403-66-3 215-765-8	Repr. 1A; H360D STOT RE 1; H372 (Kidney, inner ear) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 1	$\geq 0,1 - < 0,25$
betamethasone	378-44-9 206-825-4	Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Ad- renal gland) Aquatic Chronic 1; H410  M-Factor (Chronic aquatic toxicity): 1.000  specific concentra- tion limit STOT RE 1; H372 $\geq 0,01$ % Repr. 1B; H360D	$\geq 0,025 - < 0,1$

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



## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0	Revision Date: 06.04.2024	SDS Number: 1833021-00015	Date of last issue: 30.09.2023 Date of first issue: 13.07.2017
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		>= 0,01 %	
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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 advice 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 : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

May produce an allergic reaction.

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

- Treatment : Treat symptomatically and supportively.

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Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

Specific hazards during fire-fighting : Vapours may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon 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 methods : Use extinguishing measures that are appropriate to local circumstances 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.

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### 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 protective 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.  
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 container for disposal.  
Local or national regulations may apply to releases and dis-

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Commission Regulation (EU) 2020/878



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

posal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine 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.<br>Do not breathe dust, fume, gas, mist, vapours or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Do not eat, drink or smoke when using this product.<br>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 contaminated clothing before re-use.<br>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. Keep tightly closed. Store in accordance with the particular national regulations.                      |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

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ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Petrolatum	8009-03-8	TWA (Vapour)	50 mg/m <sup>3</sup>	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m <sup>3</sup>	FOR-2011-12-06-1358
Paraffin oil	8012-95-1	TWA (Vapour)	50 mg/m <sup>3</sup>	FOR-2011-12-06-1358
		TWA (Mist and particles)	1 mg/m <sup>3</sup>	FOR-2011-12-06-1358
4-Chloro-3-methylphenol	59-50-7	TWA	200 µg/m <sup>3</sup> (OEB 2)	Internal
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal
		Further information: OTO		
betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal
		Further information: Skin		
		Wipe limit	10 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
Alcohols, C16-18	Workers	Inhalation	Long-term systemic effects	237,76 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	237,76 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	6,52 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	6,52 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	200 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	400 mg/kg bw/day
	Workers	Skin contact	Long-term local effects	1,124 mg/cm <sup>2</sup>
	Workers	Skin contact	Acute local effects	1,124 mg/cm <sup>2</sup>
Consumers	Consumers	Inhalation	Long-term systemic effects	118,88 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute systemic effects	118,9 mg/m <sup>3</sup>

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



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## Gentamicin / Betamethasone Cream Formulation

Version  
9.0

Revision Date:  
06.04.2024

SDS Number:  
1833021-00015

Date of last issue: 30.09.2023

Date of first issue: 13.07.2017

	Consumers	Inhalation	Long-term local effects	0,652 mg/m <sup>3</sup>
	Consumers	Inhalation	Acute local effects	0,652 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	100 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	200 mg/kg bw/day
	Consumers	Skin contact	Long-term local effects	0,562 mg/cm <sup>2</sup>
	Consumers	Skin contact	Acute local effects	0,562 mg/cm <sup>2</sup>
	Consumers	Ingestion	Long-term systemic effects	75 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	75 mg/kg bw/day
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m <sup>3</sup>
	Workers	Inhalation	Short-term exposure	5 mg/m <sup>3</sup>
	Workers	Inhalation	Long-term local effects	5 mg/m <sup>3</sup>
	Workers	Inhalation	Acute local effects	5 mg/m <sup>3</sup>
4-Chloro-3-methylphenol	Workers	Inhalation	Long-term systemic effects	6,289 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	3,567 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	1,551 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	1,783 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0,892 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9,33 mg/kg food
Alcohols, C16-18	Fresh water	0,13 mg/l
	Marine water	0,12 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	13,61 mg/kg dry weight (d.w.)
	Marine sediment	1,361 mg/kg dry weight (d.w.)
	Soil	100 mg/kg dry weight (d.w.)
4-Chloro-3-methylphenol	Oral (Secondary Poisoning)	86,7 mg/kg food
	Fresh water	0,015 mg/l
	Intermittent use/release	0,015 mg/l
	Marine water	0,002 mg/l
	Sewage treatment plant	2,286 mg/l
	Fresh water sediment	13,981 mg/kg dry weight (d.w.)
Marine sediment	13,981 mg/kg dry	



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Commission Regulation (EU) 2020/878



## Gentamicin / Betamethasone Cream Formulation

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

	Soil	weight (d.w.) 6,399 mg/kg dry weight (d.w.)
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### 8.2 Exposure controls

#### Engineering measures

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

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

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

#### 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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS 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	:	cream
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

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Initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

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 : > 93,3 °C

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 : No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Relative vapour density : No data available

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 : No data available

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

Molecular weight : No data available

### 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 : Vapours may form explosive mixture with air.  
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 exposure : Skin contact  
Ingestion  
Eye contact

##### Acute toxicity

Not classified based on available information.

##### Components:

###### Paraffin oil:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

###### 4-Chloro-3-methylphenol:

Acute oral toxicity : LD50 (Mouse): 600 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 2,871 mg/l  
Exposure time: 4 h

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rat): > 5.000 mg/kg

### Gentamicin:

Acute oral toxicity : LD50 (Rat): 8.000 - 10.000 mg/kg  
LD50 (Mouse): 10.000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 0,2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.  
Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous  
LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular  
LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

### betamethasone:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
LD50 (Mouse): > 4.500 mg/kg  
Acute inhalation toxicity : LC50 (Rat): 0,4 mg/l  
Exposure time: 4 h

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Paraffin oil:

Species : Rabbit  
Result : No skin irritation

#### 4-Chloro-3-methylphenol:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : Corrosive after 1 to 4 hours of exposure

### Gentamicin:

Species : Rabbit  
Result : Mild skin irritation

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

---

### betamethasone:

Species : Rabbit  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Paraffin oil:

Species : Rabbit  
Result : No eye irritation

#### 4-Chloro-3-methylphenol:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : Irreversible effects on the eye

### Gentamicin:

Species : Rabbit  
Result : Mild eye irritation

### betamethasone:

Species : Rabbit  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### 4-Chloro-3-methylphenol:

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

Assessment : Probability or evidence of low to moderate skin sensitisation rate in humans

### Gentamicin:

Remarks : No data available

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

### betamethasone:

Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	Weak sensitizer

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### 4-Chloro-3-methylphenol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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#### Gentamicin:

Genotoxicity in vitro	:	Test Type: In vitro mammalian cell gene mutation test Result: negative  Test Type: Chromosome aberration test in vitro Result: equivocal
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intravenous injection Result: negative

#### betamethasone:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: In vitro mammalian cell gene mutation test Result: negative  Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Oral Result: equivocal
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

### Components:

#### **Gentamicin:**

Carcinogenicity - Assessment : No data available

#### **Reproductive toxicity**

May damage the unborn child.

### Components:

#### **4-Chloro-3-methylphenol:**

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Gentamicin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3,6 mg/kg body weight  
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 50 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

### betamethasone:

Effects on foetal development : Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 0,05 mg/kg body weight  
Result: Fetotoxicity, Malformations were observed.

Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0,42 mg/kg body weight  
Result: Malformations were observed.

Species: Mouse  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### Components:

#### 4-Chloro-3-methylphenol:

Assessment : May cause respiratory irritation.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### Components:

#### Gentamicin:

Target Organs : Kidney, inner ear  
Assessment : Causes damage to organs through prolonged or repeated exposure.

#### betamethasone:

Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland  
Assessment : Causes damage to organs through prolonged or repeated exposure.



# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

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### Repeated dose toxicity

#### Components:

##### Paraffin oil:

Species	: Rat, female
LOAEL	: 161 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

##### 4-Chloro-3-methylphenol:

Species	: Rat
NOAEL	: 200 mg/kg
LOAEL	: 400 mg/kg
Application Route	: Ingestion
Exposure time	: 28 Days

##### Gentamicin:

Species	: Dog
LOAEL	: 3 mg/kg
Application Route	: Intramuscular
Exposure time	: 12 Months
Target Organs	: Kidney
Symptoms	: Vomiting, Salivation

Species	: Monkey
LOAEL	: 50 mg/kg
Application Route	: Subcutaneous
Exposure time	: 3 Weeks
Target Organs	: Kidney, inner ear

Species	: Monkey
LOAEL	: 6 mg/kg
Application Route	: Intramuscular
Exposure time	: 3 Weeks
Target Organs	: Blood, Kidney, inner ear, Liver

Species	: Rat
NOAEL	: 5 mg/kg
LOAEL	: 10 mg/kg
Application Route	: Intramuscular
Exposure time	: 52 Weeks
Target Organs	: Kidney, Blood

Species	: Rat
NOAEL	: 12,5 mg/kg
LOAEL	: 50 mg/kg
Application Route	: Intramuscular
Exposure time	: 13 Weeks
Target Organs	: Kidney

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formulation

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

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### betamethasone:

Species : Rabbit  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 10 - 30 d  
Target Organs : Pituitary gland, Immune system, muscle

Species : Rat  
LOAEL : 0.05 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus gland

Species : Mouse  
LOAEL : 0.1 %  
Application Route : Skin contact  
Exposure time : 8 Weeks  
Target Organs : thymus gland

Species : Dog  
LOAEL : 0,05 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Target Organs : Blood, thymus gland, Adrenal gland

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Paraffin oil:

|| The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : 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.

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

### Experience with human exposure

#### Components:

##### **Gentamicin:**

Ingestion : Target Organs: Kidney  
Target Organs: inner ear  
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

##### **betamethasone:**

Inhalation : Target Organs: Adrenal gland  
Skin contact : Symptoms: Redness, pruritis, Irritation

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **Paraffin oil:**

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

##### **4-Chloro-3-methylphenol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,5 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l  
Exposure time: 72 h

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

		Method: OECD Test Guideline 201
		EC10 (Chlorella pyrenoidosa (algae)): 2,3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1	
Toxicity to microorganisms	: EC50 : 22,86 mg/l Exposure time: 60 h	
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,32 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211	
<b>Gentamicin:</b>		
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 86 mg/l Exposure time: 48 h Method: OECD Test Guideline 202	
	: LC50 (Americamysis): 30 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035	
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l Exposure time: 72 h Method: OECD Test Guideline 201	
	: NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l Exposure time: 72 h Method: OECD Test Guideline 201	
	: EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l Exposure time: 72 h Method: OECD Test Guideline 201	
	: NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l Exposure time: 72 h Method: OECD Test Guideline 201	
M-Factor (Acute aquatic toxicity)	: 100	
Toxicity to microorganisms	: EC50 : 288,7 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209	

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version 9.0      Revision Date: 06.04.2024      SDS Number: 1833021-00015      Date of last issue: 30.09.2023  
Date of first issue: 13.07.2017

M-Factor (Chronic aquatic toxicity) : 1

### betamethasone:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): > 50 mg/l  
Exposure time: 96 h

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC: 0,052 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

NOEC: 0,07 µg/l  
Exposure time: 219 d  
Species: Oryzias latipes (Japanese medaka)  
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 8 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

## 12.2 Persistence and degradability

### Components:

#### 4-Chloro-3-methylphenol:

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 78 %  
Exposure time: 15 d  
Method: OECD Test Guideline 301

#### Gentamicin:

Biodegradability : Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

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### II

#### 12.3 Bioaccumulative potential

##### Components:

##### **Paraffin oil:**

Partition coefficient: n-  
octanol/water : log Pow: > 4  
Remarks: Calculation

##### **4-Chloro-3-methylphenol:**

Bioaccumulation : Species: Cyprinus carpio (Carp)  
Bioconcentration factor (BCF): 5,5 - 13

Partition coefficient: n-  
octanol/water : log Pow: 0,477

##### **Gentamicin:**

Partition coefficient: n-  
octanol/water : log Pow: < -2

##### **betamethasone:**

Partition coefficient: n-  
octanol/water : log Pow: 2,11

#### 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 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.

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

Contaminated packaging : 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 handling 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. (betamethasone, Gentamicin)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone, Gentamicin)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone, Gentamicin)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone, Gentamicin)
IATA	: Environmentally hazardous substance, solid, n.o.s. (betamethasone, Gentamicin)

#### 14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

#### 14.4 Packing group

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

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### 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 aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### 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



# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

### 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) : Conditions of restriction for the following entries should be considered: Number on list 75

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.  
If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### 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.
H304	:	May be fatal if swallowed and enters airways.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
H335	:	May cause respiratory irritation.
H360D	:	May damage the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H372	:	Causes damage to organs through prolonged or repeated exposure if swallowed.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.
H413	:	May cause long lasting harmful effects to aquatic life.

#### Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Asp. Tox.	:	Aspiration hazard
Eye Dam.	:	Serious eye damage
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
FOR-2011-12-06-1358	:	Norway. Occupational Exposure limits
FOR-2011-12-06-1358 /	:	Long term exposure limit

# SAFETY DATA SHEET

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



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

### TWA

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Repr. 1B	H360D
STOT RE 1	H372
Aquatic Chronic 1	H410

### Classification procedure:

Calculation method
Calculation method
Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

# SAFETY DATA SHEET

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



## Gentamicin / Betamethasone Cream Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
9.0	06.04.2024	1833021-00015	Date of first issue: 13.07.2017

---

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.

NO / EN