

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Gentamicin / Betamethasone Cream Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

Short-term (acute) aquatic hazard : Category 2

Long-term (chronic) aquatic hazard : Category 1

##### GHS label elements

Hazard pictograms :



Signal word : Danger

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

Hazard statements : H360D May damage the unborn child.  
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.  
H401 Toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P203 Obtain, read and follow all safety instructions before use.  
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P318 IF exposed or concerned, get medical advice.  
P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	$\geq 10 - < 20$
Paraffin oil	8012-95-1	$\geq 5 - < 10$
Alcohols, C16-18, ethoxylated	68439-49-6	$\geq 1 - < 2.5$
4-Chloro-3-methylphenol	59-50-7	$\geq 0.1 - < 0.25$
Gentamicin	1403-66-3	$\geq 0.1 - < 0.25$
betamethasone	378-44-9	$\geq 0.025 - < 0.1$

### 4. 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.

If inhaled : If inhaled, remove to fresh air.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

- In case of skin contact : Get medical attention.  
: 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.
- Most important symptoms and effects, both acute and delayed : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- 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).
- Notes to physician : Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- 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
- 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.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

cannot be contained.

Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 7. HANDLING AND STORAGE

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.  
Do not breathe dust, fume, gas, mist, vapours or spray.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	TWA (Mist)	5 mg/m <sup>3</sup>	IN OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	IN OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Paraffin oil	8012-95-1	TWA (Mist)	5 mg/m <sup>3</sup>	IN OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	IN OEL
		TWA (Inhal-	5 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

		able particulate matter)		
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

**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

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type** : Combined particulates and organic vapour type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving.

**Eye 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.

**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.

**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. The effective operation of a facility should include review of engineering controls, proper personal protective equipment,

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	cream
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	> 93.3 °C
Evaporation rate	:	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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

---

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle size : No data available

---

### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Vapours may form explosive mixture with air.  
Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

---

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Petrolatum:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: Based on data from similar materials

##### **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

---

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

---

toxicity

### Alcohols, C16-18, ethoxylated:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: Based on data from similar materials

### 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  
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:

#### Petrolatum:

Species : Rabbit



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

### Paraffin oil:

Species : Rabbit  
Result : No skin irritation

### Alcohols, C16-18, ethoxylated:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

### 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

### betamethasone:

Species : Rabbit  
Result : Mild skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Petrolatum:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation  
Remarks : Based on data from similar materials

#### Paraffin oil:

Species : Rabbit  
Result : No eye irritation

#### Alcohols, C16-18, ethoxylated:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation  
Remarks : Based on data from similar materials

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

### 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:

#### Petrolatum:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

#### Alcohols, C16-18, ethoxylated:

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

#### 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:

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

Remarks : No data available

### **betamethasone:**

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

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Petrolatum:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

#### **Alcohols, C16-18, ethoxylated:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

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

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

#### **Gentamicin:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

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.

### **Components:**

#### **Petrolatum:**

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

#### **Gentamicin:**

Carcinogenicity - Assessment : No data available

### **Reproductive toxicity**

May damage the unborn child.

### **Components:**

#### **Petrolatum:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

### Alcohols, C16-18, ethoxylated:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative  
Remarks: Based on data from similar materials

### 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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

---

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.

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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

### **Components:**

#### **Gentamicin:**

Target Organs : Kidney, inner ear

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

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.

### **Repeated dose toxicity**

#### **Components:**

##### **Petrolatum:**

Species : Rat  
NOAEL : 5,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

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

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

##### **Alcohols, C16-18, ethoxylated:**

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Method : OECD Test Guideline 408  
Remarks : Based on data from similar materials

##### **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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

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

### **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



# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

---

### 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.

### 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

---

## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

### Components:

#### Petrolatum:

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 203  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEL ( Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 10 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

### 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

### Alcohols, C16-18, ethoxylated:

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l  
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
Exposure time: 48 h  
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  
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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

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

### Gentamicin:

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

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

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

### Persistence and degradability

#### Components:

##### **Petrolatum:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

##### **Alcohols, C16-18, ethoxylated:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: > 60 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

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

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version 5.2      Revision Date: 30.09.2023      SDS Number: 1833018-00014      Date of last issue: 04.04.2023  
Date of first issue: 13.07.2017

---

### Gentamicin:

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

### Bioaccumulative potential

#### Components:

##### Paraffin oil:

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

##### Alcohols, C16-18, ethoxylated:

Bioaccumulation : Species: Fish  
Bioconcentration factor (BCF): < 500  
Remarks: Based on data from similar materials

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

##### 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

### Mobility in soil

No data available

### Other adverse effects

No data available

---

## 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(betamethasone, Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

##### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(betamethasone, Gentamicin)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

##### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(betamethasone, Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

### 15. REGULATORY INFORMATION

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

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

### 16. OTHER INFORMATION

Revision Date : 30.09.2023

#### 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/>

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
IN OEL	:	India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA	:	8-hour, time-weighted average
IN OEL / TWA	:	Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL	:	Short-term exposure Limit STEL (15 min)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Gentamicin / Betamethasone Cream Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
5.2	30.09.2023	1833018-00014	Date of first issue: 13.07.2017

---

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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

IN / EN