

SAFETY DATA SHEET



Betamethasone / Clotrimazole Ointment Formulation



Version 6.0 Revision Date: 06.04.2024 SDS Number: 610357-00020 Date of last issue: 30.09.2023
Date of first issue: 08.04.2016

Section 1: Identification

Product identifier : Betamethasone / Clotrimazole Ointment Formulation

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

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

Section 2: Hazard identification

Classification of the substance or mixture

Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Long-term (chronic) aquatic hazard : Category 1

GHS Label elements, including precautionary statements

Hazard pictograms :  

Signal word : Danger

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

SAFETY DATA SHEET



Betamethasone / Clotrimazole Ointment Formulation



Version 6.0 Revision Date: 06.04.2024 SDS Number: 610357-00020 Date of last issue: 30.09.2023
Date of first issue: 08.04.2016

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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/ hearing protection.

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

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	>= 90 -<= 100
White mineral oil (petroleum)	8042-47-5	>= 1 -< 10
clotrimazole	23593-75-1	>= 1 -< 2.5
betamethasone	378-44-9	>= 0.025 -< 0.1

Section 4: First-aid measures

Description of necessary 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.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

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

Risks : 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).

Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

Section 5: Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

Special protective actions for fire-fighters

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.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Betamethasone / Clotrimazole Ointment For- mulation

Version 6.0	Revision Date: 06.04.2024	SDS Number: 610357-00020	Date of last issue: 30.09.2023 Date of first issue: 08.04.2016
----------------	------------------------------	-----------------------------	---

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

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.

Methods and materials 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 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.

Section 7: Handling and storage

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.
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.

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, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

SAFETY DATA SHEET



Betamethasone / Clotrimazole Ointment Formulation



Version 6.0 Revision Date: 06.04.2024 SDS Number: 610357-00020 Date of last issue: 30.09.2023
Date of first issue: 08.04.2016

use of administrative controls.

Conditions for safe storage, including any incompatibilities

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

Section 8: Exposure controls/personal protection

Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	PEL (long term) (Mist)	5 mg/m ³	SG OEL
		PEL (short term) (Mist)	10 mg/m ³	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
White mineral oil (petroleum)	8042-47-5	PEL (long term) (Mist)	5 mg/m ³	SG OEL
		PEL (short term) (Mist)	10 mg/m ³	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
clotrimazole	23593-75-1	TWA	0.2 mg/m ³ (OEB 2)	Internal
betamethasone	378-44-9	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

Appropriate engineering control 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.

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

Individual protection measures, such as personal protective equipment (PPE)

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.
Skin 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.
Filter type	:	Combined particulates and organic vapour type
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.

Section 9: Physical and chemical properties

Appearance	:	Viscous semi-solid
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	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	Not classified as a flammability hazard
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available

SAFETY DATA SHEET



Betamethasone / Clotrimazole Ointment Formulation



Version 6.0 Revision Date: 06.04.2024 SDS Number: 610357-00020 Date of last issue: 30.09.2023
Date of first issue: 08.04.2016

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Particle characteristics
Particle size : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

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

Acute toxicity

Not classified based on available information.

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

Product:

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

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

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

White mineral oil (petroleum):

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

clotrimazole:

Acute oral toxicity : LD50 (Rat): 708 mg/kg
LD50 (Mouse): 761 mg/kg
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Mouse): 923 mg/kg

betamethasone:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Betamethasone / Clotrimazole Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

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

White mineral oil (petroleum):

Species	: Rabbit
Result	: No skin irritation

clotrimazole:

Species	: Rabbit
Result	: No skin irritation

betamethasone:

Species	: Rabbit
Result	: Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Petrolatum:

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

White mineral oil (petroleum):

Species	: Rabbit
Result	: No eye irritation

clotrimazole:

Species	: Rabbit
---------	----------

Betamethasone / Clotrimazole Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

|| 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

White mineral oil (petroleum):

|| Test Type : Buehler Test
|| Exposure routes : Skin contact
|| Species : Guinea pig
|| Result : negative

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

Betamethasone / Clotrimazole Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

White mineral oil (petroleum):

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

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

clotrimazole:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: in vitro micronucleus test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
Species: Hamster
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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

Betamethasone / Clotrimazole Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

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

White mineral oil (petroleum):

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	24 Months
Result	:	negative

clotrimazole:

Species	:	Rat
Application Route	:	Oral
Exposure time	:	78 weeks
Result	:	negative

Reproductive toxicity

May damage the unborn child.

Components:

Petrolatum:

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

Betamethasone / Clotrimazole Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

Result: negative
Remarks: Based on data from similar materials

White mineral oil (petroleum):

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

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

clotrimazole:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: LOAEL: 50 mg/kg body weight
Result: Effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 50 mg/kg body weight
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No effects on foetal development

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 180 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

||

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.

STOT - repeated exposure

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

Components:

clotrimazole:

Target Organs	:	Liver, Kidney, Adrenal gland
Assessment	:	May cause 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

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

White mineral oil (petroleum):

Species	: Rat
LOAEL	: 160 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

Species	: Rat
LOAEL	: >= 1 mg/l
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 4 Weeks
Method	: OECD Test Guideline 412

clotrimazole:

Species	: Rabbit
LOAEL	: 5 - 40 mg/kg
Application Route	: Skin contact
Exposure time	: 3 Weeks
Target Organs	: Skin
Symptoms	: Oedema, Fissuring, Necrosis, Redness

Species	: Rat
LOAEL	: 10 mg/kg
Application Route	: Oral
Exposure time	: 18 Months
Target Organs	: Liver, Kidney, Adrenal gland

Species	: Dog
LOAEL	: 25 mg/kg
Application Route	: Oral
Exposure time	: 6 - 12 Months
Target Organs	: Adrenal gland
Symptoms	: Salivation, Lachrymation, Vomiting

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 %

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

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.

Experience with human exposure

Components:

clotrimazole:

Skin contact	:	Symptoms: Rash, Itching, Blistering, Oedema, Redness
Ingestion	:	Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

betamethasone:

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

Section 12: Ecological information

Toxicity

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	:	NOEC (Daphnia magna (Water flea)): 10 mg/l

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

aquatic invertebrates (Chronic toxicity)	Exposure time: 21 d Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
--	---

White mineral oil (petroleum):

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l Exposure time: 28 d
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 1,000 mg/l Exposure time: 21 d

clotrimazole:

Toxicity to fish	: LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.02 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l Exposure time: 72 h NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	: 10
Toxicity to fish (Chronic toxicity)	: NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l Exposure time: 32 d Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC (Daphnia magna (Water flea)): 0.01 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic	: 10

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

toxicity)

Toxicity to microorganisms : EC50: > 10,000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209

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 (Pimephales promelas (fathead minnow)): 0.052 mg/l
 Exposure time: 32 d
 Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
 Exposure time: 219 d
 Method: OECD Test Guideline 229

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

White mineral oil (petroleum):

Biodegradability : Result: Not readily biodegradable.

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

||| Biodegradation: 31 %
Exposure time: 28 d

clotrimazole:

||| Stability in water : Hydrolysis: 50 %(242 d)

Bioaccumulative potential

Components:

betamethasone:

||| Partition coefficient: n-octanol/water : log Pow: 2.11

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

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

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.

Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3077
UN proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(betamethasone, clotrimazole)

Transport hazard class(es) : 9
Packing group : III
Labels : 9
Environmental hazards : yes

IATA-DGR

UN/ID No. : UN 3077
UN proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(betamethasone, clotrimazole)

Transport hazard class(es) : 9
Packing group : III
Labels : Miscellaneous

SAFETY DATA SHEET



Betamethasone / Clotrimazole Ointment Formulation



Version 6.0 Revision Date: 06.04.2024 SDS Number: 610357-00020 Date of last issue: 30.09.2023
Date of first issue: 08.04.2016

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, clotrimazole)
Transport hazard class(es) : 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.

Section 15: Regulatory information

Safety, health and environmental regulations specific for the product in question

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Revision Date : 06.04.2024

Betamethasone / Clotrimazole Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

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/>

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 SG OEL : Singapore. Workplace Safety and Health (General Provisions) Regulations - First Schedule Permissible Exposure Limits of Toxic Substances.

ACGIH / TWA : 8-hour, time-weighted average
 SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term
 SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

AllC - 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 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

SAFETY DATA SHEET



Betamethasone / Clotrimazole Ointment Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
6.0	06.04.2024	610357-00020	Date of first issue: 08.04.2016

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.

SG / EN