SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.1%) Lotion Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, Blood, Adrenal gland, thymus gland)
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms :

Signal Word : Danger
Hazard Statements : H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, Blood, Adrenal gland, thymus gland) through prolonged or repeated 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.
SAFETY DATA SHEET

Betamethasone (0.1%) Lotion Formulation

Version: 1.2
Revision Date: 23.03.2020
SDS Number: 4371262-00003
Date of last issue: 13.09.2019
Date of first issue: 30.05.2019

P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate)</td>
<td>5593-20-4</td>
<td>Acute toxicity (Inhalation), Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, Blood, Adrenal gland, thymus gland), Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 0,1 &lt; 0,25</td>
</tr>
</tbody>
</table>

SECTION 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. 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.
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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:

Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media:

None known.

Specific hazards during firefighting:

Exposure to combustion products may be a hazard to health.

Hazardous combustion products:

No hazardous combustion products are known

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 fire-fighters:

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment.

Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:

Discharge into the environment must be avoided.

Prevent further leakage or spillage if safe to do so.

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

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.

Clean up remaining materials from spill with suitable absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
SAFETY DATA SHEET
Betamethasone (0.1%) Lotion Formulation

Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSOINAL 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 vapors or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Conditions for safe storage : Keep in properly labeled 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-dipropionate</td>
<td>5593-20-4</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Engineering measures:
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. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

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:
Particulates 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: lotion
Color: No data available
Odor: No data available
Odor 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: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
SAFETY DATA SHEET

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Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapor pressure : No data available
Relative vapor 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 : Not applicable
Autoignition 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.
Molecular weight : No data available
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
   Inhalation
   Skin contact
   Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

**Product:**
Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

**Components:**

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
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 hrs
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

**Components:**

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Species : Rabbit
Result : Mild skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

**Components:**

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

**Components:**

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Routes of exposure : Dermal
Species : Guinea pig
Result : Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
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.

Reproductive toxicity
May damage the unborn child.

Components:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Effects on fetal 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 : May damage the unborn child.
STOT-single exposure
Not classified based on available information.

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

Components:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Target Organs : Pituitary gland, Immune system, muscle, Blood, Adrenal gland, thymus gland
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Species : Rabbit
LOAEL : 0.05 %
Application Route : Skin contact
Exposure time : 10 - 30 Days
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 Days
Target Organs : Blood, Adrenal gland, thymus gland

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):
Inhalation : Target Organs: Adrenal gland
Skin contact : Symptoms: Redness, pruritis, Irritation
Ecotoxicity

Components:

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Américamysis): > 50 mg/l
- Exposure time: 96 hrs

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

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
- Exposure time: 72 hrs
- 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 Days
- Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0,07 µg/l
- Exposure time: 219 Days
- 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 Days
- Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity):
- 1.000

Persistence and degradability
No data available

Bioaccumulative potential
No data available

Components:

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate):

Partition coefficient: n-octanol/water
- log Pow: 4,07

Mobility in soil
No data available

Other adverse effects
No data available
SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate))

Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s.
(9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate))

Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate))

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.  
(9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17,21-di(propionate))

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Sodium hydroxide

International Regulations

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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
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.

BR / Z8