

SAFETY DATA SHEETS

This SDS packet was issued with item:

078413915

N/A

SAFETY DATA SHEET



Revision date: 18-Dec-2013

Version: 2.0

Page 1 of 9

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Fluocinolone Acetonide and Dimethyl Sulfoxide Otic Solution

Trade Name: SYNOTIC
Chemical Family: Corticosteroid hormone

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as anti-inflammatory
Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.
100 Campus Drive, P.O. Box 651
Florham Park, New Jersey 07932 (USA)
Rocky Mountain Poison Control Center Phone: 1-866-531-8896
Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.
Mercuriusstraat 20
1930 Zaventem
Belgium

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid
Classification of the Substance or Mixture
GHS - Classification Not classified as hazardous

EU Classification:
EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified
Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: May be absorbed through the skin and cause systemic effects. May be harmful if absorbed through the skin. May cause eye and skin irritation
Known Clinical Effects: Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Adverse effects associated with therapeutic use include itching, burning, irritation, contact dermatitis.

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 2 of 9

Version: 2.0

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Fluocinolone Acetonide	67-73-2	200-668-5	T+,R27; Repr. Cat.3,R63	Acute Tox. 1(H310) Repr. 2 (H361)	0.01
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	Not Listed	*
Dimethyl sulfoxide	67-68-5	200-664-3	Not Listed	Not Listed	60
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Systemic effects could occur; get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 3 of 9

Version: 2.0

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. It is recommended that all operations be fully enclosed and no air recirculated. Releases to the environment should be avoided. Use appropriate personal protective equipment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Dimethyl sulfoxide

Austria OEL - MAKs	50 ppm 160 mg/m ³
Denmark OEL - TWA	50 ppm 160 mg/m ³
Estonia OEL - TWA	50 ppm 150 mg/m ³
Finland OEL - TWA	50 ppm
Germany (DFG) - MAK	50 ppm 160 mg/m ³
Lithuania OEL - TWA	50 ppm 150 mg/m ³
Vietnam OEL - TWAs	20 mg/m ³
Slovenia OEL - TWA	160 mg/m ³
Sweden OEL - TWAs	50 ppm 150 mg/m ³

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 4 of 9

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL - TWAs	50 ppm 160 mg/m ³
Propylene glycol Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Fluocinolone Acetonide
Zoetis OEB

OEB 5 - Skin (control exposure to <1ug/m³, provide additional precautions to protect from skin contact)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If airborne exposures are within or exceed the OEB, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB range. Respiratory protection should be worn to supplement engineering controls when handling this compound.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Clear
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
No data available			
Decomposition Temperature (°C):	No data available.		

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 5 of 9

Version: 2.0

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): 0.056
Vapor Density (g/ml): No data available
Relative Density: 1.07
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): 94 Closed cup
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Fluocinolone Acetonide

Rat Oral LD50 > 4000 mg/kg
Rat Dermal LD50 2.31mg/kg

Dimethyl sulfoxide

Rat Oral LD50 14,500 mg/kg
Rat Dermal LD50 40,000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Dimethyl sulfoxide

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 6 of 9

Version: 2.0

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild
Skin Sensitization Guinea Pig Negative

Citric acid, anhydrous

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Dimethyl sulfoxide

13 Week(s) Rat Inhalation 2.783 mg/L NOAEL Respiratory system
18 Month(s) Monkey Oral 8910 mg/kg/day NOAEL None identified

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Fluocinolone Acetonide

Embryo / Fetal Development Rabbit Subcutaneous 0.13 mg/kg/day LOAEL Embryotoxicity
Embryo / Fetal Development Rat Subcutaneous 50 ug/kg/day LOAEL Embryotoxicity, Maternal Toxicity, Teratogenic
Embryo / Fetal Development Rabbit Subcutaneous 50 ug/kg/day LOAEL Maternal Toxicity, Embryotoxicity, Teratogenic

Dimethyl sulfoxide

Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOAEL Maternal toxicity
Embryo / Fetal Development Rat Oral 200 mg/kg/day LOAEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Fluocinolone Acetonide

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Micronucleus Mouse Negative
In Vitro Forward Mutation Assay Mouse Lymphoma Negative

Dimethyl sulfoxide

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Cytogenetics Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse Negative
In Vivo Cytogenetics Rat Positive
In Vivo Sex-Linked Recessive Lethal Test *Drosophila* Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 7 of 9

Version: 2.0

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Dimethyl sulfoxide

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 33,000-37,000 mg/L

Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours > 40,000 mg/L

Daphnia Magna (Water Flea) EC50 48 Hours 24,600 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 8 of 9

Version: 2.0

15. REGULATORY INFORMATION

WHMIS hazard class:
None required

Fluocinolone Acetonide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	200-668-5

Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Dimethyl sulfoxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 6
EU EINECS/ELINCS List	200-664-3

Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H310 - Fatal in contact with skin
H361 - Suspected of damaging fertility or the unborn child

R27 - Very toxic in contact with skin.
R63 - Possible risk of harm to the unborn child.

Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 9 of 9

Version: 2.0

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and
Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 -
Toxicology Information. Updated Section 12 - Ecological Information.

Prepared by:

Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet

SAFETY DATA SHEET



Revision date: 18-Dec-2013

Version: 2.0

Page 1 of 9

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Fluocinolone Acetonide and Dimethyl Sulfoxide Otic Solution

Trade Name: SYNOTIC

Chemical Family: Corticosteroid hormone

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as anti-inflammatory

Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc.

100 Campus Drive, P.O. Box 651

Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison Control Center Phone: 1-866-531-8896

Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A.

Mercuriusstraat 20

1930 Zaventem

Belgium

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: VMIPSrecords@zoetis.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Clear liquid

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

EU Classification:

EU Indication of danger: Not classified

Label Elements

Signal Word: Not Classified

Hazard Statements: Not classified in accordance with international standards for workplace safety.

Other Hazards

Short Term: May be absorbed through the skin and cause systemic effects. May be harmful if absorbed through the skin. May cause eye and skin irritation

Known Clinical Effects: Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Adverse effects associated with therapeutic use include itching, burning, irritation, contact dermatitis.

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 2 of 9

Version: 2.0

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Fluocinolone Acetonide	67-73-2	200-668-5	T+,R27; Repr. Cat.3,R63	Acute Tox. 1(H310) Repr. 2 (H361)	0.01
Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	Not Listed	*
Dimethyl sulfoxide	67-68-5	200-664-3	Not Listed	Not Listed	60
Propylene glycol	57-55-6	200-338-0	Not Listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Systemic effects could occur; get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 3 of 9

Version: 2.0

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Keep away from heat, sparks, and flame. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. It is recommended that all operations be fully enclosed and no air recirculated. Releases to the environment should be avoided. Use appropriate personal protective equipment.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): No data available

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Dimethyl sulfoxide

Austria OEL - MAKs	50 ppm 160 mg/m ³
Denmark OEL - TWA	50 ppm 160 mg/m ³
Estonia OEL - TWA	50 ppm 150 mg/m ³
Finland OEL - TWA	50 ppm
Germany (DFG) - MAK	50 ppm 160 mg/m ³
Lithuania OEL - TWA	50 ppm 150 mg/m ³
Vietnam OEL - TWAs	20 mg/m ³
Slovenia OEL - TWA	160 mg/m ³
Sweden OEL - TWAs	50 ppm 150 mg/m ³

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 4 of 9

Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL - TWAs

50 ppm
160 mg/m³

Propylene glycol

Australia TWA

150 ppm
474 mg/m³
10 mg/m³

Ireland OEL - TWAs

150 ppm
470 mg/m³
10 mg/m³

Latvia OEL - TWA

7 mg/m³

Lithuania OEL - TWA

7 mg/m³

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Fluocinolone Acetonide

Zoetis OEB

OEB 5 - Skin (control exposure to <1ug/m³, provide additional precautions to protect from skin contact)

Exposure Controls

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective
Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection:

If airborne exposures are within or exceed the OEB, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEB range. Respiratory protection should be worn to supplement engineering controls when handling this compound.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:

Liquid

Odor:

No data available.

Molecular Formula:

Mixture

Color:

Clear

Odor Threshold:

No data available.

Molecular Weight:

Mixture

Solvent Solubility:

No data available

Water Solubility:

No data available

pH:

No data available.

Melting/Freezing Point (°C):

No data available

Boiling Point (°C):

No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C):

No data available.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 5 of 9

Version: 2.0

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): 0.056
Vapor Density (g/ml): No data available
Relative Density: 1.07
Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): 94 Closed cup
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: Toxicological properties of the formulation have not been fully investigated. The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Fluocinolone Acetonide

Rat Oral LD50 > 4000 mg/kg
Rat Dermal LD50 2.31mg/kg

Dimethyl sulfoxide

Rat Oral LD50 14,500 mg/kg
Rat Dermal LD50 40,000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Dimethyl sulfoxide

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 6 of 9

Version: 2.0

11. TOXICOLOGICAL INFORMATION

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild
Skin Sensitization Guinea Pig Negative

Citric acid, anhydrous

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Dimethyl sulfoxide

13 Week(s) Rat Inhalation 2.783 mg/L NOEL Respiratory system
18 Month(s) Monkey Oral 8910 mg/kg/day NOEL None identified

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Fluocinolone Acetonide

Embryo / Fetal Development Rabbit Subcutaneous 0.13 mg/kg/day LOEL Embryotoxicity
Embryo / Fetal Development Rat Subcutaneous 50 ug/kg/day LOEL Embryotoxicity, Maternal Toxicity, Teratogenic
Embryo / Fetal Development Rabbit Subcutaneous 50 ug/kg/day LOEL Maternal Toxicity, Embryotoxicity, Teratogenic

Dimethyl sulfoxide

Embryo / Fetal Development Rat Oral 1000 mg/kg/day NOEL Maternal toxicity
Embryo / Fetal Development Rat Oral 200 mg/kg/day LOEL Fetotoxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Fluocinolone Acetonide

In Vitro Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative
In Vivo Micronucleus Mouse Negative
In Vitro Forward Mutation Assay Mouse Lymphoma Negative

Dimethyl sulfoxide

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Cytogenetics Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse Negative
In Vivo Cytogenetics Rat Positive
In Vivo Sex-Linked Recessive Lethal Test *Drosophila* Negative

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 7 of 9

Version: 2.0

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Dimethyl sulfoxide

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 33,000-37,000 mg/L

Lepomis macrochirus (Bluegill Sunfish) LC50 96 Hours > 40,000 mg/L

Daphnia Magna (Water Flea) EC50 48 Hours 24,600 mg/L

Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 8 of 9

Version: 2.0

15. REGULATORY INFORMATION

WHMIS hazard class:

None required

Fluocinolone Acetonide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	200-668-5

Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Dimethyl sulfoxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4 Schedule 6
EU EINECS/ELINCS List	200-664-3

Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

H310 - Fatal in contact with skin
H361 - Suspected of damaging fertility or the unborn child

R27 - Very toxic in contact with skin.
R63 - Possible risk of harm to the unborn child.

Data Sources:

The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

SAFETY DATA SHEET

Material Name: Fluocinolone Acetonide and Dimethyl
Sulfoxide Otic Solution
Revision date: 18-Dec-2013

Page 9 of 9

Version: 2.0

Reasons for Revision:

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.
Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on
Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and
Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 -
Toxicology Information. Updated Section 12 - Ecological Information.

Prepared by:

Toxicology and Hazard Communication
Zoetis Global Risk Management

Zoetis Inc. believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet