SAFETY DATA SHEETS

This SDS packet was issued with item:

078947715

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078047792 078945551

SAFETY DATA SHEET

1. Identification

Product identifier	**Synotic®**
Other means of identification	
Synonyms	SYNOTIC * Synotic® Otic Solution * Fluocinolone Acetonide and Dimethyl Sulfoxide Otic Solution
Recommended use	Veterinary product used as anti-inflammatory (Steroid)
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (US)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (EU)	Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem Belgium
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	VMIPSrecords@zoetis.com

2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Not classified.
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.
Label elements	
Hazard symbol	None.
Signal word	None.
Hazard statement	The mixture does not meet the criteria for classification.
Precautionary statement	
Prevention	Observe good industrial hygiene practices.
Response	Wash hands after handling.
Storage	Store away from incompatible materials.
Disposal	Dispose of waste and residues in accordance with local authority requirements.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	May be absorbed through the skin and cause systemic effects. May cause adverse effects on the developing fetus. 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.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
Dimethyl sulfoxide		67-68-5	60
Propylene glycol		57-55-6	35-40
Citric acid, anhydrous		77-92-9	<1
Fluocinolone Acetonide		67-73-2	0.01

Composition comments In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist. For breathing difficulties, oxygen may be necessary.

Skin contact May be absorbed through the skin and cause systemic effects. Wash off immediately with soap and plenty of water. Systemic effects could occur; get medical attention. Wash contaminated clothing before reuse.

Eye contact Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention immediately.

Ingestion Rinse mouth. Get medical advice/attention if you feel unwell. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Mild skin irritation. 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, contact dermatitis, Irritant effects.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media Alcohol resistant foam. Powder. Carbon dioxide (CO2).

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical Fire may produce irritating, corrosive and/or toxic gases.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards Material will burn in a fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Ventilate the contaminated area. Do not get in eyes, on skin, or on clothing. Do not breathe mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Ensure adequate ventilation. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Wear personal protective equipment. Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapor. Avoid prolonged exposure. When using, do not eat, drink or smoke. Wash thoroughly after handling. Observe good industrial hygiene practices. Avoid release to the environment.

Industrial use: It is recommended that all operations be fully enclosed and no air recirculated.

Conditions for safe storage, including any incompatibilities Hygroscopic. Keep tightly closed in a dry, cool and well-ventilated place. @ 15-30°C (59-86°F). Keep away from heat, sparks and open flame. Use care in handling/storage. Keep container tightly closed. Do not allow material to freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
Dimethyl sulfoxide (CAS 67-68-5)	TWA	250 ppm	
Propylene glycol (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

Biological limit values No biological exposure limits noted for the ingredient(s).

Control banding approach Fluocinolone Acetonide: Zoetis OEB 5 - Skin (control exposure to <1ug/m3, provide additional precautions to protect from skin contact)

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas. Keep air contamination levels below the exposure limits or within the OEB range listed above in this section. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. Eye wash fountain and emergency showers are recommended.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

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

Other Avoid contact with the skin. Wear suitable protective clothing. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

Thermal hazards Not applicable.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Liquid.

Color Clear.

Odor Not available.

Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	201.2 °F (94.0 °C) Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	0.06 kPa @ 20C/68F
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Solubility (other)	Oil
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Flammability class	Combustible IIIB estimated
Oxidizing properties	Not oxidizing.
Specific gravity	1.07

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Sunlight. Excessive heat. Protect from freezing. This product may react with oxidizing agents.
Incompatible materials	Alkaline metals. Isocyanates. Acids. Alkalies. Incompatible with oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition. Thermal decomposition products may include oxides of carbon, nitrogen, and sulfur. Hydrogen fluoride.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	May be absorbed through the skin and cause systemic effects. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis.
Fluocinolone Acetonide	Severity: Moderate irritant
Citric acid, anhydrous	Species: Rabbit Severity: Mild

Skin contact

Dimethyl sulfoxide	Species: Rabbit Severity: Mild
Propylene glycol	Species: Rabbit Severity: Mild

Eye contact Direct contact with eyes may cause temporary irritation.

Dimethyl sulfoxide	Species: Rabbit Severity: Mild
Propylene glycol	Species: Rabbit Severity: Mild
Citric acid, anhydrous	Species: Rabbit Severity: Severe

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Mild skin irritation. 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, contact dermatitis, Irritant effects.

Information on toxicological effects

Acute toxicity May be absorbed through the skin and cause systemic effects.

Product	Species	Test Results
Synotic®		
Acute		
Dermal		
ATE		> 10000 mg/kg

Components	Species	Test Results
Citric acid, anhydrous (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
Dimethyl sulfoxide (CAS 67-68-5)		
Acute		
Dermal		
LD50	Rat	40000 mg/kg
Inhalation		
LC50	Rat	> 2000 mg/m3
Oral		
LD50	Rat	14500 mg/kg
Chronic		
Inhalation		
NOAEL	Rat	2.783 mg/L, 13 weeks Respiratory system
Fluocinolone Acetonide (CAS 67-73-2)		
Acute		
Dermal		
LD50	Rat	2.31 mg/kg
Oral		
LD50	Rat	> 4000 mg/kg

Components	Species	Test Results
Propylene glycol (CAS 57-55-6)		
Acute		
Dermal		
LD50	Rabbit	20800 mg/kg
Oral		
LD50	Mouse	24900 mg/kg
	Rat	22000 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

Fluocinolone Acetonide	Species: Human Severity: Moderate irritant

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye Contact

Dimethyl sulfoxide	Species: Rabbit Severity: Mild
Propylene glycol	Species: Rabbit Severity: Mild
Citric acid, anhydrous	Species: Rabbit Severity: Severe

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Skin sensitization

Dimethyl sulfoxide	Species: Guinea Pig Severity: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Fluocinolone Acetonide	In Vitro Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella , E. coli
Dimethyl sulfoxide	In Vitro Bacterial Mutagenicity (Ames) Result: Negative Species: Salmonella
	In Vitro Cytogenetics Result: Negative Species: Chinese Hamster Ovary (CHO) cells
Fluocinolone Acetonide	In Vitro Forward Mutation Assay Result: Negative Species: Mouse Lymphoma
Dimethyl sulfoxide	In Vivo Cytogenetics Result: Positive Species: Rat
	In Vivo Micronucleus Result: Negative Species: Mouse

Mutagenicity

Fluocinolone Acetonide	In Vivo Micronucleus Result: Negative Species: Mouse
Dimethyl sulfoxide	In Vivo Sex-Linked Recessive Lethal Test Result: Negative Species: Drosophila

Carcinogenicity This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Due to partial or complete lack of data the classification is not possible. Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus.

Developmental effects

Fluocinolone Acetonide	0.13 mg/kg/day Embryo / Fetal Development, Embryotoxicity Result: LOAEL Species: Rabbit Organ: Subcutaneous
Dimethyl sulfoxide	1000 mg/kg/day Embryo / Fetal Development, Maternal toxicity Result: NOAEL Species: Rat Organ: Oral
	200 mg/kg/day Embryo / Fetal Development, Fetotoxicity Result: LOAEL Species: Rat Organ: Oral
Fluocinolone Acetonide	50 ug/kg/day Embryo / Fetal Development, Embryotoxicity, Maternal Toxicity, Teratogenic Result: LOAEL Species: Rat Organ: Subcutaneous
	50 ug/kg/day Embryo / Fetal Development, Maternal Toxicity, Embryotoxicity, Teratogenic Result: LOAEL Species: Rabbit Organ: Subcutaneous

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Due to partial or complete lack of data the classification is not possible. This product may affect Endocrine system. through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components	Species	Test Results
Dimethyl sulfoxide (CAS 67-68-5)		
EC50	Daphnia Magna (Water Flea)	24600 mg/L, Hours

Components		Species	Test Results
	LC50	Lepomis macrochirus (Bluegill Sunfish)	> 40000 mg/L, 96 Hours
		Oncorhynchus mykiss (Rainbow Trout)	33000 - 37000 mg/L, 96 Hours
Aquatic			
Fish	LC50	Rainbow trout,donaldson trout (Oncorhynchus mykiss)	33000 - 37000 mg/l, 96 hours
Propylene glycol (CAS 57-55-6)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 48 hours
Fish	LC50	Fathead minnow (Pimephales promelas)	710 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. 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. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code None known.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

Dimethyl sulfoxide (CAS 67-68-5) Low priority

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 05-08-2017

Version # 01

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Revision information This document has undergone significant changes and should be reviewed in its entirety.