

1. Identification

Product identifier	Sileo®
Other means of identification	
Synonyms	Dexmedetomidine oromucosal gel
Recommended use	Not available.
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Manufacturer	
Company Name (US)	Zoetis Inc. 100 Campus Drive, P.O. Box 651 Florham Park, New Jersey 07932 (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
Contact E-Mail	VMIPSrecords@zoetis.com
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)	Caution - Pharmaceutical agent. Alpha2-adrenoreceptor agonist. The active ingredient in this product produces sedation and analgesia. May cause drowsiness and dizziness. May cause decreases in blood pressure and other cardiac effects. May cause adverse effects on the developing fetus.
Supplemental information	None.

3. Composition/information on ingredients

Mixtures

Material name: Sileo®

3256 Version #: 01 Issue date: 05-12-2016

Chemical name	Common name and synonyms	CAS number	%
Dexmedetomidine hydrochloride		145108-58-3	0.1 mg/ml
Composition comments	*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. 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	If inhaled, remove to fresh air. Call a physician if symptoms develop or persist.		
Skin contact	Wash off immediately with soap and plenty of water. Get medical advice/attention if you feel unwell.		
Eye contact	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Continue rinsing. Call a physician or poison control center immediately.		
Ingestion	Rinse mouth thoroughly. Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.		
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. May cause drowsiness or dizziness. May cause decreases in blood pressure and other cardiac effects.		
Indication of immediate medical attention and special treatment needed	The active ingredient in this product produces sedation and analgesia. Alpha2-adrenoreceptor agonist. Provide general supportive measures and treat symptomatically. Monitor respiratory, cardiac and central nervous system.		
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.		
5. Fire-fighting measures			
Suitable extinguishing media	Water fog. Foam. Dry chemical 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	During fire, gases hazardous to health may be formed.		
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	Use water spray to cool unopened containers.		
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.		
General fire hazards	No unusual fire or explosion hazards noted.		
6. Accidental release measures			
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS. Ventilate the contaminated area. Do not breathe mist or vapor. Avoid contact with eyes, skin, and clothing.		
Methods and materials for containment and cleaning up	<p>Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p>		
Environmental precautions	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.		
7. Handling and storage			
Precautions for safe handling	Wear personal protective equipment. Handle and open container with care. Avoid contact with eyes. Avoid contact with skin. Wash thoroughly after handling. Observe good industrial hygiene practices.		
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). Store below 30°C (86°F). Do not freeze. Keep out of the reach of children.		

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Control banding approach	Dexmedetomidine hydrochloride - Zoetis OEB 5 (control exposure to <1ug/m3)
Appropriate engineering controls	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. General ventilation normally adequate.
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.
Other	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.
Respiratory protection	No personal respiratory protective equipment normally required. Respiratory protection should be provided in instances where exposure to dust, mists, aerosols or vapors are likely. 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.
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	Solid.
Form	Gel.
Color	Not available.
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	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
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	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
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.
Oxidizing properties	Not oxidizing.

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.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	May be absorbed through the skin and cause systemic effects.
Eye contact	Direct contact with eyes may cause temporary irritation. Harmful in contact with eyes.
Ingestion	May be absorbed through mucous membranes and cause systemic effects. However, ingestion is not likely to be a primary route of occupational exposure.

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. May be absorbed through mucous membranes and cause systemic effects. May cause effects on blood pressure [decrease in blood pressure (hypotension)]; drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance. Target Organ(s): blood vessels. Heart. Central nervous system. May cause hypersensitivity reactions in susceptible individuals. Possible risk of harm to the unborn child.

Information on toxicological effects

Acute toxicity

Components	Species	Test Results
Dexmedetomidine hydrochloride (CAS 145108-58-3)		
Acute		
Intravenous		
LD50	Dog	2 mg/kg
Subacute		
Other		
LOAEL	Dog	0.01 mg/kg, 4 weeks (Intravenous; Target organs: Liver, Central nervous system)
NOAEL	Rat	0.02 mg/kg, 4 weeks (Intramuscular; Target organs: Eye, adrenal gland, lung, male reproductive system)
		0.01 mg/kg, 4 weeks (Intravenous; Target organs: Eye, liver)
NOEL	Dog	0.01 mg/kg, 4 weeks (Intramuscular; Target organs: Liver, Central nervous system)

Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization	Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.
Respiratory sensitization	Based on available data, the classification criteria are not met.
Skin sensitization	Based on available data, the classification criteria are not met.

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

Mutagenicity

Dexmedetomidine hydrochloride

In Vitro Bacterial Mutagenicity (Ames)

Result: Negative

Species: Salmonella , E. coli

In Vitro Chromosome Aberration

Result: Positive with activation , Negative without activation

Species: Human Lymphocytes

In Vitro Mammalian Cell Mutagenicity

Result: Negative

Species: Mouse Lymphoma

In Vivo Micronucleus

Result: Positive

Species: Mouse

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not available.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity Based on available data, the classification criteria are not met. Possible risk of harm to the unborn child. Avoid exposure during pregnancy.

Developmental effects

Dexmedetomidine hydrochloride

2 ug/kg/day Peri-Postnatal Development, (Fetotoxicity, Developmental toxicity)

Result: NOAEL

Species: Rat

Organ: Subcutaneous

20 ug/kg Method not specified, (Not teratogenic, Fetotoxicity)

Result: NOAEL

Species: Rat

Organ: Subcutaneous

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Not classified.

Further information May be absorbed through mucous membranes and cause systemic effects. May be absorbed through the skin and cause systemic effects. The active ingredient in this product produces sedation and analgesia. May cause decreases in blood pressure and other cardiac effects.

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.

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. Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
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. Empty containers should be taken to an approved waste handling site for recycling or disposal.

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 applicable.

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 listed.
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.
US state regulations	
US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)	Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

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)	No
Canada	Domestic Substances List (DSL)	No
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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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** 05-12-2016**Version #** 01

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