SAFETY DATA SHEET

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

Product Identifier

Material Name: Anipryl® (Selegiline hydrochloride) Tablets

Trade Name: Anipryl®
Chemical Family: Mixture

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

Intended Use: Veterinary product for the treatment of canine cognitive dysfunction; Canine pituitary dependent hyperadrenocorticism.

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: White tablets

Classification of the Substance or Mixture

GHS - Classification

Acute Oral Toxicity: Category 3
Specific target organ systemic toxicity (repeated exposure): Category 2

EU Classification:

EU Indication of danger: Harmful

EU Symbol: Xn
R22 - Harmful if swallowed.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Label Elements

Signal Word: Warning
Hazard Statements: H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure: thymus, spleen, liver.

Precautionary Statements:

P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P330 - Rinse mouth
P314 - Get medical attention/advice if you feel unwell
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards

Short Term: May cause eye irritation (based on components) Not expected to cause skin irritation
Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. May cause central nervous system effects

Known Clinical Effects: Adverse effects associated with the therapeutic use of selegiline hydrochloride include nausea, dizziness/lightheadedness or fainting, abdominal pain, confusion, hallucinations, dry mouth, vivid dreams, dyskinesias, and headache.

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

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings 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	%
Selegiline hydrochloride	14611-52-0	Not Listed	Xn; R22, R48/22	Acute Tox 3 (H302) STOT RE 2 (H373)	2 - 17
Stearic acid	57-11-4	200-313-4	Not Listed	Not Listed	*
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	Not Listed	*
Talc (non-asbestiform)	14807-96-6	238-877-9	Not Listed	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Crospovidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	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: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. If irritation occurs or persists, get medical attention. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. Get 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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

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

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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

Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions:	Store in a cool, dry, well-ventilated area. Protect from light. Keep container tightly closed when not in use.
Incompatible Materials:	None known
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.

Selegiline hydrochloride

Zoetis OEL TWA 8-hr	20µg/m^3

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m^3
Germany - TRGS 900 - TWAs	1000 mg/m^3
Germany (DFG) - MAK	1000 mg/m^3 average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m^3
Slovenia OEL - TWA	1000 mg/m^3
Switzerland OEL -TWAs	1000 ppm

Colloidal silicon dioxide

Australia TWA	2 mg/m^3
Austria OEL - MAKs	4 mg/m^3 0.3 mg/m^3
Czech Republic OEL - TWA	0.1 mg/m^3 4.0 mg/m^3
Estonia OEL - TWA	2 mg/m^3
Finland OEL - TWA	5 mg/m^3
Germany - TRGS 900 - TWAs	4 mg/m^3
Germany (DFG) - MAK	4 mg/m^3
Ireland OEL - TWAs	6 mg/m^3 2.4 mg/m^3
Latvia OEL - TWA	1 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf Listed
Slovakia OEL - TWA	4.0 mg/m^3
Switzerland OEL -TWAs	4 mg/m^3 0.3 mg/m^3

Talc (non-asbestiform)

ACGIH Threshold Limit Value (TWA)	2 mg/m^3
Australia TWA	2.5 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	2 mg/m^3
Belgium OEL - TWA	2 mg/m^3
Bulgaria OEL - TWA	1.0 fiber/cm3
	6.0 mg/m^3
	3.0 mg/m^3
Czech Republic OEL - TWA	2.0 mg/m^3
Denmark OEL - TWA	0.3 fiber/cm3
Finland OEL - TWA	0.5 fiber/cm3
Greece OEL - TWA	10 mg/m^3
	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	0.8 mg/m^3
Lithuania OEL - TWA	2 mg/m^3
	1 mg/m^3
Netherlands OEL - TWA	0.25 mg/m^3
OSHA - Final PELs - Table Z-3 Mineral D:	20 mppcf
Poland OEL - TWA	4.0 mg/m^3
	1.0 mg/m^3
Portugal OEL - TWA	2 mg/m^3
Romania OEL - TWA	2 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
	10 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Spain OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	2 mg/m^3
	1 mg/m^3
Switzerland OEL -TWAs	2 mg/m^3

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA)	10 mg/m^3
Australia TWA	10 mg/m^3
Belgium OEL - TWA	10 mg/m^3
Estonia OEL - TWA	10 mg/m^3
France OEL - TWA	10 mg/m^3
Ireland OEL - TWAs	10 mg/m^3
	4 mg/m^3
Latvia OEL - TWA	2 mg/m^3
Vietnam O EL - TWAs	10 mg/m^3
	5 mg/m^3
OSHA - Final PELS - TWAs:	15 mg/m^3
Portugal OEL - TWA	10 mg/m^3
Romania OEL - TWA	10 mg/m^3
Spain OEL - TWA	10 mg/m^3
Switzerland OEL -TWAs	3 mg/m^3

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).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin:	Not required for the normal use of this product. Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	Not required for the normal use of this product. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Tablet	**Color:**	White
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.
Evaporation Rate (Gram/s):	No data available
Vapor Pressure (kPa):	No data available
Vapor Density (g/ml):	No data available
Relative Density:	No data available
Viscosity:	No data available

Flammablity:

Autoignition Temperature (Solid) (°C):	No data available
Flammability (Solids):	No data available
Flash Point (Liquid) (°C):	No data available
Upper Explosive Limits (Liquid) (% by Vol.):	No data available
Lower Explosive Limits (Liquid) (% by Vol.):	No data available
Polymerization:	Will not occur

10. STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability:	Stable
Possibility of Hazardous Reactions	
Oxidizing Properties:	None
Conditions to Avoid:	None known
Incompatible Materials:	None known
Hazardous Decomposition Products:	Thermal decomposition products may include carbon monoxide, carbon dioxide and oxides of nitrogen.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient.

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

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Stearic acid
Rat Oral LD50 > 4640 mg/kg
Rabbit Dermal LD50 > 5000mg/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Selegiline hydrochloride
Rat Oral LD50 303 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.

Inhalation Acute Toxicity No data available

Ingestion Acute Toxicity See Acute toxicity table.

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

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Stearic acid
Skin Irritation Rabbit Moderate
Eye Irritation Rabbit Mild

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Selegiline hydrochloride
Eye Irritation Rabbit Slight
Skin Irritation Rabbit Non-irritating

Stearic acid
30 Week(s) Rat Oral300 ppm LOAEL Adipose tissue

Chronic Effects/Carcinogenicity In a one-year chronic toxicity/carcinogenicity study in rats, decreased body weight gain and food consumption, and increased activity were seen in the high dose group (17.5 mg/kg/day). The NOAEL was determined to be 3.5 mg/kg/day. In a one-year study in dogs, effects seen at doses from 4 mg/kg/day included increased activity, salivation and pale gums, statistically significant reduced reduced body weight gain, increased ALT values, slightly increased liver weights relative to body weights, and decreased absolute and relative spleen and thymus weights. The NOAEL was determined to be 1 mg/kg/day.

11. TOXICOLOGICAL INFORMATION

Subchronic Effects

In a six-month study in rats, excitability and decreased body weight and food consumption were seen at doses from 30 mg/kg/day. In six-month studies in dogs, increased activity, including panting and/or repetitive movements, quiet behavior prior to daily dosing, pale gums, salivation, and decreased body weight gain were seen at doses from 3 mg/kg/day.

Reproductive Effects

Reproductive toxicity studies of selegiline revealed evidence of a capacity for embryotoxic potential, but only at maternally-toxic doses.

Teratogenicity

In rats, no teratogenic effects were seen at doses of 4, 12, and 36 mg/kg/day, administered by gavage during organogenesis.

Stearic acid

In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
Unscheduled DNA Synthesis *E. coli* Negative

Mutagenicity

Selegiline showed no evidence of mutagenic activity in bacterial cells in vitro, or clastogenic activity in vivo.

Stearic acid

26 Week(s) Rat Subcutaneous 0.5 mg/kg/week NOAEL Not carcinogenic
52 Week(s) Mouse Subcutaneous 0.05 mg/kg/week LOAEL Tumors

Carcinogen Status:

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

Crospovidone

IARC: Group 3 (Not Classifiable)

Talc (non-asbestiform)

IARC: Group 3 (Not Classifiable)

Colloidal silicon dioxide

IARC: Group 3 (Not Classifiable)

At increase risk from exposure:

Individuals who have shown hypersensitivity to this drug and individuals using meperidine and/or other opioids may be more susceptible to toxicity in cases of overexposure. Individuals taking monoamine oxidase (MAO) inhibitors should avoid exposure to this material.

Product Level Toxicity Data

Oral Acute Toxicity Estimate (ATE) calculated: 1786-15,151 mg/kg

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity: No data available

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
WHMIS hazard class:
Class D, Division 2, Subdivision B

15. REGULATORY INFORMATION

Selegiline hydrochloride

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

Crospovidone

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	Not Listed

Polyethylene glycol

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 3
EU EINECS/ELINCS List	Not Listed

Stearic acid

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	200-313-4

Colloidal silicon dioxide

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	231-545-4

Talc (non-asbestiform)

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	238-877-9

Microcrystalline cellulose

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	232-674-9

16. OTHER INFORMATION

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

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure

Xn - Harmful

R22 - Harmful if swallowed.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

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 13 - Disposal Considerations.

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