




SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Mirataz - Transdermal Ointment
Synonyms:	2-methyl-1,2,3,4,10,14b-hexahydropyrazino[2,1-a]pyrido[2,3-c][2]benzazepine Mirtazapine
Proper Shipping name:	Not Applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	Management of weight loss in cats.
Uses advised against:	Not Applicable
1.3 Details of the supplier of the substance or mixture	
Registered company name (US):	Dechra Veterinary Products
Address:	7015 College Blvd, Suite 525 Overland Park, KS 66211 USA
Telephone:	1 (866) 933-2472
Fax:	Not Available
Website:	www.dechra.com
Email:	Not Available
Distributor name (Canada):	Dechra Veterinary Products
Address:	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
Telephone:	1 855 332-9334
Website:	www.dechra.ca
Email:	Not Available

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
<p>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada. Consult prescribing/packaging information. The classification and labeling listed below is for bulk drug product.</p> <p>This mixture is classified as hazardous under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA).</p>	
Classification according to regulation (EC) No 1272/2008 [CLP] (EU) ¹ :	
Classification (US):	
2.2 Label Elements	
GHS Label Elements:	
Signal Word:	WARNING
Hazard statement(s):	
H319 - Causes serious eye irritation.	
Supplementary Statement(s) US:	
Precautionary Statement(s) Prevention:	
	P264 - Wash hands thoroughly after handling. P280 - Wear protective gloves/eye protection/face protection. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice/ attention.
Precautionary Statement(s) Response:	
Not Applicable	
Precautionary Statement(s) Storage:	
Not Applicable.	
Precautionary Statement(s) Disposal:	
Not Applicable.	
2.3 Other Hazard Information	
No data were available for the mixture.	



SECTION 3: INFORMATION ON THE INGREDIENTS				
3.1 Substances				
See section below for composition of mixtures				
3.2 Mixtures				
Mixture - contains mirtazapine				
Ingredient	CAS #	EINECS/ ELINCS#	Amount	GHS Classification
Polyethylene oxide/ polyethylene glycol	25322-68-3	500-038-2	50-75%	Not classified
2-(2-ethoxy-ethoxy)ethanol	111-90-0	203-919-7	10-25%	Eye Irrit 2: H319
Mirtazapine	85650-52-8	288-060-6	1-10%	ATO4: H302; STOT-SE3: H336
Polydimethylsiloxanes	63148-62-9	618-493-1	1-10%	CA 2: H411
Starch	9005-25-8	232-679-6	1-10%	Not classified
Note:	<p>The substances listed above are considered hazardous. The remaining components are not hazardous and/or present at amounts below reportable limits.</p> <p>Starch and polyethylene glycol are included because they have OELs and are present at or above 1%.</p> <p>Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications.</p>			

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Immediate Medical Attention Needed: Yes	
Eye contact:	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
Skin contact:	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
Inhalation:	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
Ingestion:	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
Protection of first aid responders:	Protection of first aid responders: See Section 8 for Exposure Controls/Personal Protection recommendations.



4.2 Most important symptoms and effects, both acute and delayed	
See Sections 2 and 11.	
Eye contact:	Not Available
Skin contact:	Not Available
Ingestion:	Not Available
Self-injection:	Not Available
See Section 11 for more detailed information	
Indication of immediate medical attention and special treatment needed, if necessary:	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Suitable:	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
Unsuitable:	Not Available
5.2 Special hazards arising from the substance or mixture	
No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and nitrogen-containing compounds.	
Fire incompatibility:	Not Available
5.3 Special protective actions for fire-fighters:	
Firefighting:	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.
Fire / explosion hazard:	No explosivity or flammability data identified.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment (see section 8). Area should be adequately ventilated. Do not breathe dust/mist/vapors/spray.	
6.2 Environmental Precautions	
Do not empty into drains. Avoid release to the environment.	
6.3 Methods and material for containment and cleaning up	
Minor Spills:	For small spills, soak up material with absorbent, e.g., paper towels.



Major Spills:	For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
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SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Follow recommendations for handling bulk formulated/packaged pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling.
Other Information:	Store at < 25°C (77°F)

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Not Available
Storage incompatibility:	Not Available


7.3 Specific end uses

No information identified.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters/ Occupational Exposure Limit Values

Compound	Issuer	Type	OEL
Polyethylene oxide/ polyethylene glycol	ECHA	DNEL	500 µg/m ³
	AIHA	8-hour TWA	10 mg/m ³ (Polyethylene glycols MW >200)
2-(2-ethoxy-ethoxy)ethanol	AIHA	TWA-8 HR	25 ppm
	Estonia	TWA-8 HR	10 ppm (skin)
	Germany	Ceiling	100 mg/m ³ (inhalable fraction)
	Germany	TWA-8 HR	50 mg/m ³ (inhalable fraction)
	Germany	TWA-8 HR	6 ppm
	Sweden	STEL	30 ppm
	Sweden	TWA-8 HR	15 ppm
Mirtazapine	N/A	N/A	N/A
Polydimethylsiloxanes	N/A	N/A	N/A

8.1 Control Parameters/ Occupational Exposure Limit Values (Continued)			
Starch	ACGIH, Belgium, Bulgaria, Portugal, Spain, Singapore	TWA-8 HR	10 mg/m ³
	Czech Republic, Slovak Republic	TWA-8 HR	4 mg/m ³
	Greece, NIOSH	TWA-8 HR	10 mg/m ³ (inhalable fraction); 5 mg/m ³ (respirable fraction)
	Ireland, United Kingdom	TWA-8 HR	10 mg/m ³ (inhalable fraction); 4 mg/m ³ (respirable fraction)
	OSHA	TWA-8 HR	15 mg/m ³ (total dust); 5 mg/m ³ (respirable fraction)
	United Kingdom	STEL	30 mg/m ³ (inhalable fraction); 12 mg/m ³ (respirable fraction)
	NIOSH	TWA-10 HR	10 mg/m ³ (total dust); 5 mg/m ³ (respirable fraction)
8.2 Exposure controls			
Appropriate engineering controls:	None required for normal handling of packaged product. If handling bulk product and/or containers are open/crushed/broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Use engineered local exhaust ventilation (LEV) and/or enclosure for procedures where aerosolization may occur such as opened transfers, pumping, and spraying. Solutions can be handled outside a containment system or without LEV during procedures with no potential for aerosolization. All containers for solutions and slurries must be covered while being transferred.		
Personal protection:			
Eye and face protection:	None required for normal handling of packaged product. Wear safety glasses with side shields if eye contact is likely, e.g., during cleanup of large spill. Base the choice of protection on the job activity and potential for contact with eyes and face.		
Skin protection:	Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.		



Hands/ feet protection:	None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact is possible.
Body protection:	Not Available
Other protection:	Wash hands in the event of contact with mixture, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).
Thermal hazards:	Not Available
Respiratory protection:	None required for normal handling of packaged product. If handling bulk product and/or containers are open/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. At a minimum, a tight-fitting full-face respirator with HEPA filters is required when performing aerosol generating operations. A powered air-purifying respirator (PAPR) with HEPA filters and head cover is required for spill cleanup.

8.3 Environmental exposure controls

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Ointment, white
Container:	Not Available
Physical state:	Ointment
Odour:	Waxy
Odour Threshold:	Not Available
pH (as supplied):	Not Applicable
Melting point / freezing point (degrees C):	Not Available
Initial boiling point and boiling range:	Not Available
Flash Point:	Not Available
Evaporation rate:	Not Available
Flammability (Solid, gas):	Not Applicable
Upper/lower flammability or explosive limits:	Not Applicable
Vapour pressure:	Not Available
Vapour density:	Not Available
Relative Density:	Not Available
Solubility in water and solvents (mg/l):	Not Available
Auto ignition temperature (degrees C):	Not Available
Decomposition temperature (degrees C):	Not Available
Viscosity:	Not Available
Explosive properties:	Not Available
Oxidizing properties:	Not Available

9.2 Other information

Molecule formula:	Not Applicable (Mixture)
Molecular weight:	Not Applicable (Mixture)

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:	Stable under normal conditions.
10.2 Chemical stability:	Stable under normal handling and storage conditions.
10.3 Possibility of hazardous reactions:	Not expected to occur.
10.4 Conditions to avoid:	No information identified.
10.5 Incompatible materials:	No information identified.
10.6 Hazardous decomposition:	See Section 5 - Hazardous combustion products.

SECTION 11: TOXICOLOGICAL INFORMATION

Note :	No data on product formulation. The following information is for mirtazapine and other ingredients, where applicable.
Inhalation:	Not Available
Ingestion:	Not Available
Skin contact:	Not Available
Eye contact:	Not Available
Chronic:	Not Available
Self-injection:	Not Available
Route of entry:	May be absorbed by inhalation, skin contact and ingestion.
Acute toxicity:	

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Polyethylene oxide/ polyethylene glycol	LD ₅₀	Oral	Rat	>30,000 mg/day
	LD ₅₀	Dermal	Rabbit	>20,000 mg/kg
2-(2-ethoxy-ethoxy) ethanol	LD ₅₀	Oral	Rat	1920 - >5000 mg/kg
	LD ₅₀	Oral	Mouse/ Rabbit	>2000 mg/kg
	LD ₅₀	Dermal	Rabbit	>2000 mg/kg
	LC ₅₀	Inhalation	Rat	>5240 mg/m ³
Mirtazapine	LD ₅₀	Oral	Rat (female)	320 mg/kg
	LD ₅₀	Oral	Rat (male)	490 mg/kg
Polydimethylsiloxanes	--	--	--	--
Starch	--	--	--	--



Corrosion/irritation:
No studies identified
Sensitization:
No studies identified
Genotoxicity:
No studies identified
Carcinogenicity:
No studies identified. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
Reproductive toxicity:
No studies identified
Developmental toxicity:
No studies identified
STOT – single exposure:
No studies identified
STOT–repeated exposure:
No studies identified
Aspiration hazard:
Not Available
Human Health Data:
See "Section 2 - Other Hazards"



SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Compound	Type	Species	Concentration
Polyethylene oxide/ polyethylene glycol	EC ₅₀ (24 h)	<i>Daphnia magna</i> (daphnid)	>1000 mg/L
	LC ₅₀ (96 h)	<i>Poecilia reticulata</i> (freshwater fish)	>100 mg/L
2-(2-ethoxy-ethoxy)ethanol	LC ₅₀ (96 h)	Fish (various species)	>1000 mg/L
	EC ₅₀ (48 h)	Freshwater invertebrates	>1000 mg/L
Mirtazapine	--	--	--
Polydimethylsiloxanes	LC ₅₀ (96 h)	Fish	3.16 mg/L
	EC ₅₀ (48 h)	Crustacean (Daphnia)	44.50 mg/L
Starch	--	--	--

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No Data Available

12.4 Mobility in Soil

No Data Available

12.5 Results of PBT and vPvB assessment

Not Available

Notes

The ecological characteristics of this mixture have not been fully investigated. Releases to the environment should be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product / packaging disposal:	Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.
Waste Treatment Options:	Not Available
Sewage Disposal Options:	Not Available



SECTION 14: TRANSPORT INFORMATION

Transport:	
Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.	
UN Number	Not assigned
UN Proper Shipping Name	Not assigned
Transport hazard classes and packing group	Not assigned
Environmental hazards	This product/mixture is not regulated as an environmental hazard or a marine pollutant.
Special precautions for user	Due to lack of data, avoid release to the environment.
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture	
This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.	
15.2 Chemical Safety Assessment	
Not conducted.	
Echa summary	Not Applicable
TSCA status	Drugs are exempt from TSCA.
SARA section 313	Not listed.
California proposition 65	Not listed.
Additional information	No other information identified.



SECTION 16: OTHER INFORMATION

This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations.

Full text Risk and Hazard codes:

H phrases and GHS classifications

EI2A	Eye irritant Category 2A
H319	Causes serious eye irritation
ATO4	Acute Toxicity (Oral) Category 4
H302	Harmful if swallowed
STOT-SE3	Specific Target Organ Toxicity Following Single Exposure Category 3
H336	May cause drowsiness or dizziness
CA2	Chronic Aquatic Toxicity Category 2
H411	Toxic to aquatic life with long lasting effects

Source of data

Information from published literature and internal company data.

Abbreviations

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

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