Safety Data Sheet (SDS)

OSHA Haz Com Standard 29 CFR 1910.1200 and GHS Rev03

Section 1. Identification

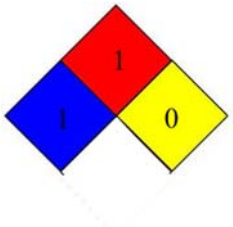
Product Name:	Veltassa™ (patiromer) For Oral Suspension (Also known as: RLY5016 for Oral Suspension)
Molecular Formula:	N/A
Product Use:	Pharmaceutical Drug Product Packaged as: a) 8.4 gram 30 count carton, NDC # 53436-084-30 b) 8.4 gram 4 count carton, NDC # 53436-084-04 c) 16.8 gram 30 count carton, NDC # 53436-168-30 d) 25.2 gram 30 count carton, NDC # 53436-252-30
Company:	Relypsa, Inc. 100 Cardinal Way Redwood City, CA 94063
Business Phone:	(650) 421-9500

Section 2. Hazard(s) Identification

Classification of the substance:	None identified
Human health hazards:	See Section 11 for more detailed information on health effects and symptoms.

Classification System:

National Fire Protection Association (U.S.A.) NFPA Ratings (scale 0-4)



Health – 1
Flammability -1
Instability/Reactivity – 0
where: 0=minimal, 1=slight, 2=moderate, 3=serious, 4=severe

Hazardous Material Information System (HMIS) Rating (scale 0-4)

Hazardous Material Information System:
Health – 1
Flammability – 1
Physical Hazards – 0
*where: 0=insignificant, 1=slight, 2=moderate, 3=high, 4=extreme, *=chronic*

Section 3. Composition/Information on Ingredients

Content: No hazardous ingredients.

Ingredient	CAS No.	%WT
Calcium, hydrolyzed divinylbenzene-Me 2-fluoro-2-propenoate-1,7-octadiene polymer sorbitol complexes	1415477-49-4	99.3
Xantural 75 (xanthan gum)	11138-66-2	0.7

Section 4. First-Aid Measures

Inhalation:	If inhaled, remove to fresh air. If breathing is difficult or ceases, give oxygen or perform cardiac resuscitation. Call a physician if necessary.
Skin Exposure:	Remove contaminated clothing. In case of skin contact, flush with soap and water.
Eye Exposure:	In case of eye contact, flush with copious amounts of water for at least 15 minutes. Call a physician if necessary.
Ingestion:	Rinse mouth with water. Call a physician if necessary.
Recommendations to Physicians:	Treat symptoms and eliminate overexposure.

Section 5. Firefighting Measures

Flash Point:	Not flammable
Autoignition Temperature:	Not applicable
Flammable Limits:	Not applicable
Unusual Fire and Explosion Hazard:	None
Extinguishing Media:	Water, Carbon Dioxide, Foam, Dry Chemical, Halon
Special firefighting procedure:	None

Section 6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures:	Wear protective equipment to prevent inhalation and direct contact with skin or eyes. Collect spillage by carefully sweeping or vacuuming with HEPA filtered vacuum and placing in a labeled, sealed container for disposal. Wash the area with a suitable cleaning solvent.

Section 7. Handling and Storage

Handling:	All employees who handle this material should be thoroughly trained to handle it safely. Open containers slowly, on a stable surface, in areas that have been designated for use of this substance.
Storage:	Store containers between 2 to 8°C, in a dry location. Keep storage containers tightly closed when not in use.

Section 8. Exposure Controls/Personal Protection

Ventilation and Engineering Controls:	Ensure eyewash/safety shower stations are in areas where this substance is used. Ventilation must be adequate to ensure that exposures to the powder are minimized.
Respiratory Protection:	Use a dust mask when used in a fume hood. A half-face high-efficiency particulate air filter respirator should be worn during operations that can generate excessive amounts of dust or particles.
Eye Protection:	Wear safety googles.

Hand Protection:	Wear appropriate latex or nitrile disposable gloves.
Body Protection:	Wear a laboratory coat.
Hygiene Practices:	As with all chemicals, exercise appropriate precautions to minimize direct contact with skin or eyes and prevent inhalation of dust. Do not eat, drink, smoke, or apply cosmetics while handling. Wash thoroughly after handling.

Section 9. Physical and Chemical Properties

Information on basic physical and chemical properties of active moiety

Appearance:	Off-white to light-brown powder
Odor:	Slight
Relative Vapor Density:	Not applicable
Bulk Density:	0.92 g/mL
Solubility in Water:	Not soluble (water solubilizes sorbitol)
Vapor Pressure:	Not applicable
Evaporation Rate:	Not applicable
Molecular Weight:	5.6×10^{17} g/mol

Section 10. Stability and Reactivity

Information on stability and reactivity of active moiety

Stability:	The product is stable.
Conditions to Avoid:	Avoid the creation of dust when handling. Avoid all possible sources of ignition (spark or flame) Take precautionary measures against electrostatic discharges.
Incompatibles:	Not applicable
Hazards:	Not applicable
Polymerization:	Compound is a thermoset polymer
Decomposition Products:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological Information

Potential acute health effects

RLY5016 for Oral Suspension is a non-absorbed polymeric drug designed for the specific binding and removal of potassium from the gastrointestinal tract. RLY5016 for Oral Suspension is not systemically absorbed therefore it is not expected to produce systemic toxicity.

A comprehensive toxicology program was conducted with the active moiety of RLY5016 for Oral Suspension. These include 4-week toxicology studies in the rat and dog at doses as high as 15 and 7 g/kg, respectively, resulting in no adverse toxicological findings. The active moiety of RLY5016 for Oral Suspension has been evaluated for its ability to induce genetic damage in three standard genetic toxicology assays (bacterial *Salmonella-Escherichia coli* gene mutation assay, *in vitro* chromosome aberration assay in Chinese Hamster Ovary cells, and *in vitro* rate bone marrow micronucleus assay). Based on results from these assays, there is no evidence that RLY5016 for Oral Suspension induces genetic damage. Results from a battery of safety pharmacology studies (cardiovascular assessment, neuropharmacological profile, pulmonary assessment, and gastrointestinal motility assessment) indicate that the active moiety of RLY5016 for Oral Suspension does not have any effects on CNS or respiratory endpoints after a single administration up to 6000 mg/kg in rats. There was a slight decrease in gastrointestinal motility at 3000 mg/kg and an effect on stomach emptying at 3000 and 6000 mg/kg in rats. There were no cardiovascular effects observed in dogs up to 3500 mg/kg. The active moiety of RLY5016 for Oral Suspension did not induce maternal or embryo/fetal toxicity or exhibit teratogenic potential when administered in the diets of rats and rabbits up to 6000 mg/kg and 3000 mg/kg, respectively.

Testing to determine whether the active ingredients in this compound causes cancer has not been performed.

Section 12. Ecological Information

Toxicity

The RLY5016 for Oral Suspension active moiety is insoluble and therefore expected to partition primarily to sludge. No significant ecological impacts are predicted to occur due to the production and patient use of the product.

Water Solubility:	Expected to be insoluble (calculated as <0.100 g/L)
Biodegradation, Hydrolysis:	Not tested due to analytical limitations
Soil/Water Partition Coefficient (K_{oc}):	Not determined

Toxicity Testing

Test	Result	Species	Exposure Time
Microbial Inhibition	EC_{10} > 1,000 mg/L EC_{50} > 1,000 mg/L	-	-
Terrestrial Plants	NOEC = 250 mg/kg EC_{25} = 540 mg/kg EC_{50} > 1,000 mg/kg	*Avena sativa* (oat) *Raphanus sativus* (radish) *Lactuca sativus* (lettuce)	14 days
Terrestrial Invertebrates	NOEC = 1000 mg/kg LC_{50} > 1,000 mg/kg	*Eisenia fetida* (earthworms)	7 and 14 days
Terrestrial Wildlife	Not evaluated	-	-
Freshwater Algae	NOEC = 30 mg/L LOEC > 30 mg/L EC_{10} > 30 mg/L EC_{20} > 30 mg/L EC_{50} > 30 mg/L	*Pseudokirchneriella subcapitata* (freshwater green alga)	72 hours

Section 13. Disposal Consideration

No specific disposal considerations are in place for this compound. Observe all federal, state, and local environmental regulations.

Section 14. Transportation Information

Contact Relypsa, Inc. for transportation information, RLY5016 for Oral Suspension should be maintained at 2 to 8 °C and avoid excessive heat.

Section 15. Regulatory Information

Regulatory classification has been estimated as follows for this compound.

- U.S. Toxic Substances Control Act: This product is excluded from TSCA regulation by Section 3(2)(B)(vi) when used for a FDA application.

Section 16. Other Information

Though the above information is believed to be accurate, it should be used only as a guide. Relypsa, Inc. assumes no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular use.

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Revision: 0 (initial version)