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	SAFETY DATA SHEET (SDS)	
	Rufinamide Oral Suspension, 40mg/mL	Effective date: 06/06/2025

1. Product Information

Product Name: **Rufinamide Oral Suspension, 40mg/mL**

2. Composition

Ingredients: Rufinamide
CAS: 106308-44-5

3. Hazards Identification

Fire and Explosion	: Expected to be non-combustible.
Health Hazards	: Rufinamide is contraindicated in patients With Familial Short QT syndrome
Environment	: No information is available about the potential of this product to produce adverse environmental effects.

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 off immediately with plenty of water. Continue to rinse for at least 15 minutes


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

Inhalation: Remove to fresh air, if not breathing, give artificial respiration. Get medical attention.

Medical Treatment: Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

Overdosage: Because strategies for the management of overdose are continually evolving, it is advisable to contact a Certified Poison Control Center to determine the latest recommendations for the management of an overdose of any drug.

One overdose of 7200 mg per day rufinamide was reported in an adult during the clinical trials. The overdose was associated with no major signs or symptoms, no medical intervention was required, and the patient continued in the study at the target dose.

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Treatment or Management of Overdose: There is no specific antidote for overdose with rufinamide. If clinically indicated, elimination of unabsorbed drug should be attempted by induction of emesis or gastric lavage. Usual precautions should be observed to maintain the airway. General supportive care of the patient is indicated including monitoring of vital signs and observation of the clinical status of the patient.

Hemodialysis: Standard hemodialysis procedures may result in limited clearance of rufinamide. Although there is no experience to date in treating overdose with hemodialysis, the procedure may be considered when indicated by the patient's clinical state.

5. Fire Fighting Measures

Fire and Explosion Hazards: Assume that this product is capable of sustaining combustion.

Extinguishing Media:

Extinguish fires with CO₂, extinguishing powder, foam, or water spray.

Special Hazards Arising from the Substance or Mixture

For single units (packages): No special requirements needed.

For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products: Hazardous combustion or decomposition products are expected when the product is exposed to fire.

6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures


Personnel involved in clean-up should wear appropriate personal protective equipment. 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: Collect and place it in a suitable, properly labeled container for recovery or disposal.

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7. Handling and Storage

Precautions for Safe Handling

No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store the oral suspension at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]. Replace cap securely after opening. The cap fits properly in place when the adapter is in place.

8. Exposure Controls/Personal Protection

Ventilation: Not required under normal condition of therapeutic use.

Respiratory Protection: Not required under normal condition of therapeutic use.

Personal Protection: Safety glasses recommended. Protective gloves and clothing not required under normal condition of therapeutic use

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).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

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9. Physical and Chemical Properties

Physical State:	Liquid
Odor:	Orange Flavor

10. Stability and Reactivity


Reactivity:	Stable under normal conditions
Chemical Stability:	Stable under normal conditions of use.
Possibility of Hazardous Reactions:	Stable under normal conditions
Conditions to Avoid:	None known
Incompatible Materials:	As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products:	None known

11. Toxicological Information

Information on Toxicological Effects

Rufinamide was given in the diet to mice at 40, 120, and 400 mg/kg per day and to rats at 20, 60, and 200 mg/kg per day for 2 years. The doses in mice were associated with plasma AUCs 0.1 to 1 times the human plasma AUC at the maximum recommended human dose (MRHD, 3200 mg/day). Increased incidences of tumors (benign bone tumors (osteomas) and/or hepatocellular adenomas and carcinomas) were observed in mice at all doses. Increased incidences of thyroid follicular adenomas were observed in rats at all but the low dose; the low dose is < 0.1 times the MRHD on an mg/m² basis. Rufinamide was not mutagenic in the in vitro bacterial reverse mutation (Ames) assay or the in vitro mammalian cell point mutation assay. Rufinamide was not clastogenic in the in vitro mammalian cell chromosomal aberration assay or the in vivo rat bone marrow micronucleus assay.

Oral administration of rufinamide (doses of 20, 60, 200, and 600 mg/kg per day) to male and female rats prior to mating and throughout mating, and continuing in females up to day 6 of gestation resulted in impairment of fertility (decreased conception rates and mating and fertility indices; decreased numbers of corpora lutea, implantations, and live embryos; increased preimplantation loss; decreased sperm count and motility) at all doses tested. Therefore, a no-effect dose was not established. The lowest dose tested was associated with a plasma AUC \approx 0.2 times the human plasma AUC at the MRHD.

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12. Ecological Information

Environmental Overview: Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

Toxicity:

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bio accumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

13. Disposal Considerations

Incinerate in an approved facility. Follow all federal state and local environmental regulations.

14. Transport Information

International Regulations: Not Classified by transport regulations, non-regulated

IATA / ICAO – Non-Hazardous - Not Regulated

IATA Proper shipping name: N/A

IATA UN / ID No: N/A

IATA Hazard Class: N/A

IATA Packing Group: N/A

IATA Label: N/A

IMDG – Non-Hazardous - Not Regulated

IMDG Proper shipping name: N/A

IMDG UN / ID No: N/A

IMDG Hazard Class: N/A

IMDG Flash Point N/A

IMDG Label: N/A

DOT – Non-Hazardous - Not Regulated

DOT Proper shipping name: N/A


DOT UN / ID No: N/A

DOT Hazard Class: N/A

DOT Flash Point N/A

DOT Packing Group: N/A

DOT Label: N/A

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15. Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

16. Other Information

Prepared by: MSN Pharmaceutical Inc, Piscataway, New Jersey – 08554

MSN Pharmaceutical 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.

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End of Safety Data Sheet