



Safety Data Sheet

Section 1. Identification	
Product Name: RiVive Naloxone HCl Nasal Spray 3 mg	Chemical Formula: C ₁₉ H ₂₂ C ₁ NO ₄ ·2H ₂ O
Container Information: Nasal spray device	Product Type: Regulated over-the-counter (OTC) drug
Product Number: FP001	Brand: Harm Reduction Therapeutics
Product Use(s): <ul style="list-style-type: none"> • To “revive” someone during an overdose from many prescription pain medications or street drugs such as heroin • This medicine can save a life 	
Manufacturer/Supplier Company: Harm Reduction Therapeutics	
Address: 4800 Montgomery Ln Ste 400, Bethesda, Maryland, 20814, United States	
Phone Number: 1-858-603-2514	
Emergency Phone: 1-800-262-8200 (CHEMTREC)	
Section 2. Hazards Identification	
Hazard Classification	No applicable GHS categories
Physical Hazards	None Known
Health Hazards	None Known
Signal Word	None
Hazards Not Otherwise Classified	None Known
Additional Information	Store at 20-25°C (68°F to 77°F). Do not refrigerate. Avoid excessive heat above 40°C (104°F).
Section 3. Composition/Information on Ingredients	
Active ingredient:	Naloxone Hydrochloride (CAS 51481-60-8)
Comments	<p>Non-hazardous ingredients include water for injection. Hazardous ingredient present at less than 1% may include trisodium citrate dihydrate and sodium chloride. Hydrochloric acid and sodium hydroxide may be used to adjust the pH.</p> <p>Specific composition (concentration) of excipients has been withheld as a trade secret.</p>



Section 4. First Aid Measures	
General Information	In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person. Naloxone Hydrochloride is a solution containing naloxone hydrochloride, a competitive antagonist of opioid receptors. Clinically, Naloxone prevents or reverses the effects of opioids including respiratory depression, sedation and hypotension. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the central nervous system and cardiovascular system
Inhalation	If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
Eye Contact	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention if irritation persists.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Section 5. Fire-Fighting Measures	
Suitable Extinguishing Media	Use dry chemical, CO ₂ , water spray (fog) or foam
Hazards Resulting from the substance or mixture	Not determined
Advice for fire-fighters	None anticipated for this aqueous product
Section 6. Accidental Release Measures	
Personal Precautions, PPE, and Emergency Response	Put on appropriate personal protective equipment (see section 8).
Methods and Materials for Containment/Cleanup	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water.
Environmental Precautions	Do not allow spills to enter drains or waterways. Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.
Section 7. Handling and Storage	
Precautions for Safe Handling	No special handling required for hazard control under conditions of normal product use.
Conditions for Safe Storage	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.



Section 8. Exposure Controls and Personal Protection			
Occupational Exposure Limits			
Ingredient name	Performance-Based Exposure Band (PBEB)		Company OEG (ug/m³)
Naloxone Hydrochloride Dihydrate (CAS 51481-60-8)	3 (10-100 ug/m ³)		50
Engineering Controls	Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.		
Individual Protection Measures			
Eye/Face	Eye protection not needed for intended product use.		
Skin	Protective gloves (e.g. latex or nitrile) not required.		
Respiratory	Respiratory protection is not needed during intended product use.		
Other	Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse		
Section 9. Physical and Chemical Properties			
Appearance	A clear, colorless to pale yellow solution (liquid)	Upper/lower flammability or explosive limits	Not Available
Odor	Odorless	Vapor Pressure	Not Available
Odor threshold	Not Available	Vapor Density	Not Available
pH	3.5 – 4.5	Relative Density	Not Available
Melting/Freezing Point	Not Available	Solubilities	Not Available
Boiling Point and Range	Not Available	Partition coefficient	Not Available
Flash point	Not Available	Auto-ignition temperature	Not Available
Evaporation rate	Not Available	Decomposition temperature	Not Available
Flammability	Not Available	Viscosity	Not Available
Section 10. Stability and Reactivity			
Reactivity	No specific test data related to reactivity available for this product or its ingredients.		
Chemical Stability	The product is stable under normal ambient temperature and condition while in storage and being handled.		
Conditions to Avoid	None known based on available information.		
Incompatible Materials	None known based on available information.		
Hazardous Decomposition Products	None known based on available information.		



Section 11. Toxicological Information	
Classification	Hazard Description
Acute toxicity (oral)	Not applicable
Acute toxicity (dermal)	Not applicable
Acute toxicity (inhalation)	Not applicable
Skin corrosion/irritation	Not applicable
Respiratory sensitization	Not applicable
Skin sensitization	Not applicable
Germ cell mutagenicity	Not applicable
Carcinogenicity	Not applicable
Reproductive toxicity	Not applicable
STOT-single exposure	Not applicable
STOT-repeated exposure	Not applicable
Aspiration hazard	Not applicable
Other	
This product is not listed in the National Toxicology Program Report on Carcinogens nor is it recognized by the International Agency for Research on Cancer or OSHA as a potential carcinogen.	
Section 12. Ecological Information	
Toxicity	No information available
Persistence and degradability	No information available
Bioaccumulative potential	No information available
Mobility in Soil	No information available
Other Adverse Effects	No information available
Section 13. Disposal Considerations	
Disposal should be in accordance with applicable regional, national, and local laws, and regulations.	
Section 14. Transport Information	
Is the product hazardous for transport according to the: N/A	
Section 15. Regulatory Information	
N/A	
Section 16. Other Information	
Issue Date: 04Mar2024	
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