



<p align="center">IN CASE OF EMERGENCY Emergency Phone: (614) 276-4000</p>




Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Butorphanol Tartrate Nasal Spray USP 10 mg/mL		
Chemical Name: (-)-17-(cyclobutylmethyl)morphinan-3,14-diol [S-(R*,R*)]-2,3-dihydroxybutanedioate (1:1) (salt)		
Synonyms: None		
Molecular Formula: C ₂₁ H ₂₉ NO ₂ •C ₄ H ₆ O ₆		
Molecular Weight: 477.55		
CAS No: 58786-99-5		
Chemical Family: Opioid agonist-antagonist analgesic		
Product Use: Treatment for the management of pain where appropriate.		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Butorphanol Tartrate (active ingredient)	58786-99-5	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered intranasally. Colorless solution that contains 10 mg/mL active ingredient. Odor: Odorless WARNING! Butorphanol Tartrate is an opioid analgesic. May be harmful if inhaled or swallowed. Accidental ingestion of large amounts may be fatal.	
Primary Route(s) of Entry	Inhalation	
Potential Health Effects:	Inhalation: May be harmful if inhaled. Inhalation may cause dizziness, drowsiness, nausea, nervousness and sweatiness. Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness. Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. Ingestion: May be harmful if ingested. Ingestion may cause nausea, dizziness, lethargy and palpitations.	
Toxicity Data:	See Section 11	



Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by inhalation or ingestion may cause clamminess, slowed respiratory function, slowed heartbeat, drowsiness, dizziness and loss of consciousness.				
Target Organs:	Brain, Central Nervous System				
4. FIRST AID MEASURES					
Eye Exposure	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.				
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.				
Ingestion	Call a physician or poison control center immediately.				
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.				
5. FIRE AND EXPLOSION HAZARDS					
Flammability	Lower: N/A		Upper: N/A		
Flash Point	Not available				
Extinguishing Media	Use water spray, carbon dioxide, dry chemical, foam or material appropriate for fire in surrounding area.				
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.				
Unusual Fire/Explosion Hazards	Not Applicable				
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen				
6. ACCIDENTAL RELEASE INFORMATION					
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED: Use appropriate personal protective equipment (see Section 8). Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.					
7. PRECAUTIONS FOR SAFE HANDLING AND USE					
Precautions Handling Significant Quantities of Liquid:	Observe good industrial hygiene practices.				
Storage	Store at 15° to 30°C (59° to 86°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.				
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT					
Exposure Limits	None				
Engineering Controls	Not required when handling liquid or containers. Good ventilation should be used. Ventilation should be matched to conditions.				
Respiratory Protection	Not required when handling liquid or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.				
Personal Protection	Not required when handling final product. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves				
Recommended Facilities	Eye wash, washing facilities				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Colorless liquid solution	Melting point	Not available	Solubility in water	Soluble
Odor	Odorless	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available



10. STABILITY AND REACTIVITY DATA	
Stability	Stable
Incompatibility	None known
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen
Conditions to Avoid	Excessive heat, light
Hazardous Polymerization	Will not occur.
11. TOXICOLOGICAL INFORMATION	
Acute Toxicity:	
Active Ingredient: LD50 Oral (rat): 315 mg/kg LD50 Oral (mouse): 395 mg/kg	
Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.	
12. ENVIRONMENTAL IMPACT INFORMATION	
No information is currently available on the environmental impact of this product.	
13. DISPOSAL INFORMATION	
Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.	
14. TRANSPORTATION INFORMATION	
This product is not subject to the regulations for the safe transport of hazardous chemicals. DOT: Not regulated TDG: Not regulated IATA: Not regulated IMDG: Not regulated	
15. REGULATORY INFORMATION	
DEA: Butorphanol Tartrate  is a DEA Schedule IV Controlled Substance.	
FDA: Butorphanol Tartrate  is an approved prescription medication.	
Inventory Status: This material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use. This material is not listed on the DSL Inventory but is exempt.	
16. OTHER DATA	
ABBREVIATIONS: N/A – not applicable	
Prepared by: Boehringer Ingelheim Roxane Inc.	
References:	
<ol style="list-style-type: none"> 1. Butorphanol Tartrate  Nasal Spray, Package Insert, Boehringer Ingelheim Roxane Inc., Columbus, Ohio 2. RTECS No. QC7795000 - Morphinan-3,14-diol, 17-(cyclobutylmethyl)-, (S-(R*,R*))-2,3-dihydroxybutanedioate (1:1)(salt) 3. Ariel Webinsight. Regulatory and ChemExpert Database. 4. PDR – Physicians Desk Reference 	



Date: New MSDS: 12/22/1999

Revised: 9/24/2008

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Boehringer Ingelheim Roxane Inc. assumes no responsibility or liability resulting from the use of this information.