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	Granisetron HCl Injection, USP			Material Safety Data Sheet (MSDS)	
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Section 1 - Chemical Product and Company

Distributor:

Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 700
Schaumburg, IL 60195
847-908-1600


Emergency Telephone: 866-625-1618

Product Identifier: Granisetron Hydrochloride Injection, USP
Product Code: 25021-778
 25021-779
 25021-781
Common/Trade Name: Kytril®
Chemical Name: *endo*-N-(9-methyl-9-azabicyclo [3.3.1] non-3-yl)-1-methyl-1H-indazole-3-carboxamide hydrochloride
Chemical Family: Antinauseant and Antiemetic
Product Use: Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials

Section 2 - Composition / Information on Ingredients

Ingredient	Weight %	CAS No.
Granisetron Hydrochloride	0.112	107007-99-8
Sodium Chloride, USP	9.00	7647-14-5
Citric Acid Anhydrous USP	2.00	77-92-9
Sodium Hydroxide, NF	q.s to pH	1310-73-2
Hydrochloric Acid, NF	q.s to pH	7647-01-0
Methylparaben, NF*	.18	99-76-3
Propylparaben, NF*	0.02	94-13-3
Water for Injection, USP	q.s to 1 mL	7732-18-5
Nitrogen, NF	q.s	7727-37-9

* Product codes 778-01 and 779-01 are preservative-free and do not contain these ingredients.


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Section 3 - Hazards Identification

Primary Physical and Health Hazards:	The primary health effects anticipated in an occupational setting include mild irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection, effects such as headache, sleepiness, agitation, anxiety, central nervous system stimulation, insomnia, diarrhea, constipation, hypertension (high blood pressure), hypotension (low blood pressure), arrhythmias and hypersensitivity reactions (anaphylaxis), sometimes severe, with skin rashes, weakness and fever may occur.
Routes of Entry:	Inhalation, skin or eye contact, ingestion
Signs & Symptoms of Exposure:	Possible adverse reactions include: headache, asthenia, somnolence, diarrhea, and constipation. Occupational exposure has not been fully investigated.
Chemical Listed as Carcinogen:	NTP: No IARC: No OSHA: No
Medical Conditions Generally Aggravated by Exposure:	Individuals with a known hypersensitivity to the drug or to any of its components.

Section 4 - First Aid Measures

Eye Exposure:	Flush eyes continuously with water for at least 15 minutes and obtain immediate medical assistance.
Skin Exposure:	Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if pain, redness, or swelling persists.
Ingestion:	Contact a physician or poison control center. If conscious, have victim rinse mouth with water. Do not induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

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Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposure to the therapeutic doses of this product. However, therapeutic effects including headache, sleepiness, agitation, anxiety, central nervous system stimulation, insomnia, extrapyramidal syndrome, diarrhea, constipation, hypertension, hypotension, arrhythmias (e.g., sinus bradycardia, atrial fibrillation, ventricular ectopy including non-sustained tachycardia, ECG abnormalities), hypersensitivity reactions (anaphylaxis), sometimes severe, with skin rashes, weakness and fever may occur. See package insert for other adverse reactions associated with therapeutic doses of this product.

Inhalation: Remove victim from fresh air. If necessary, use artificial respiration to support vital functions. See medical attention if adverse effect continues after removal to fresh air.

Notes to Physician: See patient package insert in shipping carton for complete information.

Section 5 - Fire Fighting Measures

Flash Point: Not established

Auto-ignition Temperature: Not established

Flammable Limits in Air: Lower %: Not established
Upper %: Not established

Flammable Limits: Not established


Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide, halon, and any "ABC" class suppression method.

Special Fire Fighting Procedures: Wear self-containing breathing apparatus and protective clothing.

Unusual Fire/Explosion Hazards: May decompose and product irritating fumes and toxic gases (including carbon oxides, nitrogen oxides, and hydrogen chloride.)

Section 6 - Accidental Release Measures

Spill: Absorb with absorbent materials and dispose according to local, state, and federal guidelines.

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Release to Air: If aerosolized, reduce exposures by ventilating area. Respiratory protection should not be necessary.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

Section 7 - Handling and Storage

General Handling: When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist and/or vapors associated with this product.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Storage Conditions: Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature.] Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

Respiratory Protection: Generally not needed unless large quantities of spray or mist may be generated.


Eye Protection: Safety glasses or goggles recommended

Ventilation: General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

Skin Protection: Disposable garments if direct skin contact is anticipated.

Other Protective Equipment: Disposable latex gloves recommended.


Additional Exposure Precautions: Not Established

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<u>Exposure Limits</u>			
<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Granisetron Hydrochloride	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Sodium Chloride, USP	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Citric Acid Anhydrous USP	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Sodium Hydroxide, NF	OSHA ACGIH ACGIH -----	PEL TLV CEIL STEL	2 ppm NE 2 mg/m3 NE
Hydrochloric Acid, NF	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Methylparaben, NF*	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Propylparaben, NF*	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Water for Injection, USP	OSHA ACGIH -----	PEL TLV STEL	NE NE NE
Nitrogen, NF	OSHA ACGIH -----	PEL TLV STEL	NE NE NE

NE: Not Established

CEIL: Ceiling Limit

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Section 9 - Physical and Chemical Properties

Physical State:	Liquid	Specific Gravity:	Approx to water
Appearance and Odor:	Clear, colorless	Evaporation Rate:	Approx to water
Boiling Point:	100°C (212°F)	Melting Point:	Not available
Vapor Pressure:	Not available	Solubility in Water:	Completely soluble in water
Vapor Density:	Not available	pH:	4.0-6.0
		Molecular Weight:	348.9


Section 10 - Stability and Reactivity

Stability:	Stable under normal storage conditions.
Incompatibility (Materials to avoid):	Not available
Hazardous Decomposition:	Does not occur
Hazardous Polymerization:	Does not occur
Conditions to Avoid:	Freezing, extreme heat, or any conditions that are incompatible with water.

Section 11 - Toxicological Information

Acute Toxicity

Component	Type	Route	Species	Dosage
Granisetron Hydrochloride	TD _{LO}	Oral	Rat	4500 mg/kg/30 days/intermittent
Granisetron Hydrochloride	TD _{LO}	Oral	Rat	18,200 mg/kg/26 weeks/intermittent
Granisetron Hydrochloride	TD _{LO}	Oral	Rat	1820 mg/kg/1 year/intermittent
Granisetron Hydrochloride	TD _{LO}	Subcutaneous	Rat	52 mg/kg

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Component	Type	Route	Species	Dosage
Granisetron Hydrochloride	TD _{LO}	Oral	Dog	325 mg/kg/30 days/intermittent
Granisetron Hydrochloride	LD ₅₀	Oral	Rat	350 mg/kg
Granisetron Hydrochloride	LD ₅₀	Intravenous	Rat	14 mg/kg
Granisetron Hydrochloride	LD ₅₀	Oral	Mouse	350 mg/kg
Granisetron Hydrochloride	LD ₅₀	Intravenous	Mouse	17 mg/kg
Granisetron Hydrochloride	LDLo	Oral	Dog	15 mg/kg
Granisetron Hydrochloride	LDLo	Intravenous	Dog	3 mg/kg

Other: Pregnancy Category B: There are no adequate and well-controlled studies in pregnant women.

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.


Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

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Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 304 - *Not on this list*

SARA 313 - *Not on this list*


OSHA Substance Specific - *No*

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
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Glossary: This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)