

MATERIAL SAFETY DATA SHEET

NFPA	HMIS	Personal Protective Equipment						
	<table border="1"> <tr> <td>Health Hazard</td> <td style="text-align: center;">1</td> </tr> <tr> <td>Fire Hazard</td> <td style="text-align: center;">1</td> </tr> <tr> <td>Reactivity</td> <td style="text-align: center;">0</td> </tr> </table>	Health Hazard	1	Fire Hazard	1	Reactivity	0	
Health Hazard	1							
Fire Hazard	1							
Reactivity	0							
See Section 8.								

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product code:	G3375
Product Name:	GLICLAZIDE
Chemical Name:	Urea, 1-(hexahydrocyclopenta(c)pyrrol-2(1H)-yl)-3-(p-tolylsulfonyl)-
Synonyms:	-(3-Azabicyclo(3.3.0)oct-3-yl)-3-(p-tolylsulfonyl)urea 1-(Hexahydrocyclopenta(c)pyrrol-2(1H)-yl)-3-(p-tolylsulfonyl)urea Benzenesulfonamide, N-(((hexahydrocyclopenta(c)pyrrol-2(1H)-yl)amino)carbonyl)-4-methyl- Diamicon Glimicon N-(4-Methylbenzenesulfonyl)-N'-(3-azabicyclo(3.3.0)oct-3-yl)urea Nordialex
Recommended use:	Medication. Hypoglycemic (anti-diabetic) drug.
CAS #:	21187-98-4
Formula:	C15-H21-N3-O3-S
RTECS #	YT4500000
Cl#:	Not available
Supplier:	Spectrum Chemicals and Laboratory Products, Inc. 14422 South San Pedro St. Gardena, CA 90248 (310) 516-8000
Emergency Telephone Number:	CHEMTREC: 1-800-424-9300
Contact Person:	Martin LaBenz (West Coast)
Contact Person:	Chris Terpak (East Coast)

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW			
May cause skin and eye irritation. May cause irritation of respiratory tract.			
Odor: No information available	Physical state: Solid.	Appearance: Powder.	Color: White. Off-white.

OSHA Regulatory Status This material is not considered hazardous by the OSHA Hazard Communication Standard (29 1910.1200)

2. HAZARDS IDENTIFICATION

POTENTIAL HEALTH EFFECTS

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Potential Health Effects:**Skin Contact:**

May cause skin irritation.

Eye Contact:

May cause eye irritation.

Inhalation:

May cause irritation of respiratory tract.

Ingestion:

May cause gastrointestinal disturbances. May cause abdominal pain. May cause diarrhea. May cause vomiting. May cause loss of appetite. May cause hypoglycemia. May cause central nervous system effects. It may affect the kidneys. May affect the liver. May affect respiration. May affect the blood.

Chronic Potential Health Effects:**Component**

Gliclazide
21187-98-4 (100)

Carcinogen Status:

No information available

Target Organs:

Pancreas. Liver. Kidneys.

Teratogenic Effects:

No information available

Mutagenic Effects:

No information available

Aggravated Medical Conditions: Liver disease. Kidney disease. Diabetic ketoacidosis.

See Section 11 for additional Toxicological Information

POTENTIAL ENVIRONMENTAL EFFECTS

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Gliclazide	21187-98-4	100

4. FIRST AID MEASURES

General Advice:

Poison information centres in each State capital city can provide additional assistance for scheduled poisons (13 1126)

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if irritation develops.

Eye Contact:	Flush eye with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.
Inhalation:	Move to fresh air. If breathing is difficult, give oxygen. In case of shortness of breath, give oxygen. Get medical attention.
Ingestion:	Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.
Notes to Physician:	Treat symptomatically

5. FIRE-FIGHTING MEASURES

Flammable Properties

Flashpoint (°C/°F):	No information available.
----------------------------	---------------------------

Tested according to: Not available
--

Lower Explosion Limit (%):	No information available
-----------------------------------	--------------------------

Upper Explosion Limit (%):	No information available
-----------------------------------	--------------------------

Autoignition Temperature (°C/°F):	Not applicable.
--	-----------------

Suitable Extinguishing Media:	Carbon dioxide (CO ₂). Dry chemical. Water spray mist or foam.
--------------------------------------	--

Unsuitable Extinguishing Media:	No information available.
--	---------------------------

Hazardous Combustion Products:	Carbon monoxide; Carbon dioxide; Nitrogen oxides; Sulfur oxides
---------------------------------------	---

Specific hazards:	May be combustible at high temperatures.
--------------------------	--

Special Protective Equipment for Firefighters:	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear
---	---

Specific Methods:	No information available.
--------------------------	---------------------------

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Remove all sources of ignition.

Environmental Precautions:

No information available.

Methods for Cleaning Up:

Sweep up and shovel into suitable containers for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice:

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapours/dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Storage**Technical Measures/Storage Conditions:**

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Store away from incompatible materials.

Incompatible Products:

Oxidizing agents. Acids. Bases.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective Equipment

- Eye protection:** Safety glasses. Safety glasses with side-shields.
- Skin and body protection:** Long sleeved clothing. Chemical resistant apron. Gloves.
- Respiratory protection:** Wear respirator with dust filter.
- Hygiene measures:** Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

National occupational exposure limits**United States**

U.S Occupational Exposure Limits: Not determined

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Gliclazide - 21187-98-4	None	None	None	None

Canada

Canada Occupational Exposure Limits: Not determined

Components	Alberta	British Columbia	Ontario	Quebec
Gliclazide 21187-98-4	None	None	None	None

Australia and Mexico

Occupational Exposure Limits for Australia and Mexico: Not determined

Components	Australia	Mexico
Gliclazide 21187-98-4	None	None

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:

Solid.

Appearance:

Powder.

Color:

White. Off-white.

Odor:

No information available

Taste

No information available

Molecular/Formula weight:

323.41

Flash point (°C):

Not applicable

Lower Explosion Limit (%):

Not applicable

Upper Explosion Limit (%):

Not applicable

Autoignition Temperature (°C/°F):

No information available

pH:

No information available

Boiling point/range(°C/°F):

No information available

Melting point/range(°C/°F):

162-169 °C/323.6-336 °F

Decomposition temperature(°C/°F):

No information available

Specific gravity:

No information available

Density (g/cm³):

No information available

Bulk density:

No information available

Vapor pressure @ 20°C (kPa):

No information available

Vapor density:

No information available

Evaporation rate:

No information available

VOC content (g/L):

No information available

Odor threshold (ppm):

No information available

**Partition coefficient
(n-octanol/water):**

2.12

Miscibility:

No information available

Solubility:

Practically insoluble in water

Freely soluble in Methylene chloride

Slightly soluble in Ethanol

Sparingly soluble in Acetone

10. STABILITY AND REACTIVITY

Stability:

Stable at normal conditions

Conditions to avoid:

Heat. Avoid dust formation. Dust may form explosive mixture in air. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Incompatible materials.

Materials to avoid:

Strong oxidising agents. Acids. Bases.

Hazardous decomposition products:

Carbon monoxide. Carbon dioxide. Nitrogen oxides (NO_x). Sulphur oxides.

Possibility of Hazardous Reactions:

No information available

Polymerization:

Hazardous polymerisation does not occur

Corrosivity:

No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Acute Toxicity**Component Information**

Gliclazide - 21187-98-4

LD50/oral/rat =

3 g/kg Oral LD50 Rat (LOLI)

1750 mg/kg (RTECS)

LD50/oral/mouse = 3000 mg/kg

LD50/dermal/rabbit =

No information available

LD50/dermal/rat = No information available

LC50/inhalation/rat = No information available

LC50/inhalation/mouse = No information available

Other LD50 or LC50 information =

No information available

Product Information

LC50/inhalation/rat =

No information available

LC50/Inhalation/mouse = No information available

LD50/dermal/rabbit =

No information available

LD50/dermal/rat = No information available

LD50/oral/rat = 3 g/kg (LOLI)

1750 mg/kg (RTECS)

LD50/oral/mouse = 3000 mg/kg

Local Effects

Skin irritation:

May cause skin irritation.

Eye irritation:

Contact with eyes may cause irritation.

Inhalation:

May cause irritation of respiratory tract.

Ingestion:

May cause gastrointestinal disturbances. May cause abdominal pain. May cause diarrhea. May cause vomiting. May cause hypoglycemia (low blood sugar), which is characterized by symptoms such as blurred vision, chills, cold sweat, dizziness, drowsiness, shaking, rapid heart rate, confusion, weakness, headache, fainting, hunger, tingling of the hands or feet. May cause loss of appetite. May affect behavior/central nervous system (convulsions). May affect behavior/central nervous system (dizziness, drowsiness).

Sensitization:

No information available

Chronic Toxicity

Chronic Toxicity

Prolonged or repeated ingestion may affect the blood (normocytic anemia). Prolonged or repeated ingestion may affect the blood (changes in serum composition). Prolonged or repeated ingestion may affect the liver, and kidneys. Prolonged or repeated ingestion may affect the urinary system (increased urine volume). Prolonged or repeated ingestion may affect the liver (jaundice, liver function tests impaired). Prolonged or repeated ingestion may cause loss of appetite. Prolonged or repeated ingestion may affect respiration (pulmonary edema).

Carcinogenic effects:

Not considered carcinogenic

Components	NTP	IARC	OSHA HCS - Carcinogens	ACGIH - Carcinogens	Australia - Prohibited Carcinogenic Substances	Australia - Notifiable Carcinogenic Substances
Gliclazide	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects: No information available

Reproductive Effects: No information available

Teratogenic Effects: No information available

Target Organs: Pancreas. Liver. Kidneys.

12. ECOLOGICAL INFORMATION

ECOTOXICITY

Toxicity to terrestrial and aquatic plants and animals: No information available

Ecotoxicity effects: No data available.

Aquatic toxicity: No information available

Mobility: No information available

Persistence and degradability: No information available

Bioaccumulative potential: No information available

13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Gliclazide	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not regulated

Proper Shipping Name: No information available

Hazard Class: No information available

Packing Group: None

Subsidiary Risk: Not applicable

Marine Pollutant: No data available

ERG No: No information available

DOT RQ (lbs): No information available

TDG (Canada)

UN-No: Not Regulated

Proper Shipping Name: No information available

Hazard Class: No information available

Packing Group: No information available

Subsidiary Risk: No information available

Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available
CEFIC Tremcard No: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Description: No information available
IMDG Page: No information available
Marine Pollutant No information available
MFAG: No information available
Maximum Quantity: No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available
Classification Code: No information available
Description: No information available

ICAO

UN-No: Not Regulated
Hazard Class: No information available
Proper Shipping Name: No information available
Packing Group: No information available
Subsidiary Risk: No information available
Description: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available
Description: No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	Philippines (PICCS)	KOREA KECL	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
<i>Gliclazide</i>	Not Listed	Not present	KE-18563	Not present	Not present	Not present	244-260-5

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Gliclazide	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting <i>de minimis</i>
Gliclazide	None	None	None	None	None

U.S. TSCA

Components	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Gliclazide	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

Non-controlled

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Gliclazide	Not Listed	Not Listed

Components	CEPA Schedule I - Toxic Substances	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Gliclazide	Not listed	Not listed

EU Classification

R -phrase(s)

not determined

S -phrase(s)

none

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
Not dangerous

16. OTHER INFORMATION

The MSDS format complies with ANSI Z400.1-2004 standards.

Preparation Date	29-Jul-2011
Reason for revision:	Not applicable
Prepared by:	Sonia Owen
Literature reference:	No information available

All chemicals may pose unknown hazards and should be used with caution. This Material Safety Data Sheet (MSDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this MSDS. The physical properties reported in this MSDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this MSDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.