



# SAFETY DATA SHEET

Creation Date 04-Apr-2016

Revision Date 22-Jul-2016

Revision Number 2

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identification

**Product Description:** **Gliclazide**  
**Cat No. :** **461070000; 461070010; 461070050**  
**Synonyms** 1-(3-Azabicyclo[3.3.0]oct-3-yl)-3-p-tolylsulfonylurea  
**CAS-No** 21187-98-4  
**EC-No.** 244-260-5  
**Molecular Formula** C15 H21 N3 O3 S

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Recommended Use** Laboratory chemicals.  
**Uses advised against** No Information available

### 1.3. Details of the supplier of the safety data sheet

**Company** Acros Organics BVBA  
Janssen Pharmaceuticaaan 3a  
2440 Geel, Belgium  
**E-mail address** begel.sdsdesk@thermofisher.com

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

#### **Physical hazards**

Based on available data, the classification criteria are not met

#### **Health hazards**

Reproductive Toxicity

Category 2 (H361)

#### **Environmental hazards**

Based on available data, the classification criteria are not met

### 2.2. Label elements

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**Signal Word**

**Warning**

**Hazard Statements**

H361 - Suspected of damaging fertility or the unborn child

**Precautionary Statements**

P201 - Obtain special instructions before use

P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

P308 + P313 - IF exposed or concerned: Get medical advice/ attention

**2.3. Other hazards**

No information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1. Substances**

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008
Gliclazide	21187-98-4	EEC No. 244-260-5	>95	Repr. 2 (H361)

Full text of Hazard Statements: see section 16

## SECTION 4: FIRST AID MEASURES

**4.1. Description of first aid measures**

**General Advice**

If symptoms persist, call a physician.

**Eye Contact**

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

**Skin Contact**

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

**Ingestion**

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

**Inhalation**

Move to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

**Protection of First-aiders**

No special precautions required.

**4.2. Most important symptoms and effects, both acute and delayed**

None reasonably foreseeable.

**4.3. Indication of any immediate medical attention and special treatment needed**

**Notes to Physician**

Treat symptomatically.

ACR46107

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## SECTION 5: FIREFIGHTING MEASURES

### 5.1. Extinguishing media

#### **Suitable Extinguishing Media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### **Extinguishing media which must not be used for safety reasons**

No information available.

### 5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### **Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NO<sub>x</sub>), Sulfur oxides.

### 5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

### 6.2. Environmental precautions

Should not be released into the environment.

### 6.3. Methods and material for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

### 6.4. Reference to other sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for safe handling

Wear personal protective equipment. Ensure adequate ventilation. Avoid ingestion and inhalation. Avoid dust formation. Do not get in eyes, on skin, or on clothing.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Wash hands before breaks and at the end of workday.

### 7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. To maintain product quality: Keep refrigerated.

### 7.3. Specific end use(s)

Use in laboratories

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## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control parameters

#### Exposure limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies

#### Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

#### Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available

<u>Route of exposure</u>	<b>Acute effects (local)</b>	<b>Acute effects (systemic)</b>	<b>Chronic effects (local)</b>	<b>Chronic effects (systemic)</b>
Oral Dermal Inhalation				

**Predicted No Effect Concentration (PNEC)** No information available.

### 8.2. Exposure controls

#### Engineering Measures

None under normal use conditions.

#### Personal protective equipment

##### Eye Protection

Safety glasses with side-shields (European standard - EN 166)

##### Hand Protection

Protective gloves

<b>Glove material</b>	<b>Breakthrough time</b>	<b>Glove thickness</b>	<b>EU standard</b>	<b>Glove comments</b>
Nitrile rubber Neoprene Natural rubber PVC	See manufacturers recommendations	-	EN 374	(minimum requirement)

##### Skin and body protection

Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

##### Respiratory Protection

No protective equipment is needed under normal use conditions.

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<b>Large scale/emergency use</b>	Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced <b>Recommended Filter type:</b> Particle filter
<b>Small scale/Laboratory use</b>	Maintain adequate ventilation
<b>Environmental exposure controls</b>	No information available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

<b>Appearance</b>		
<b>Physical State</b>	Solid	
<b>Odor</b>	no data available	
<b>Odor Threshold</b>	No data available	
<b>pH</b>	No information available	
<b>Melting Point/Range</b>	163 - 169 °C / 325.4 - 336.2 °F	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	No information available	
<b>Flash Point</b>	No information available	<b>Method -</b> No information available
<b>Evaporation Rate</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available	
<b>Explosion Limits</b>	No data available	
<b>Vapor Pressure</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Specific Gravity / Density</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Water Solubility</b>	Insoluble	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Autoignition Temperature</b>		
<b>Decomposition Temperature</b>	No data available	
<b>Viscosity</b>	Not applicable	Solid
<b>Explosive Properties</b>	No information available	
<b>Oxidizing Properties</b>	No information available	

### 9.2. Other information

<b>Molecular Formula</b>	C15 H21 N3 O3 S
<b>Molecular Weight</b>	323.41

## SECTION 10: STABILITY AND REACTIVITY

<b><u>10.1. Reactivity</u></b>	None known, based on information available
<b><u>10.2. Chemical stability</u></b>	Stable under recommended storage conditions.
<b><u>10.3. Possibility of hazardous reactions</u></b>	
<b>Hazardous Polymerization</b>	No information available.
<b>Hazardous Reactions</b>	None under normal processing.
<b><u>10.4. Conditions to avoid</u></b>	Incompatible products.
<b><u>10.5. Incompatible materials</u></b>	

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Strong oxidizing agents. Acids. Bases.

## 10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides (NO<sub>x</sub>). Sulfur oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### Product Information

#### (a) acute toxicity;

Oral

Based on available data, the classification criteria are not met

Dermal

No data available

Inhalation

No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Gliclazide	LD50 = 3 g/kg (Rat)		

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

#### (d) respiratory or skin sensitization;

Respiratory

No data available

Skin

No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity; Category 2

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs

None known.

(j) aspiration hazard; Not applicable

Solid

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects, both acute and delayed No information available

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

#### Ecotoxicity effects

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

### 12.2. Persistence and degradability

Persistence

Insoluble in water.

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<b>12.3. Bioaccumulative potential</b>	May have some potential to bioaccumulate
<b>12.4. Mobility in soil</b>	Spillage unlikely to penetrate soil. Is not likely mobile in the environment due its low water solubility.
<b>12.5. Results of PBT and vPvB assessment</b>	No data available for assessment.
<b>12.6. Other adverse effects</b>	
<b>Endocrine Disruptor Information</b>	This product does not contain any known or suspected endocrine disruptors
<b>Persistent Organic Pollutant</b>	This product does not contain any known or suspected substance
<b>Ozone Depletion Potential</b>	This product does not contain any known or suspected substance

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>13.1. Waste treatment methods</b>	
<b>Waste from Residues / Unused Products</b>	Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.
<b>Contaminated Packaging</b>	Empty remaining contents. Dispose of in accordance with local regulations. Do not re-use empty containers.
<b>European Waste Catalogue (EWC)</b>	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
<b>Other Information</b>	Waste codes should be assigned by the user based on the application for which the product was used.

## SECTION 14: TRANSPORT INFORMATION

<b>IMDG/IMO</b>	Not regulated
<b>14.1. UN number</b>	
<b>14.2. UN proper shipping name</b>	
<b>14.3. Transport hazard class(es)</b>	
<b>14.4. Packing group</b>	
<b>ADR</b>	Not regulated
<b>14.1. UN number</b>	
<b>14.2. UN proper shipping name</b>	
<b>14.3. Transport hazard class(es)</b>	
<b>14.4. Packing group</b>	
<b>IATA</b>	Not regulated
<b>14.1. UN number</b>	
<b>14.2. UN proper shipping name</b>	
<b>14.3. Transport hazard class(es)</b>	
<b>14.4. Packing group</b>	
<b>14.5. Environmental hazards</b>	No hazards identified
<b>14.6. Special precautions for user</b>	No special precautions required
<b>14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	Not applicable, packaged goods

## SECTION 15: REGULATORY INFORMATION

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## 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

### International Inventories

Complete Regulatory Information contained in following SDS's X = listed The product is classified and labeled according to EC directives or corresponding national laws The product is classified and labeled in accordance with Directive 1999/45/EC Europe Korea U.S.A. (TSCA) Canada (DSL/NDSL) Europe (EINECS/ELINCS/NLP) Australia (AICS) Korea (ECL) China (IECSC) Japan (ENCS) Philippines (PICCS)

Component	EINECS	ELINCS	NLP	TSCA	DSL	NDSL	PICCS	ENCS	IECSC	AICS	KECL
Gliclazide	244-260-5	-		-	-	-	-	-	-	-	X

### National Regulations

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.

Take note of Dir 94/33/EC on the protection of young people at work

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

## 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

### Full text of H-Statements referred to under sections 2 and 3

H361 - Suspected of damaging fertility or the unborn child

### Legend

**CAS** - Chemical Abstracts Service

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**ENCS** - Japanese Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**PNEC** - Predicted No Effect Concentration

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - Volatile Organic Compounds

### Key literature references and sources for data

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

### Training Advice

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

**Creation Date** 04-Apr-2016

**Revision Date** 22-Jul-2016

**Revision Summary** Not applicable, SDS sections updated, 2, 3, 7.

**This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**



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## Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**