SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date 04-Sep-2017 **Revision date** 29-Aug-2020 **Revision Number** 3

1. Identification

1.1. Product identifier

Product Name **Glipizide Tablets and Extended-Release Tablets**
Active Ingredient **Glipizide**

Pure substance/mixture Mixture

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

Uses/ Identified uses Pharmaceutical
Uses advised against Use only as directed

1.3. Details of the supplier of the safety data sheet

Manufacturer

400 Interpace Parkway
Parsippany, NJ. 07054
USA

Teva Corporate Headquarters
5 Bazel Street PO Box 3190
Petah Tikva, Israel

For further information, please contact
E-mail address SDS.TevaIL@teva.co.il

1.4. Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]
International: +1-703-741-5970 (Chemtrec) [24-hours]

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Exempt from requirements - regulated as a medicinal product

2.2. Label elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

None known.

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
Glipizide	EEC No. Present	29094-61-9	Proprietary	No data available	No data available
Excipients	-	-	Remainder	-	No data available

4. First-aid measures

4.1. Description of first aid measures

Inhalation Remove to fresh air. If symptoms persist, call a physician.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If eye irritation persists: Get medical advice/attention.

Skin contact Wash off immediately with plenty of water. Get medical attention if symptoms occur.

Ingestion IF SWALLOWED. Rinse mouth thoroughly with water. Do NOT induce vomiting. Get medical attention if symptoms occur.

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

Symptoms No information available.

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

Note to physicians Treat symptomatically.

5. Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Water spray. Carbon dioxide (CO2). Foam. Dry sand. Halons.

Unsuitable extinguishing media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Thermal decomposition can lead to release of irritating gases and vapors.

5.3. Advice for firefighters

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Methods for containment No data available.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapor or mist. Provide a good standard of controlled ventilation (10 to 15 air changes per hour).

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with product label.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

8. Exposure controls/personal protection

8.1. Control parameters

Exposure Limits Not determined. Mixture.

TEVA OEL No exposure limits determined for this mixture.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls Provide a good standard of controlled ventilation (10 to 15 air changes per hour).

Personal protective equipment

Eye/face protection Use eye protection appropriate for the task.

Skin and body protection Wear suitable protective clothing.

Respiratory protection Use appropriate respiratory protection.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid

Appearance No information available

Color No information available

Odor No information available.

Odor threshold No information available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No information available.	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	
Partition coefficient n-octanol /water (log KOW)	No information available	

9.2. Other information

Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

10.1. Reactivity
Reactivity No information available.

10.2. Chemical stability
Stability Stable under normal conditions.
10.3. Possibility of hazardous reactions
Possibility of hazardous reactions None under normal processing.
10.4. Conditions to avoid
Conditions to avoid Heat, flames and sparks.
10.5. Incompatible materials
Incompatible materials None in particular.
10.6. Hazardous decomposition products
Hazardous decomposition products None known based on information supplied.

11. Toxicological information

11.1. Information on toxicological effects
Information on likely routes of exposure
Product Information .

Inhalation	No known effects under normal use conditions.
Eye contact	No known effects under normal use conditions.
Skin contact	No known effects under normal use conditions.
Ingestion	No known effects under normal use conditions.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No known effects under normal use conditions.
Serious eye damage/eye irritation	No known effects under normal use conditions.
Respiratory or skin sensitization	No known effects under normal use conditions.
Germ cell mutagenicity	No known effects under normal use conditions.
Carcinogenicity	No known effects under normal use conditions.
Reproductive toxicity	No known effects under normal use conditions.
STOT - single exposure	No known effects under normal use conditions.
STOT - repeated exposure	No known effects under normal use conditions.
Aspiration hazard	No known effects under normal use conditions.

12. Ecological information

12.1. Toxicity

Ecotoxicity No information available.

12.2. Persistence and degradability
Persistence and degradability No information available.
12.3. Bioaccumulative potential
Bioaccumulation No information available.

12.4. Mobility in soil
Mobility in soil No information available.
12.5. Results of PBT and vPvB assessment
PBT and vPvB assessment No information available.

12.6. Other adverse effects
Other adverse effects No information available.

13. Disposal considerations

13.1. Waste treatment methods
Waste from residues/unused products Dispose of in accordance with local regulations.
Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

IMDG
14.1 UN number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Marine pollutant Not applicable
14.6
14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

RID
14.1 UN number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6

ADR
14.1 UN number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Hazard class Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6

IATA
14.1 UN number Not regulated
14.2 UN proper shipping name Not regulated
14.3 Transport hazard class(es) Not regulated
14.4 Packing group Not regulated
14.5 Environmental hazards Not applicable
14.6

15. Regulatory information

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

European Union

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

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

16. Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

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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