

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078933856

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078940260



# 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 25-Apr-2018

Revision date 15-Jan-2020

Revision Number 2

## 1. Identification

### 1.1. Product identifier

Product Name **Enulose Lactulose Solution**  
Active Ingredient **Lactulose**

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

Teva Corporate Headquarters  
5 Basel Street PO Box 3190  
Petach Tikva, Israel

For further information, please contact

E-mail address SDS.TevalL@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
Lactulose	EEC No. Present	4618-18-2	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.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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## 5. Fire-fighting measures

### 5.1. Extinguishing media

Suitable Extinguishing Media	Water spray. Carbon dioxide (CO2). Foam. Dry sand. Halons.
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Unsuitable extinguishing media	No information available.
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### 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.
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### 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.
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## 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.
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### 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.
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## 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.
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### 7.3. Specific end use(s)

Risk Management Methods (RMM)	The information required is contained in this Material Safety Data Sheet.
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## 8. Exposure controls/personal protection

**8.1. Control parameters**

**Exposure Limits** Not determined. Mixture.

**TEVA OEL**

No occupational exposure limit values have been defined by authorities in production  
Country: Not Determined: 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** Tablets / Capsules  
**Appearance** No information available  
**Color** No information available  
**Odor** No information available.  
**Odor threshold** No information available

<b>Property</b>	<b>Values</b>	<b>Remarks • Method</b>
<b>pH</b>	No data available	None known
<b>Melting point / freezing point</b>	No data available	None known
<b>Boiling point / boiling range</b>	No data available	None known
<b>Flash point</b>	No data available	None known
<b>Evaporation rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	No information available.	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	
<b>Partition coefficient n-octanol /water (log KOW)</b>	No information available	
<b>9.2. Other information</b>		
<b>Softening point</b>	No information available	
<b>Molecular weight</b>	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.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Lactulose	= 18160 mg/kg ( Rat )		

### 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

Code

#### 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

<b>TSCA</b>	Contact supplier for inventory compliance status
<b>DSL/NDL</b>	Contact supplier for inventory compliance status
<b>EINECS/ELINCS</b>	Contact supplier for inventory compliance status
<b>ENCS</b>	Contact supplier for inventory compliance status
<b>IECSC</b>	Contact supplier for inventory compliance status
<b>KECL</b>	Contact supplier for inventory compliance status
<b>PICCS</b>	Contact supplier for inventory compliance status
<b>AICS</b>	Contact supplier for inventory compliance status

#### Legend:

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

**Issuing Date** 15-Jan-2020  
**Revision date** 15-Jan-2020

#### 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**

Region	Template name	Revision Note
European Union	EGHS	2.0

#### Key literature references and sources for data used to compile the SDS

ATSDR	Agency for Toxic Substances and Disease Registry (ATSDR)
CHEMVIEW not translate code	U.S. Environmental Protection Agency ChemView Database
EFSA not translate code	European Food Safety Authority (EFSA)
EPA not translate code	EPA (Environmental Protection Agency)
EPA_AEGL not translate code	Acute Exposure Guideline Level(s) (AEGL(s))
EPA_FIFRA not translate code	U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
EPA_HPVS not translate code	U.S. Environmental Protection Agency High Production Volume Chemicals
FOOD_JOURN not translate code	Food Research Journal
HSDB not translate code	Hazardous Substance Database
IUCLID not translate code	International Uniform Chemical Information Database (IUCLID)
JAPAN_GHS not translate code	Japan GHS Classification
NICNAS not translate code	Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH not translate code	NIOSH (National Institute for Occupational Safety and Health)
NLM_CIP not translate code	National Library of Medicine's ChemID Plus (NLM CIP)
NLM_PUBMED not translate code	National Library of Medicine's PubMed database (NLM PUBMED)
NTP not translate code	National Toxicology Program (NTP)
NZ_CCID not translate code	New Zealand's Chemical Classification and Information Database (CCID)
OECD_EHSP not translate code	Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
OECD_HPVS not translate code	Organization for Economic Co-operation and Development High Production Volume Chemicals Program
OECD_SIDS not translate code	Organization for Economic Co-operation and Development Screening Information Data Set
RTECS not translate code	RTECS (Registry of Toxic Effects of Chemical Substances)
WHO not translate code	World Health Organization

Sites Teva > Canada > 30Novo

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