



# 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-Feb-2010

Revision date 01-Sep-2020

Revision Number 15

## 1. Identification

### 1.1. Product identifier

**Product Name** PERGOLIDE MESYLATE  
**CAS No.** 66104-23-2  
**Chemical name** 6-n-propyl-8β-(methylthiomethyl)-ergoline methanesulphonate  
**Synonyms** Permax  
**Pure substance/mixture** Substance

Contains 6-n-propyl-8β-(methylthiomethyl)-ergoline methanesulphonate

**Formula** C<sub>19</sub> H<sub>26</sub> N<sub>2</sub> S. CH<sub>4</sub> O<sub>3</sub> S

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

**Uses/ Identified uses** Active Pharmaceutical Ingredient

**Uses advised against** No information available

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

#### Manufacturer

Teva Czech Industries s.r.o.                      Teva Corporate Headquarters  
Ostravská 29/305,                                      5 Bazel Street PO Box 3190  
747 70 Opava- Komárov,                              Petah Tikva, Israel  
Czech Republic

#### 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

Regulation (EC) No 1272/2008

<b>Acute toxicity - Oral</b>	Category 2 - (H300)
<b>Acute toxicity - Dermal</b>	Category 1 - (H310)
<b>Acute toxicity - Inhalation (Dusts/Mists)</b>	Category 2 - (H330)
<b>Carcinogenicity</b>	Category 2 - (H351)

Reproductive toxicity	Category 1B - (H360Fd)
Effects on or via lactation	Yes - (H362)

**2.2. Label elements**

Contains 6-n-propyl-8 $\beta$ -(methylthiomethyl)-ergoline methanesulphonate

**Signal word**

Danger

**Hazard statements**

H300 - Fatal if swallowed  
 H310 - Fatal in contact with skin  
 H330 - Fatal if inhaled  
 H351 - Suspected of causing cancer  
 H362 - May cause harm to breast-fed children  
 H360Fd - May damage fertility. Suspected of damaging the unborn child

**Precautionary Statements - EU (§28, 1272/2008)**

P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
 P262 - Do not get in eyes, on skin, or on clothing  
 P263 - Avoid contact during pregnancy and while nursing  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection  
 P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing  
 P310 - Immediately call a POISON CENTER or doctor  
 P403 + P233 - Store in a well-ventilated place. Keep container tightly closed

**Additional information**

This product requires tactile warnings if supplied to the general public. This product requires child resistant fastenings if supplied to the general public.

**2.3. Other hazards**

No information available

**3. Composition/information on ingredients****3.1 Substances**

Chemical Name	EC No	CAS No	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
6-n-propyl-8 $\beta$ -(methylthiomethyl)-ergoline methanesulphonate	-	66104-23-2	100	Acute Tox. 2 (H330) Acute Tox. 2 (H300) Acute Tox. 1 (H310) Carc. 2 (H351) Repr. 1B (H360Fd) Lact. (H362)	No data available

Full text of H- and EUH-phrases: see section 16

**4. First-aid measures**

#### 4.1. Description of first aid measures

<b>General advice</b>	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
<b>Inhalation</b>	If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen.
<b>Eye contact</b>	Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing.
<b>Skin contact</b>	Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Ingestion</b>	Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person.
<b>Self-protection of the first aider</b>	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information.

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

**Symptoms** Coughing and/ or wheezing. Difficulty in breathing.

#### 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** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**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. Combustible material.

#### 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. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Avoid generation of

dust. Do not breathe dust. Keep people away from and upwind of spill/leak.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

### **6.2. Environmental precautions**

**Environmental precautions** Prevent further leakage or spillage if safe to do so. Should not be released into the environment. Do not allow to enter into soil/subsoil. Prevent product from entering drains.

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

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate 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** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Take off contaminated clothing and wash before reuse. Do not breathe dust. Avoid generation of dust. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

**General hygiene considerations** Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

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

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

### **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**

**TEVA OEL** Teva OEL (8hr-TWA): 0.125 µg/m<sup>3</sup>

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

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

## 8.2. Exposure controls

### Personal protective equipment

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Hand protection** Wear suitable gloves. Impervious gloves.

**Skin and body protection** Impervious clothing. Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

**Respiratory protection** When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**General hygiene considerations** Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

**Environmental exposure controls** No information available.

## **9. Physical and chemical properties**

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

**Physical state** Solid; Powder  
**Appearance** No information available  
**Color** white  
**Odor** odorless.  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	No data available	None known
<b>Melting point / freezing point</b>	225 °C	
<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	
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	Slightly soluble	
<b>Solubility(ies)</b>	Soluble in Methanol , Ethanol	
<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

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.

#### Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions Hazardous polymerization does not occur.

### 10.4. Conditions to avoid

Conditions to avoid Excessive heat.

### 10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

### 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	Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on components).
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available. Fatal in contact with skin. (based on components).

**Ingestion** Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Coughing and/ or wheezing. Difficulty in breathing.

#### Numerical measures of toxicity

#### Acute toxicity

#### Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
6-n-propyl-8β-(methylthiomethyl)-ergoline methanesulphonate	15 mg/kg (Rat)		

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

**Skin corrosion/irritation** No information available.

**Serious eye damage/eye irritation** No information available.

**Respiratory or skin sensitization** No information available.

**Germ cell mutagenicity** No information available.

**Carcinogenicity** Classification based on data available for ingredients.

**Reproductive toxicity** Classification based on data available for ingredients. May cause harm to breastfed babies.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

## 12. Ecological information

### 12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

### 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. Dispose of waste in accordance with environmental legislation.

**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** UN2811  
**14.2 UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S.  
**14.3 Transport hazard class(es)** 6.1  
**14.4 Packing group** II  
**Description** UN2811, TOXIC SOLID, ORGANIC, N.O.S. (6-n-propyl-8β-(methylthiomethyl)-ergoline methanesulphonate), 6.1, II  
**14.5 Marine pollutant** Not applicable  
**14.6 Special Provisions** 274  
**EmS-No.** F-A, S-A  
**14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code** No information available

#### RID

**14.1 UN number** UN2811  
**14.2 UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S.  
**14.3 Transport hazard class(es)** 6.1  
**Labels** 6.1  
**14.4 Packing group** II  
**Description** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, II  
**14.5 Environmental hazards** Not applicable  
**14.6 Classification code** T2

#### ADR

**14.1 UN number** UN2811  
**14.2 UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S.  
**14.3 Hazard class** 6.1  
**Labels** 6.1  
**14.4 Packing group** II  
**Description** UN2811, TOXIC SOLID, ORGANIC, N.O.S. (6-n-propyl-8β-(methylthiomethyl)-ergoline methanesulphonate), 6.1, II  
**14.5 Environmental hazards** Not applicable  
**14.6 Special Provisions** 274, 614  
**Classification code** T2  
**Tunnel restriction code** (D/E)



**IATA**

<b>14.1 UN number</b>	UN2811
<b>14.2 UN proper shipping name</b>	TOXIC SOLID, ORGANIC, N.O.S.
<b>14.3 Transport hazard class(es)</b>	6.1
<b>14.4 Packing group</b>	II
<b>Description</b>	UN2811, TOXIC SOLID, ORGANIC, N.O.S. (6-n-propyl-8β-(methylthiomethyl)-ergoline methanesulphonate), 6.1, II
<b>14.5 Environmental hazards</b>	Not applicable
<b>14.6</b>	

**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

**Dangerous substance category per Seveso Directive (2012/18/EU)**

H1 - ACUTE TOXIC  
H2 - ACUTE TOXIC

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

**International Inventories**

<b>TSCA</b>	Contact supplier for inventory compliance status
<b>DSL/NDSL</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/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

#### Full text of H-Statements referred to under section 3

H300 - Fatal if swallowed  
 H310 - Fatal in contact with skin  
 H330 - Fatal if inhaled  
 H351 - Suspected of causing cancer  
 H360FD - May damage fertility. May damage the unborn child  
 H362 - May cause harm to breast-fed children

#### 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

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapor	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitization	Calculation method
Skin sensitization	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

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

Agency for Toxic Substances and Disease Registry (ATSDR)  
 U.S. Environmental Protection Agency ChemView Database  
 European Food Safety Authority (EFSA)  
 EPA (Environmental Protection Agency)  
 Acute Exposure Guideline Level(s) (AEGL(s))  
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
 U.S. Environmental Protection Agency High Production Volume Chemicals  
 Food Research Journal  
 Hazardous Substance Database  
 International Uniform Chemical Information Database (IUCLID)  
 Japan GHS Classification  
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
 NIOSH (National Institute for Occupational Safety and Health)  
 National Library of Medicine's ChemID Plus (NLM CIP)  
 National Library of Medicine's PubMed database (NLM PUBMED)  
 National Toxicology Program (NTP)  
 New Zealand's Chemical Classification and Information Database (CCID)  
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
 Organization for Economic Co-operation and Development Screening Information Data Set  
 RTECS (Registry of Toxic Effects of Chemical Substances)

World Health Organization

**Issuing Date** 04-Feb-2010

**Revision date** 01-Sep-2020

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

**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**