



Material Safety Data Sheet

TASMAR(R) Kernels/Tablets (100 mg)

1. Product and Company Identification

Product name	TASMAR(R) Kernels/Tablets (100 mg)	
Product code	24 6006 8	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone	001-973/235 50 00
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	
Roche Nutley Inventory Code	27070652	
Characterization	final product	

2. Composition/Information on ingredients

Ingredients	Concentration
Tolcapone CAS: 134308-13-7	~ 60 %
Microcrystalline cellulose CAS: 9004-34-6	~ 9 %
Talc CAS: 14807-96-6	< 1 %
Sodium starch glycolate CAS: 9063-38-1	~ 6 %
Dibasic calcium phosphate, anhydrous CAS: 7757-93-9	~ 14 %

3. Hazards identification

Emergency Overview

Form	solid
Color	beige
Hazard Overview	- Do not allow the material to enter the sewers or waterways

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Potential Health Effects	<ul style="list-style-type: none">- Exposure: Ingestion- Target Organs: skin, eyes, mucous membranes, gastrointestinal system, Central nervous system- Acute Effects: May cause eye irritation., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.- Chronic Effects: No adverse effects known- Carcinogenicity: formulation not listed by NTP, IARC or OSHA- Carcinogenicity: IARC Gr3 not classifiable *1
Additional Health Information	<ul style="list-style-type: none">- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Liver conditions and/or impaired liver function.

*1 referring to: Talc

4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

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6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Environmental protection	- do not allow to enter drains or waterways
Methods for cleaning up	- Scoop or shovel spilled material into a suitable labeled open head drum - Secure the drum cover and move the container to a safe holding area - Clean spill area thoroughly - Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. - Check area for residual material and repeat clean up if detected

7. Handling and storage

Handling

Technical measures	- local exhaust ventilation necessary - avoid dust formation; consider dust explosion hazard
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Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place
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8. Exposure controls/Personal protection

Engineering Measures	- see 7.
Threshold value (USA) air	- ACGIH-TLV: 2 mg/m ³ (not classifiable as a human carcinogen, respirable fraction) *1 - ACGIH-TLV: 10 mg/m ³ *2 - ACGIH-TLV: 10 mg/m ³ *3 - ACGIH-TLV: 10 mg/m ³ *4
Threshold value (Roche) air	- IOEL: 1.0 mg/m ³ *5
Personal protective equipment	
Respiratory protection	- Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. - respiratory protection not necessary
Hand protection	- protective gloves
Eye protection	- safety glasses

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Body protection - protective clothing

*1 referring to: Talc
*2 referring to: Sodium starch glycolate
*3 referring to: Microcrystalline cellulose
*4 referring to: Dibasic calcium phosphate, anhydrous
*5 referring to: Tolcapone

9. Physical and chemical properties

Color beige

Form solid

10. Stability and reactivity

Stability - stable under normal conditions

Conditions to avoid - None known

Materials to avoid - None known

11. Toxicological information

Acute toxicity - LD₅₀ 1'600 mg/kg (oral, rat) *5

Local effects - eye: irritant (rabbit) *5

Sensitization - not sensitizing (several species) *5

Mutagenicity - not mutagenic (various in vivo and in vitro test systems) *5

Carcinogenicity - no indication for carcinogenicity (man) *5

Reproduction toxicity - not teratogenic (several species) *5
- elevation of abortion rate (>= 100 mg/kg/d, rabbit) *5

*5 referring to: Tolcapone

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12. Ecological information

Ready biodegradability	<ul style="list-style-type: none"> - not readily biodegradable 2.3 %, 28 d (FDA Technical Assistance Document No. 3.11) 	*5
Inherent biodegradability	<ul style="list-style-type: none"> - inherently biodegradable 48 %, 28 d (MITI Test II, OECD No. 302 C) 	*5
Ecotoxicity	<ul style="list-style-type: none"> - strongly toxic for fish (rainbow trout) EC₅₀ (96 h) 1.49 mg/l NOEC (96 h) 1.08 mg/l (FDA Technical Assistance Document No. 4.11) - moderately toxic for planktonic crustaceans (Daphnia magna) EC₅₀ (48 h) 19.8 mg/l NOEC (48 h) 9.66 mg/l (FDA Technical Assistance Document No. 4.08) - strongly toxic for algae (Selenastrum capricornutum) EC₀ (10 d) 0.915 mg/l NOEC (10 d) 0.469 mg/l (FDA Technical Assistance Document No. 4.01) - barely toxic for microorganisms (activated sludge) NOEC (3 h) 50 mg/l (OECD No. 209) 	*5 *5 *5
Mobility	<ul style="list-style-type: none"> - low mobility (Soil-Water, 25 °C) K_{oc} = 31009 (silty loam) K_{oc} = 76757 (clay loam) K_{oc} = 35979 (loam) (FDA Technical Assistance Document No. 3.08) 	*5
*5 referring to:	Tolcapone	

13. Disposal considerations

Waste from residues	<ul style="list-style-type: none"> - incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal
Contaminated packaging	<ul style="list-style-type: none"> - Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	<ul style="list-style-type: none"> - not regulated under RCRA

14. Transport information

Note	<ul style="list-style-type: none"> - not classified by transport regulations, proper shipping name non-regulated
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15. Regulatory information

TSCA Status	<ul style="list-style-type: none"> - FDA Exemption - not on inventory - On TSCA inventory*1 - On TSCA inventory*2 - On TSCA inventory*3
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Reporting Requirements

- On TSCA inventory*4
- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which enter a waterway or into soil, or which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

*1 referring to:

Talc

*2 referring to:

Sodium starch glycolate

*3 referring to:

Microcrystalline cellulose

*4 referring to:

Dibasic calcium phosphate, anhydrous

16. Other information

Use

- Tasmar is an antiparkinsonian agent.

Edition documentation

- first edition

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.