

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material	PARNATE TABLETS
Synonyms	PARNATE TABLETS 10 MG * NDC NO 0007-4471-20 * NDC NO 0007-4471-64 * TRANYLCPROMINE SULPHATE, FORMULATED PRODUCT
Company Name	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response GlaxoSmithKline, Corporate Environment, Health & Safety 2200 Renaissance Blvd, Suite 105 King of Prussia, PA 19406 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
TRANYLCPROMINE SULFATE	13492-01-8	7.5
NON-HAZARDOUS INGREDIENTS	Unassigned	92.5

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
* Health	Caution - Pharmaceutical agent. Exposure might occur via ingestion skin eyes. Harmful by ingestion. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: increased heart rate; sweating; hallucinations; restlessness; agitation; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing). Health effects information is based on hazards of components.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of tranylcypromine .
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product. Ocular symptoms may be indicative of allergic reaction.
Health Surveillance Procedures	Exposed individuals are encouraged to report symptoms of skin and respiratory irritation to an occupational health professional or line management. These symptoms may include, but are not limited to, skin conditions, bronchitis, asthma, or nasal irritation.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE**HANDLING**

General Requirements	Avoid breaking or crushing tablets.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT

TRANYLCYPROMINE SULFATE

GSK Occupational Hazard Category

3

GSK Occupational Exposure Limit

30 MCG/M3 (8 HR TWA)

*** Other Equipment or Procedures**

Wear appropriate clothing to avoid skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance**Colour**

Geranium red.

Physical Form

Sugar-coated tablet.

10. STABILITY AND REACTIVITY

Stability

This product is expected to be stable.

Conditions to Avoid

None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity

Adverse effects might occur following ingestion.

Inhalation Toxicity

No studies have been conducted.

Skin Effects

Irritation is not expected following direct contact.

Eye Effects

Irritation is not expected following direct contact with eyes.

Target Organ Effects

Adverse effects might occur in the following organ(s) following overexposure: cardiovascular system; central nervous system.

Sensitisation

Allergic skin reactions might occur following dermal exposure.

Genetic Toxicity

Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity

No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects

Insufficient information available to classify for reproductive toxicity.

*** Pharmacological Effects**

This preparation contains ingredient(s) with the following activity: a monoamine oxidase inhibitor.

*** Other Adverse Effects**

None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary

No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations

Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements

Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

* EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 15-Aug-2005

SDS Version Number 9

SDS Sections Updated

Sections

COMPOSITION / INFORMATION ON INGREDIENTS
EXPOSURE CONTROLS / PERSONAL PROTECTION
HAZARDS IDENTIFICATION
REGULATORY INFORMATION
TOXICOLOGY INFORMATION

Subsections

Other Equipment or Procedures
Health

Other Adverse Effects
Pharmacological Effects

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.