

MATERIAL SAFETY DATA SHEET



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

Material **DORALESE TILTAB TABLETS**

Tradenames/Synonyms DORALESE TABLETS 20 MG * INDORAMIN HYDROCHLORIDE, FORMULATED PRODUCT * D1003587

Company Name GlaxoSmithKline, Environment Health & Safety
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2 COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
INDORAMIN HYDROCHLORIDE	38821-52-2	8
OPADRY	Unassigned	2
AMBERLITE	Unassigned	2
NON-HAZARDOUS INGREDIENTS	Unassigned	88

3 HAZARDS IDENTIFICATION

HEALTH HAZARDS

Skin Contact Potential to produce irritation or allergic reaction is not known. Itching, redness or swelling might occur immediately or after repeated contact.

Eye Contact Potential to produce irritation is not known. Assume symptoms might include redness or swelling.

Inhalation Not expected to occur during normal handling of this product.

Ingestion Effects after overexposure might include drowsiness or sedation.

Conditions Aggravated by Exposure None for occupational exposure.

ENVIRONMENTAL HAZARDS

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

4 FIRST-AID MEASURES

Skin Contact In the event of occupational skin contact, wash contaminated area thoroughly.

Eye Contact Flush eyes continuously with water for at least 15 minutes. Do not use a chemical neutraliser. Obtain medical assistance if symptoms occur.

Inhalation No specific first-aid recommendations for routine handling.

Ingestion	In the event of occupational ingestion, seek medical advice. Induction of vomiting is not a recommended first-aid procedure.
Notes to Physician	None. This material is a prostate selective alpha-1 receptor antagonist indicated for treatment of benign prostatic hyperplasia.
Antidotes	No specific antidotes known.

5 FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Fire Control	This material is expected to be combustible. 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 material 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 Decomposition Products	None for normal handling of this material. Toxic, corrosive or flammable thermal decomposition products are expected when the material is exposed to fire.

6 ACCIDENTAL RELEASE MEASURES

Spills	No special requirements for spills from single containers. For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems. Use protective clothing during clean-up prior to disposal of spilled material.
Decontamination Procedures	Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this substance.

7 HANDLING AND STORAGE

Handling	Avoid breaking or crushing tablets.
Storage	No storage requirements necessary for occupational hazards. Follow storage recommendations for the product.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

INDORAMIN HYDROCHLORIDE

SB Hazard Category	2
SB Personal Exposure Limit	400 MCG/M3 8 HR TWA
Allowable Daily Limit	4 mg/day

PERSONAL PROTECTIVE EQUIPMENT

Other Equipment or Procedures	Wash hands and arms thoroughly after handling. None required for normal handling.
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9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Colour	Light yellow.
Physical Form	Film-coated tablet.
Solubility (Water)	Most components are soluble in water.

10 STABILITY AND REACTIVITY

Stability This material is expected to be stable.

11 TOXICOLOGICAL INFORMATION

Oral Toxicity Low oral toxicity based on extensive use in humans.

Inhalation Toxicity No studies have been conducted.

Skin Toxicity Irritation might occur based on effects of individual components.

Eye Effects Irritation is not expected based on effects of individual components.

Sensitisation Sensitisation (allergic skin reaction) might occur, based on effects of individual components.

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

12 ECOLOGICAL INFORMATION

Summary No information is available about the potential of this material 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. Observe all local and national regulations when disposing of this material. In addition, all current local and national requirements must be observed when disposing of this material. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. SmithKline Beecham operations should refer to SB Standard E-1 and associated guidance G-E-1 for additional information.

14 TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release.

Classification and Labelling Transportation and shipping of this material 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

European Union Classification and Labelling No European Union labelling requirements.

US Environmental (EPA) Requirements No US EPA reporting requirements.

US OSHA Labeling Requirements No specific OSHA labeling requirements.

16 OTHER INFORMATION

INFORMATION ON HAZARD LABELLING:

DORALESE TILTAB TABLETS

This product is exempt from hazard labelling requirements since it is regulated either as a medicine or cosmetic product.

References

SB HAZARD DETERMINATION

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MSDS Sections Updated

Sections

EXPOSURE CONTROLS / PERSONAL PROTECTION
REGULATORY INFORMATION
TOXICOLOGY INFORMATION

Subsections

Other Equipment or Procedures
US OSHA Labeling Requirements
Carcinogenicity