SAFETY DATA SHEET

GlaxoSmithKline

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

Material **REQUIP TABLETS**

Synonyms REQUIP 0.25mg TABLETS * REQUIP 0.5mg TABLETS * REQUIP 1mg TABLETS * REQUIP 2mg TABLETS * REQUIP 3mg TABLETS * REQUIP 4mg TABLETS * REQUIP 5mg TABLETS * NDC NO. 0007-4890-14 * NDC NO. 0007-4890-20 * NDC NO. 0007-4890-61 * NDC NO. 0007-4890-62 * NDC NO. 0007-4890-63 * NDC NO. 0007-4890-64 * NDC NO. 0007-4890-65 * NDC NO. 0007-4890-66 * NDC NO. 0007-4891-20 * NDC NO. 0007-4891-61 * NDC NO. 0007-4891-64 * NDC NO. 0007-4892-20 * NDC NO. 0007-4892-61 * NDC NO. 0007-4893-20 * NDC NO. 0007-4893-61 * NDC NO. 0007-4893-62 * NDC NO. 0007-4893-63 * NDC NO. 0007-4894-20 * NDC NO. 0007-4895-20 * NDC NO. 0007-4895-61 * NDC NO. 0007-4896-20 * ROPINIROLE HYDROCHLORIDE, FORMULATED PRODUCT

Company Name

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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
ROPINIROLE	91374-20-8	4
NON-HAZARDOUS INGREDIENTS	Unassigned	96

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

*** Health** Caution - Pharmaceutical agent.
Exposure might occur via skin; eyes; ingestion.
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	Medical treatment in cases of overexposure should be treated as an overdose of D2-dopamine agonist. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
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 or foam extinguishers are recommended. Carbon dioxide or dry powder 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	No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements	Avoid breaking or crushing tablets.
STORAGE	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	ROPINIROLE	
GSK Occupational Hazard Category	3	
GSK Occupational Exposure Limit	20 MCG/M3 (8 HR TWA)	REPRODUCTIVE HAZARD

ENGINEERING CONTROLS

Containment	Open handling may result in overexposure.
Ventilation	Local exhaust ventilation (LEV) should be used in conjunction with other control measures as a means of removing material incidentally released.
Administrative	Entry to the working area should be controlled. Only authorised personnel may enter the working area.
Other Equipment or Procedures	None required for normal handling. Wear appropriate clothing to avoid skin contact.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	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	Not expected to be toxic 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.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
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	Not expected to produce adverse effects on fertility or development under occupational exposure conditions. Contains components which have been classified as: Known or presumed to affect the quantity and quality of breast milk in humans.
Pharmacological Effects	This product contains active ingredient(s) with the following activity: a dopaminergic agonist.

12. ECOLOGICAL INFORMATION

*** Summary**

This material contains an active pharmaceutical ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration

This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: 500 mg/L, 3 Hours, Residential sludge

Microtox

Microtox is a general toxicity test which utilizes a sensitive marine photo bacteria as the test species. This material contains an active pharmaceutical ingredient that is not toxic to these microorganisms.

EC50: 362 mg/L, 15 Minutes

*** Algal**

This material contains an active pharmaceutical ingredient that is harmful to algae.

IC50: 29.3 mg/L, 72 Hours, Selenastrum capricornutum, green algae

NOEL: 8.8 mg/L, 72 Hours, Selenastrum capricornutum, green algae

*** Daphnid**

This material contains an active pharmaceutical ingredient that is harmful to daphids.

EC50: 41.1 mg/L, 48 Hours, Daphnia magna, Static test

NOEL: 4.4 mg/L, 48 Hours, Daphnia magna, Static test

*** Fish**

This material contains an active pharmaceutical ingredient that is harmful to fish.

Adult Lepomis macrochirus, bluegill sunfish

EC50: 11 mg/L, 96 Hours, Static test

Adult Lepomis macrochirus, bluegill sunfish

NOEL: 3.7 mg/L, 96 Hours, Static test

MOBILITY

*** Solubility**

This material contains an active pharmaceutical ingredient that for environmental fate predictions has solubility in water.

*** Volatility**

This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 5.67E-07 atm m^3/mol, Calculated

*** Adsorption**

This material contains an active pharmaceutical ingredient that is not likely to adsorb to sludge or biomass if released directly to the environment.

Soil Sediment Sorption (log Koc): 0.74, Calculated at pH 7

Sludge Biomass Distribution Coefficient (log Kd): 1.92 Measured

*** Partitioning** This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

*** Hydrolysis** This material contains an active pharmaceutical ingredient that has been shown to be chemically unstable in water. Hydrolysis may be a significant depletion mechanism.

Half-Life, Neutral: 163 Days, Measured

Photolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water when exposed to light. Aqueous photolysis is unlikely to be a significant depletion mechanism.

Half-Life, Aqueous: 433 to 13700 Days, Measured

*** Biodegradation** This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

*** BIOACCUMULATION** This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

Bioconcentration Factor: 1 Estimated

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 17-Dec-2004 **SDS Version Number** 16

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	
HAZARDS IDENTIFICATION	Health

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.