SAFETY DATA SHEET

1. Identification

Product identifier **RETIGABINE IR TABLET**

Other means of identification Not available.

Synonym(s) POTIGA * TROBALT * POTIGA TABLETS (50 MG, 100 MG, 200 MG, 300 MG , 400 MG) * TROBALT TABLETS (50 MG, 100 MG, 200 MG, 300 MG , 400 MG) * EZOGABINE IMMEDIATE RELEASE TABLETS * RETIGABINE IMMEDIATE RELEASE TABLETS * RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE) * RETIGABINE, FORMULATED PRODUCT

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
RETIGABINE	GW582892X RETIGABIN EZOGABINE N-2(-AMINO-4-(4-FLUOROBENZYLAMINO)- ACID ETHYL ESTER RETIGABINE PURE - UNSCREENED (AMRI RENSSELAER INC)	150812-12-7	60.0 - 63.0
Other components below reportable levels			>35.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

Skin contact Remove and isolate contaminated clothing and shoes.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion	Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: dizziness; somnolence; fatigue; weakness; memory effects; headache; dyspeptic symptoms; nausea; diarrhoea; constipation; abnormal nervous system sensations; blurred vision; vertigo; tremor; incoordination; mental impairment; anxiety; malaise; hallucinations; nervousness; anaemia; irregular heartbeat.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	In the event of fire, cool tanks with water spray.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Immediately evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	This material is classified as a water pollutant under the Clean Water Act and should be prevented from contaminating soil or from entering sewage and drainage systems which lead to waterways. Stop the flow of material, if this is without risk. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not taste or swallow. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
RETIGABINE (CAS 150812-12-7)	8 HR TWA	2000 mcg/m3	SKIN
	OHC	1	
	Short Term Excursion	5000 mcg/m3	

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

Eye/face protection	If contact is likely, safety glasses with side shields are recommended.

Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Wear suitable protective clothing.
Respiratory protection	Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Keep away from food and drink. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance	
Physical state	Solid.
Form	Tablet.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Toxic if swallowed.

Inhalation Prolonged inhalation may be harmful. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Health injuries are not known or expected under normal use.

Eye contact Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: dizziness; fatigue; weakness; memory effects; headache; dyspeptic symptoms; nausea; diarrhoea; constipation; abnormal nervous system sensations; blurred vision; vertigo; tremor; incoordination; mental impairment; anxiety; malaise; hallucinations; nervousness; anaemia; weight gain; swelling; irregular heartbeat.

Information on toxicological effects

Acute toxicity Toxic if swallowed.

Components	Species	Test Results
RETIGABINE (CAS 150812-12-7)		
Acute		
Oral		
LD	Rat	100 mg/kg
Chronic		
Oral		
NOAEL	Rat	5.1 mg/kg/day, 90-day
Subchronic		
Oral		
NOAEL	Dog	< 4.64 mg/kg/day, 52 weeks
		3 mg/kg/day, 13 weeks
	Rat	17.8 mg/kg/day, 26 weeks
		10 mg/kg/day, 13 weeks

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity
RETIGABINE
Result: Non-irritant
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye
RETIGABINE
Reconstituted Human Corneal Epithelium (HCE)
Result: Negative; not likely to be a severe irritant

Respiratory sensitization Not available.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization
RETIGABINE
Buehler assay
Result: Negative

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

RETIGABINE
Rat UDS assay
Result: Negative
bacterial mutation assay (Ames)
Result: Negative
human peripheral lymphocyte test (chromosome aberration)
Result: Positive
in vitro UDS assay
Result: Negative
mammalian cell mutation assay (CHO/HGPRT forward mutation assay)
Result: Negative
mouse micronucleus assay
Result: Negative

Carcinogenicity
RETIGABINE
ICH S1B
Result: Negative
Species: Rat
Test Duration: 2 years

Carcinogenicity

RETIGABINE — Neonatal, Dose day 8 and day 15
Result: Negative
Species: Mouse
Observation Period: 1 years

Reproductive toxicity — Contains no ingredient listed as toxic to reproduction

RETIGABINE — 4.64 - 46.4 mg/kg/day Fertility and general reproductive performance
Result: Negative
Species: Rat

Specific target organ toxicity - single exposure — None known.

Specific target organ toxicity - repeated exposure — None known.

Aspiration hazard — Not likely, due to the form of the product.

Chronic effects — Prolonged inhalation may be harmful.

Further information — Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity — No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
RETIGABINE (CAS 150812-12-7)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, OECD 209
	NOEC	Residential sludge	100 mg/l, 3 hours
Algae	EC50	Green algae (Pseudokirchnereilla subcapitata)	0.13 mg/l, 72 hours, Measured, OECD 201
	NOEC	Green algae (Pseudokirchnereilla subcapitata)	0.037 mg/l, 72 hours
Chronic			
Crustacea	LOEC	Water flea (Daphnia magna)	3.1 mg/l, 21 days, Measured, OECD 211
	NOEC	Water flea (Daphnia magna)	0.9 mg/l, 21 days
Fish	Growth test LOEC	Fathead minnow (Juvenile Pimephales promelas)	0.1 mg/l, 28 days, Measured, OECD 210
	Growth test NOEC	Fathead minnow (Juvenile Pimephales promelas)	0.032 mg/l, 28 days
Other	LOEC	Chironomid (Chironomus riparius)	100 mg/l, 28 days, Measured , OECD 218
	NOEC	Chironomid (Chironomus riparius)	32 mg/l, 28 days

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Photolysis
UV/visible spectrum wavelength
RETIGABINE — 304 nm Measured, pH 1-13

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)
RETIGABINE — 2.18 (Measured).

Mobility in soil

Adsorption
Soil/sediment sorption - log Kd
RETIGABINE — 1.3 - 2.2 Measured

Mobility in general

Distribution
Octanol/water distribution coefficient log DOW
RETIGABINE — 2.1 Measured., pH 5
2.2 Measured., pH 7

Distribution

Octanol/water distribution coefficient log DOW

RETIGABINE	2.2 Measured., pH 9

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN3249
UN proper shipping name	Medicine, solid, toxic, n.o.s. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE)), MARINE POLLUTANT
Transport hazard class(es)	6.1
Subsidiary class(es)	Not available.
Packing group	III
Special precautions for user	Not available.
Labels required	6.1
Special provisions	T3, TP33
Packaging exceptions	153
Packaging non bulk	213
Packaging bulk	240
Qty limits cargo	200 kg
Qty limits passenger	100 kg

IATA

UN number	UN3249
UN proper shipping name	Medicine, solid, toxic, n.o.s. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE))
Transport hazard class(es)	6.1
Subsidiary class(es)	-
Packaging group	III
Labels required	6.1
ERG Code	6L
Passenger & cargo	Allowed.
Additional Information:	
Packaging Instruction	670
Pkg Inst cargo only	677
Pkg Inst passenger & cargo	Y645
SP see 44	A3,A801
Max net qty pkg	100 kg
Max net qty pkg cargo only	200 kg
Max net qty pkg LQ	10 kg

IMDG

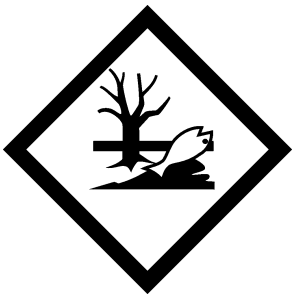
UN number	UN3249
UN proper shipping name	MEDICINE, SOLID, TOXIC, N.O.S. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE))
Transport hazard class(es)	6.1(PGIII)
Subsidiary class(es)	T2
Packaging group	III
Environmental hazards	
Marine pollutant	Yes
Labels required	6.1

EmS	Not available.
Special precautions for user	Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

General information DOT Regulated Marine Pollutant. IMDG Regulated Marine Pollutant.

DOT; IATA

Marine pollutant



15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - No Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No
SARA 311/312 Hazardous chemical	No

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
Food and Drug Administration (FDA)	Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	10-30-2013
Revision date	10-30-2013
Version #	06
Further information	This material has not been assessed for HMIS or NFPA ratings.
References	GSK Hazard Determination
Disclaimer	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.
Revision Information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Transport Information: Proper Shipping Name/Packing Group Regulatory Information: Risk Phrases - Labeling GHS: Classification