SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	RETIGABINE IR TABLET
Registration number	-
Synonyms	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
Issue date	30-October-2013
Version number	06
Revision date	30-October-2013
Supersedes date	28-October-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	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.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent.
See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
RETIGABINE	60.0 - 63.0	150812-12-7 -	-	-	

Classification: **DSD:** T;R23/25, N;R50/53

CLP: Acute Tox. 3;H301, Acute Tox. 3;H331, Aquatic Acute 1;H400, Aquatic Chronic 1;H410

Other components below reportable levels >35.0

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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.

4.1. Description of 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.

4.2. Most important symptoms and effects, both 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.

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures In the event of fire, cool tanks with water spray.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Immediately evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. 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.

7.2. 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).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- 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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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.

Environmental exposure controls

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Tablet.

Colour	Not available.
Odour	Not available.
Odour 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.
Vapour pressure	Not available.
Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents. Fluorine.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
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	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.

11.1. 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 sensitisation Due to partial or complete lack of data the classification is not possible.

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

Sensitisation
RETIGABINE
Buehler assay
Result: negative

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Mutagenicity
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
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

Reproductive toxicity

Reproductivity
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.
Mixture versus substance information	No information available.
Other information	Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity 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.

12.2. Persistence and degradability

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

RETIGABINE 304 nm Measured, pH 1-13

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

RETIGABINE 5 - 10 % , 99 days, Aquatic-sediment, OECD 308

Percent degradation (Aerobic biodegradation-ready)

RETIGABINE < 5 % , 28 days, BOD, OECD 301F

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

RETIGABINE 2.18 (Measured).

12.4. 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
2.2 Measured., pH 9

12.5. Results of PBT and vPvB assessment	Not available.
12.6. Other adverse effects	Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	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.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

General	IMDG Regulated Marine Pollutant.
ADR	
14.1. UN number	UN3249
14.2. UN proper shipping name	Medicine, solid, toxic, n.o.s. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE))
14.3. Transport hazard class(es)	6.1(PGIII)
Subsidiary class(es)	-
14.4. Packing group	III
14.5. Environmental hazards	No
Tunnel code	E
Labels required	6.1
Additional information:	
Special Provisions	221, 274, 601
IATA	
14.1. UN number	UN3249
14.2. UN proper shipping name	Medicine, solid, toxic, n.o.s. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE))
14.3. Transport hazard class(es)	6.1
Subsidiary class(es)	-
14.4. Packing group	III
Labels required	6.1
Additional Information:	
Passenger & cargo	Allowed.
Packaging Instruction	670
Pkg Inst cargo only	677
Pkg Inst pasenger & cargo	Y645
LQ	
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	
14.1. UN number	UN3249
14.2. UN proper shipping name	MEDICINE, SOLID, TOXIC, N.O.S. (RETIGABINE IMMEDIATE RELEASE TABLETS (CONTAINING 60% - 63% RETIGABINE))
14.3. Transport hazard class(es)	6.1(PGIII)
Subsidiary class(es)	T2
14.4. Packing group	III

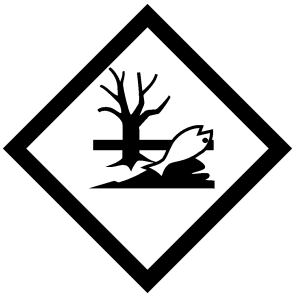
14.5. Environmental hazards

Marine pollutant	Yes
Labels required	6.1
14.6. Special precautions for user	Not available.
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

ADR

IATA

Marine pollutant



SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R23/25 Toxic by inhalation and if swallowed. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R51 Toxic to aquatic organisms. H301 Toxic if swallowed. H331 Toxic if inhaled. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Revision information	This document has undergone significant changes and should be reviewed in its entirety.
Training information	Follow training instructions when handling this material.
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.