

## SAFETY DATA SHEET



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

<b>Material</b>	<b>AVANDIA TABLETS</b>
<b>Synonym(s)</b>	BRL-49653-C TABLETS * AVANDIA 1 MG TABLETS * AVANDIA 2 MG TABLETS * AVANDIA 4 MG TABLETS * AVANDIA 8 MG TABLETS * NDC NO. 0029-3158-13 * NDC NO. 0029-3158-18 * NDC NO. 0029-3158-20 * NDC NO. 0029-3158-21 * NDC NO. 0029-3158-25 * NDC NO. 0029-3158-38 * NDC NO. 3158-61 * NDC NO. 3158-62 * NDC NO. 3158-65 * NDC NO. 3158-66 * NDC NO. 0029-3158-90 * NDC NO. 0029-3159-13 * NDC NO. 0029-3159-18 * NDC NO. 0029-3159-20 * NDC NO. 0029-3159-21 * NDC NO. 0029-3159-25 * NDC NO. 0029-3159-38 * NDC NO. 3159-61 * NDC NO. 3159-62 * NDC NO. 3159-65 * NDC NO. 3159-67 * NDC NO. 0029-3159-90 * NDC NO. 0029-3160-13 * NDC NO. 0029-3160-17 * NDC NO. 0029-3160-20 * NDC NO. 0029-3160-21 * NDC NO. 0029-3160-24 * NDC NO. 0029-3160-23 * NDC NO. 0029-3160-25 * NDC NO. 0029-3160-28 * NDC NO. 0029-3160-38 * NDC NO. 3160-61 * NDC NO. 0029-3160-90 * NDC NO. 3159-78 * NDC NO. 3159-79 * NDC NO. 3160-67 * ROSIGLITAZONE MALEATE, FORMULATED PRODUCT
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>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</p> <p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
NON-HAZARDOUS INGREDIENTS	Unassigned	99	
ROSIGLITAZONE MALEATE	155141-29-0	1	

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	Expected to be non-combustible.
<b>Health</b>	Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.
<b>Environment</b>	This material contains an active pharmaceutical ingredient that may have reproductive or developmental effects on environmental organisms.

## 4. FIRST-AID MEASURES

<b>Ingestion</b>	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.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	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.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Medical treatment in cases of overexposure should be treated as an overdose of a drug for the treatment of Type 2 diabetes. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	None for occupational exposure.
<b>Antidotes</b>	No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Not expected for the product, although the packaging is combustible.
<b>Extinguishing Media</b>	Water or foam extinguishers are recommended. Carbon dioxide or dry powder extinguishers may be ineffective.
<b>Special Firefighting Procedures</b>	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.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard.
<b>Environmental Precautions</b>	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
<b>Clean-up Methods</b>	Collect and place it in a suitable, properly labelled container for recovery or disposal.
<b>Decontamination Procedures</b>	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

<b>INGREDIENT</b>	ROSIGLITAZONE MALEATE	
<b>GSK Occupational Hazard Category</b>	3	
<b>GSK Occupational Exposure Limit</b>	30 mcg/m <sup>3</sup> (8 HR TWA)	REPRODUCTIVE HAZARD
<b>ENGINEERING CONTROLS</b>		
<b>Containment</b>	Open handling may result in overexposure.	
<b>Ventilation</b>	Local exhaust ventilation (LEV) should be used in conjunction with other control measures as a means of removing material incidentally released.	
<b>Administrative</b>	Entry to the working area should be controlled.	
<b>Other Equipment or Procedures</b>	None required for normal handling. Wash hands and arms thoroughly after handling.	

## 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance</b>	
<b>Colour</b>	White.
<b>Physical Form</b>	Tablet.

## 10. STABILITY AND REACTIVITY

<b>Stability</b>	This product is expected to be stable.
<b>Conditions to Avoid</b>	None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

<b>Pharmacological Effects</b>	This product contains active ingredient(s) with the following activity: a peroxisome proliferator activated receptor (PPAR) agonist.
<b>Target Organ Effects</b>	No specific target organ effects have been identified.
<b>Routes of Exposure</b>	
<b>Oral Toxicity</b>	Not expected to be toxic following ingestion.
<b>Skin Effects</b>	Minor irritation might occur following direct contact.
<b>Eye Effects</b>	Minor irritation might occur following direct contact with eyes.
<b>Sensitisation</b>	Sensitisation (allergic skin reaction) is not expected.
<b>Genetic Toxicity</b>	Not expected to be genotoxic under occupational exposure conditions.
<b>Carcinogenicity</b>	No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.
<b>Reproductive Effects</b>	Contains components which have been classified as: Possible risk of impaired fertility in human females. Possible risk of toxicity in developing human offspring.
<b>Other Adverse Effects</b>	None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	This material contains two or more active pharmaceutical ingredients that have been tested, one of which may be harmful if released directly to the environment. Specific information on that active pharmaceutical ingredient, Rosiglitazone maleate, is provided below. 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.
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### ECOTOXICITY

#### Aquatic

<b>Activated Sludge Respiration</b>	This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.
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**Material** AVANDIA TABLETS

	IC50:	> 1000 mg/L, 3 Hours, Activated sludge, Nominal
<b>Algal</b>	This material contains an active pharmaceutical ingredient that is very toxic to algae.	
	IC50:	0.88 mg/L, 96 Hours, Selenastrum capricornutum, green algae
	NOEC:	0.14 mg/L, 96 Hours, Selenastrum capricornutum, green algae
<b>Daphnid</b>	This material contains an active pharmaceutical ingredient that is toxic to daphnids.	
	EC50:	6.8 mg/L, 48 Hours, Daphnia magna, Static test
	Chronic LOEC:	0.32 mg/l, 7 Days, Ceriodaphnia dubia, 7 day static renewal
	Chronic NOEC:	0.1 mg/L, 7 Days, Ceriodaphnia dubia, 7 day static renewal
<b>Fish</b>	No toxicity to fish was observed for the active pharmaceutical ingredient, but the upper range of the test was limited by the low water solubility of the compound.	
	Juvenile Pimephales promelas, fathead minnow	
	EC50:	> 14.5 mg/L, 96 Hours, Static renewal test
<b>MOBILITY</b>		
<b>Solubility</b>	This material contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.	
<b>Volatility</b>	This material contains an active pharmaceutical ingredient that will not readily enter into air from water.	
	Henry's Law Constant	1.69E-14 atm m <sup>3</sup> /mol, Calculated
<b>Adsorption</b>	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):	1.93, Calculated at pH 7
	Sludge Biomass Distribution Coefficient (log Kd):	2.8 Measured
<b>Partitioning</b>	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.	
<b>PERSISTENCE/DEGRADATION</b>		
<b>Biodegradation</b>	This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment.	
	Aerobic - Inherent	
	Percent Degradation:	50 %, 1 Day, Batch activated sludge (BAS), Activated sludge
<b>Bioaccumulation</b>	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.	
	Bioconcentration Factor:	7.6 Calculated

<b>13. DISPOSAL CONSIDERATIONS</b>
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<b>Disposal Recommendations</b>	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.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this material.

## 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

### SDS Version Number

23

### SDS Sections Updated

#### Sections

COMPOSITION / INFORMATION ON INGREDIENTS

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

#### Subsections

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.