SAFETY DATA SHEET

GlaxoSmithKline

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

Material **AVANDAMET**

Synonyms AVANDIA/METFORMIN COMBINATION TABLET * ROSIGLITAZONE 1 MG + METFORMIN 500 MG TABLET * ROSIGLITAZONE 2 MG + METFORMIN 500 MG TABLET * ROSIGLITAZONE 4 MG + METFORMIN 500 MG TABLET * ROSIGLITAZONE 2MG + METFORMIN 1000MG TABLET * ROSIGLITAZONE 4MG + METFORMIN 1000MG TABLET * NDC NO. 0007-3166-18 * NDC NO. 0007-3166-20 * NDC NO. 3166-61 * NDC NO. 0007-3167-18 * NDC NO. 0007-3167-20 * NDC NO. 0007-3167-25 * NDC NO. 3167-61 * NDC NO. 0007-3168-18 * NDC NO. 0007-3168-20 * NDC NO. 0007-3168-25 * NDC NO. 3168-61 * NDC NO. 0007-3163-18 * NDC NO. 0007-3163-20 * NDC NO. 0007-3164-18 * NDC NO. 0007-3164-20 * NDC NO. 0007-3166-21 * NDC NO. 0007-3167-21 * NDC NO. 0007-3168-21 * ROSIGLITAZONE/METFORMIN, FORMULATED PRODUCT

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
ROSIGLITAZONE MALEATE	155141-29-0	0.5 to 0.9
METFORMIN HYDROCHLORIDE	1115-70-4	87.7 to 90.9
NON-HAZARDOUS INGREDIENTS	Unassigned	8.4 to 11.5

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

Health	Handling this product in its final form presents minimal risk from occupational exposure. 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 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.
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	ROSIGLITAZONE MALEATE	
GSK Occupational Hazard Category	3	
GSK Occupational Exposure Limit	30 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD
INGREDIENT	METFORMIN HYDROCHLORIDE	
GSK Occupational Hazard Category	1	
GSK Occupational Exposure Limit	3000 mcg/m3 (8 HR TWA)	

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.

Other Equipment or Procedures None required for normal handling. Wash hands and arms thoroughly after handling.

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.

Skin Effects Minor irritation might occur following direct contact.

Eye Effects Minor irritation might occur following direct contact with eyes.

Target Organ Effects No specific target organ effects have been identified.

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 Contains components which have been classified as: Possible risk of impaired fertility in human females. Possible risk of toxicity in developing human offspring.

Pharmacological Effects This product contains active ingredient(s) with the following activity: a peroxisome proliferator activated receptor (PPAR) agonist.

*** Other Adverse Effects** None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary** 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.

ECOTOXICITY

Aquatic

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

IC50: > 1000 mg/L, 3 Hours, Activated sludge, Nominal

*** Algal** This material contains an active pharmaceutical ingredient that is very toxic to algae.

IC50: 0.88 mg/L, 96 Hours, Selenastrum capricornutum, green algae

NOEL: 0.14 mg/L, 96 Hours, Selenastrum capricornutum, green algae

*** Daphnid** This material contains an active pharmaceutical ingredient that is toxic to daphids.

EC50: 6.8 mg/L, 48 Hours, Daphnia magna, Static test

*** Fish** 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

MOBILITY

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

*** Volatility** 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^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): 1.93, Calculated at pH 7

Sludge Biomass Distribution Coefficient (log Kd): 2.8 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

*** Biodegradation** 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

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

Bioconcentration Factor: 7.6 Calculated

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 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

Date Approved/Revised 01-Feb-2005 **SDS Version Number** 15

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	Activated Sludge Respiration
	Adsorption
	Algal
	Algal Degradation
	Bioaccumulation
	Biodegradation

SDS Sections Updated

Sections	Subsections
ECOLOGICAL INFORMATION	Daphnid
	Distribution
	Earthworm
	Ecotoxicity
	Fish
	Hydrolysis
	Microbial Growth Inhibition
	Microtox
	Mobility
	Other Adverse Effects
	Other Species - Aquatic
	Other Species - Terrestrial
	Partitioning
	Persistence/Degradation
	Photolysis
	Solubility
	Summary
	Volatility
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	Inhalation Toxicity
	Other Adverse Effects

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. For further information please refer to the appropriate product information.