SAFETY DATA SHEET

GlaxoSmithKline

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

Material **COREG TABLETS**

Synonyms COREG 3.125 MG TABLETS * COREG 6.25 MG TABLETS * COREG 12.5 MG TABLETS * COREG 25 MG TABLETS * COREG 50 MG TABLETS * EUCARDIC TABLETS * KREDEX TABLETS * NDC NO. 0007-4139-20 * NDC NO. 0007-4140-20 * NDC NO. 0007-4141-20 * NDC NO. 0007-4142-20 * CARVEDILOL, FORMULATED PRODUCT * KREDEX 3.125 MG TABLETS * KREDEX 6.25 MG TABLETS * KREDEX 12.5 MG TABLETS * KREDEX 25 MG TABLETS * KREDEX 50 MG TABLETS

Company Name

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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
CARVEDILOL	72956-09-3	8
NON-HAZARDOUS INGREDIENTS	Unassigned	92

3. HAZARDS IDENTIFICATION

Fire and Explosion Expected to be non-combustible.

*** Health**	Caution - Pharmaceutical agent. Exposure might occur via ingestion; skin; eyes. May produce allergic skin reactions. Possible effects of overexposure in the workplace include: difficult or irregular breathing; slow pulse; fainting; dizziness; bluish-coloured skin or extremities. Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.
Environment	Dangerous for the environment. Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

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 beta-adrenergic receptor blocker. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. In allergic individuals, exposure to this material may require treatment for initial or delayed allergic symptoms and signs. This may include immediate and/or delayed treatment of anaphylactic reactions.
*** Medical Conditions Caused or Aggravated by Exposure**	None for occupational exposure.
Health Surveillance Procedures	The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting skin conditions. In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting skin conditions and other allergy symptoms.
*** Antidotes**	For medical treatment in cases of overexposure, a recommended antidote would be adrenaline, noradrenaline, or beta-sympathomimetics. The decision as to whether the severity of poisoning requires administration of any antidote and actual dose required should be made by qualified medical personnel.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	Water, dry powder or foam extinguishers are recommended. Carbon dioxide 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	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.
Clean-up Methods	Spread an inert absorbent on the spill and place 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	CARVEDILOL	
GSK Occupational Hazard Category	3	
GSK Occupational Exposure Limit	30 MCG/M3 (8 HR TWA)	SENSITISER

ENGINEERING CONTROLS

Exposure Controls	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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Other Equipment or Procedures	Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	Film-coated 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	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Target Organ Effects	No specific target organ effects have been identified.
Sensitisation	Allergic skin reactions might occur following dermal exposure.
Genetic Toxicity	Not expected to be genotoxic under occupational exposure conditions.
Carcinogenicity	Not expected to produce cancer in humans under occupational exposure conditions. 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.
Pharmacological Effects	It is an agent intended for the treatment of hypertension. Adverse effects of overexposure might include: difficult or irregular breathing; slow pulse; fainting; dizziness; bluish-coloured fingernails or palms.
*** Other Adverse Effects**	None known for occupational exposure.

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. 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: 98.4 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 harmful to these microorganisms.

EC50: 5.43 mg/L, 15 Minutes

*** Algal**

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

IC50: 1.6 mg/L, 72 Hours, Scenedesmus subspicatus, green algae

NOEL: 0.46 mg/L, 72 Hours, Scenedesmus subspicatus, green algae

Daphnid

No toxicity to daphnids was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of this compound.

EC50: > 2.8 mg/L, 48 Hours, Daphnia pulex, Static test

NOEL: < 0.37 mg/L, 48 Hours, Daphnia pulex, Static test

*** Fish**

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

Adult Lepomis macrochirus, bluegill sunfish
EC50: 0.99 mg/L, 96 Hours, Static test
Adult Lepomis macrochirus, bluegill sunfish
NOEL: < 0.43 mg/L, 96 Hours, Static 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 3.93E-07 atm m^3/mol, Measured

*** Adsorption**

This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. It may persist in soil or sediment if released directly to the environment.

This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass. It may persist in sludges or other biomass if released directly to the environment.

Soil Sediment Sorption (log Koc): 4.37 to 4.61, Measured

Sludge Biomass Distribution Coefficient (log Kd): 3.74 to 4.31 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 stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: > 1 Years, Measured

Photolysis

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

Half-Life, Aqueous: 1.48 Hours, Measured

*** 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 %, 28 days, Batch activated sludge (BAS), Activated sludge

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 22-Nov-2004 **SDS Version Number** 15

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	
	Activated Sludge Respiration
	Adsorption
	Algal
	Biodegradation
	Daphnid
	Fish
	Hydrolysis
	Microtox
	Partitioning
	Photolysis
	Solubility
	Summary
	Volatility
FIRST-AID MEASURES	Antidotes
	Eye Contact
	Health Surveillance Procedures
	Ingestion
	Inhalation

SDS Sections Updated

Sections	Subsections
FIRST-AID MEASURES	Medical Conditions Caused or Aggravated by Exposure
	Medical Treatment
	Skin Contact
HAZARDS IDENTIFICATION	Conditions Aggravated by Exposure
	Environment
	Eye Contact
	Health
	Ingestion
	Inhalation
	Overview
	Skin Contact
	Summary
PHYSICAL AND CHEMICAL PROPERTIES	
REGULATORY INFORMATION	European Union Classification and Labelling Requirements
TOXICOLOGY INFORMATION	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.