

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	COREG CR CAPSULES
Synonyms	COREG CR 10 MG CAPSULES * COREG CR 20 MG CAPSULES * COREG CR 40 MG CAPSULES * COREG CR 80 MG CAPSULES * NDC: 0007-3370-13 * NDC: 0007-3370-59 * NDC: 0007-3371-13 * NDC: 0007-3371-59 * NDC: 0007-3372-13 * NDC: 0007-3372-59 * NDC: 0007-3373-13 * NDC: 0007-3373-59 * COREG CR EXTENDED RELEASE CAPSULES * CARVEDILOL PHOSPHATE, FORMULATED PRODUCT
Company Name	<p>GlaxoSmithKline, Corporate Environment, Health & 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 & 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 RN	Percentage
CARVEDILOL PHOSPHATE	Unassigned	21
NON-HAZARDOUS INGREDIENTS	Unassigned	79

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	<p>Caution - Pharmaceutical agent. Exposure might occur via ingestion; skin; eyes.</p> <p>May produce allergic skin reactions.</p> <p>Possible effects of overexposure in the workplace include: difficult or irregular breathing; slow pulse; fainting; dizziness; bluish-coloured skin or extremities.</p> <p>Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.</p>

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 capsules.

STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT CARVEDILOL PHOSPHATE

GSK Occupational Hazard Category 3

GSK Occupational Exposure Limit 30 MCG/M3 (8 HR TWA) SKIN 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.

Containment Open handling may result in overexposure. Consider use of enclosures.

Ventilation Local exhaust ventilation (LEV) should be applied at the source to capture contaminants from open or semi-enclosed operations.

Administrative Entry to the working area should be controlled. Restrict access to authorised personnel.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection Wear approved safety glasses with side shields if eye contact is possible.

*** Other Equipment or Procedures** Follow all local regulations if personal protective equipment (PPE) is used in the workplace. Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Capsule.

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.

Inhalation Toxicity No studies have been conducted.

Skin Effects	Irritation might occur following direct contact.
Eye Effects	Irritation might occur following direct contact with eyes.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: cardiovascular system.
Sensitisation	Allergic skin reactions might occur following dermal exposure.
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. Not expected to produce cancer in humans under occupational exposure conditions.
Reproductive Effects	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Pharmacological Effects	This product contains active ingredient(s) with the following activity: an adrenergic beta-2 receptor antagonist.
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: 122 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: 6.73 mg/L, 15 Minutes

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

IC50: 1.98 mg/L, 72 Hours, Scenedesmus subspicatus, green algae

NOEL: 0.57 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: > 3.47 mg/L, 48 Hours, Daphnia pulex, Static test

NOEL: < 0.46 mg/L, 48 Hours, Daphnia pulex, Static test

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

Adult Lepomis macrochirus, bluegill sunfish

EC50: 1.23 mg/L, 96 Hours, Static test

Adult Lepomis macrochirus, bluegill sunfish

NOEL: < 0.53 mg/L, 96 Hours, Static test

MOBILITY

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 4.37 to 4.61, Measured
(log Koc):

Sludge Biomass 3.74 to 4.31 Measured
Distribution Coefficient
(log Kd):

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 26-Oct-2006

SDS Version Number 4

SDS Sections Updated**Sections**

EXPOSURE CONTROLS / PERSONAL PROTECTION

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

Subsections

Other Equipment or Procedures

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.