

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	CONTAC SEVERE COLD AND FLU MAXIMUM STRENGTH CAPLETS
Synonyms	CONTAC SEVERE COLD AND FLU FORMULA - MAXIMUM STRENGTH CAPLETS (US) * CONTAC COLD NASAL CONGESTION NIGHTTIME REGULAR STRENGTH CAPLETS (CANADA) * CONTAC SCF MAXIMUM STRENGTH CAPLETS * MFC 55011-47-0102 * MMI 4351 * PARACETAMOL, DEXTROMETHORPHAN HYDROBROMIDE, PSEUDOEPHEDRINE HYDROCHLORIDE AND CHLORPHENIRAMINE MALEATE, 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
PARACETAMOL	103-90-2	69
DEXTROMETHORPHAN HYDROBROMIDE	125-69-9	2
PSEUDOEPHEDRINE HYDROCHLORIDE	345-78-8	4.2
CHLORPHENIRAMINE MALEATE	113-92-8	0.3
NON-HAZARDOUS INGREDIENTS	Unassigned	24.5

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
* Health	Exposure might occur via ingestion; skin; eyes. Health effects information is based on hazards of components.

* **Environment** Harmful to aquatic organisms.

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 acetaminophen/paracetamol. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

Medical Conditions Caused or Aggravated by Exposure None for occupational exposure.

Antidotes 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. For medical treatment in cases of overexposure, a recommended antidote would be mucomyst (N-acetylcysteine).

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 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	PARACETAMOL
GSK Occupational Hazard Category	1
GSK Occupational Exposure Limit	4000 MCG/M3 (8 HR TWA)
INGREDIENT	DEXTROMETHORPHAN HYDROBROMIDE
GSK Occupational Hazard Category	4
GSK Occupational Exposure Limit	10 mcg/m3 (8 HR TWA)
INGREDIENT	PSEUDOEPHEDRINE HYDROCHLORIDE
GSK Occupational Hazard Category	2
GSK Occupational Exposure Limit	200 mcg/m3 (8 HR TWA)
INGREDIENT	CHLORPHENIRAMINE MALEATE
GSK Occupational Hazard Category	4
GSK Occupational Exposure Limit	10 MCG/M3 (8 HR TWA)

PERSONAL PROTECTIVE EQUIPMENT

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	Light blue.
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 Adverse effects might occur following ingestion.

Inhalation Toxicity No studies have been conducted.

Skin Effects Irritation is not expected 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: liver; central nervous system.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
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. No adverse effects have been reported following extensive use or exposure in humans.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

* Summary	This product contains an active 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.
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ECOTOXICITY

Aquatic

Daphnid

This mixture contains a major component(s) that is toxic to daphnids.

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

Exempt when packaged for sale to consumers in a retail establishment.

Other US Regulations

TSCA Status

Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 12-Dec-2006

SDS Version Number 15

SDS Sections Updated**Sections**

ECOLOGICAL INFORMATION

Subsections

Activated Sludge Respiration
Adsorption
Algal
Algal Degradation
Bioaccumulation
Biodegradation
Crustacea
Daphnid
Distribution
Earthworm
Ecotoxicity
EHAC Notation
Fish
GSK Environmental Hazard Category
Hydrolysis
Microbial Growth Inhibition
Microtox
Mobility
Other Adverse Effects
Other Species - Aquatic
Other Species - Terrestrial
Partitioning
Persistence/Degradation
Photolysis
Solubility
Summary
Volatility
Conditions Aggravated by Exposure
Environment
Eye Contact
Health
Ingestion
Inhalation
Overview
Skin Contact
Summary

HAZARDS IDENTIFICATION

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.