



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** CITRUCEL ORANGE

### Other means of identification

#### Synonyms

CITRUCEL FIBER LAXATIVE ORANGE (US) \* CITRUCEL ORANGE \* METHYL CELLULOSE FIBER THERAPY FOR REGULARITY \* PERRIGO CODE 5E6AA \* PROJECT FLUSH \* MFC 50677 / 50678 \* METHYL CELLULOSE, FORMULATED PRODUCT

**Recommended use** Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES::  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
SUCROSE	SUGAR * CANE SUGAR * BEET SUGAR * CONFECTIONER'S SUGAR * ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL * GRANULATED SUGAR * SUCRALOX	57-50-1	71 - 75
METHYL CELLULOSE	CELLULOSE, METHYL ETHER (1/2%) * METHYLCELLULOSE	9004-67-5	10 - 14
MALTODEXTRIN	MALTRIN * MALTRIN M 100 * OHS13581 * MALTODEXTRIN	9050-36-6	5 - 7
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOX YLIC ACID * CITIRIC ACID	77-92-9	3 - 5

Chemical name	Common name and synonyms	CAS number	%
CALCIUM PHOSPHATE, DIBASIC	CALCIUM ACID PHOSPHATE * CALCIUM HYDROGEN ORTHOPHOSPHATE * CALCIUM HYDROGEN PHOSPHATE * CALCIUM MONOHYDROGEN PHOSPHATE * CALCIUM ORTHOPHOSPHATE (CAHPO4) * DIBASIC CALCIUM PHOSPHATE * DICALCIUM ORTHOPHOSPHATE * DICALCIUM PHOSPHATE * MONOCALCIUM ACID PHOSPHATE * CALCIUM PHOSPHATE	7757-93-9	0 - 2
TITANIUM DIOXIDE	TITANIUM OXIDE * TITANIUM(IV) OXIDE * TITANIUM PEROXIDE (TiO2) * PIGMENT WHITE 6	13463-67-7	< 0.05
Other components below reportable levels			< 10

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	Direct contact with eyes may cause temporary irritation.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder.
<b>Unsuitable extinguishing media</b>	Carbon dioxide (CO2).
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Use water spray to cool unopened containers.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	Assume that this product is capable of sustaining combustion.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Avoid inhalation of dust from the spilled material. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Collect dust using a vacuum cleaner equipped with HEPA filter. Minimize dust generation and accumulation. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

**Precautions for safe handling** Provide appropriate exhaust ventilation at places where dust is formed. Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes. Avoid prolonged exposure. Practice good housekeeping.

**Conditions for safe storage, including any incompatibilities** Store in original tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### GSK

Components	Type	Value
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)	OHC	1
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3
METHYL CELLULOSE (CAS 9004-67-5)	OHC	1

#### US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m3	Total dust.

#### US. ACGIH Threshold Limit Values

Components	Type	Value
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m3

#### US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3 10 mg/m3	Respirable. Total

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Appropriate engineering 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. General ventilation normally adequate.

### Individual protection measures, such as personal protective equipment

**Eye/face protection** Not normally needed. If contact is likely, safety glasses with side shields are recommended.

**Hand protection** Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

#### Skin protection

**Other** Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection** No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Solid.
<b>Form</b>	Powder.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

### Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Heat, flames and sparks.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Symptoms related to the physical, chemical and toxicological characteristics** None known.

**Information on toxicological effects**

**Acute toxicity** Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test Results
CALCIUM PHOSPHATE, DIBASIC (CAS 7757-93-9)		
<b>Acute</b>		
<i>Dermal</i>		
LD50	Rabbit	> 7940 mg/kg
<i>Oral</i>		
LD50	Rat	> 10 g/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
MALTODEXTRIN (CAS 9050-36-6)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
TITANIUM DIOXIDE (CAS 13463-67-7)		
<b>Acute</b>		
<i>Inhalation</i>		
LC50	Rat	6820 mcg/m3
<i>Oral</i>		
LD50	Rat	> 24 g/kg
<b>Chronic</b>		
<i>Inhalation</i>		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
<b>Subacute</b>		
<i>Inhalation</i>		
LOEL	Rat	0.1 - 35 mg/m3, 4 weeks Mild macrophage hyperplasia, no change in bronchio-alveolar lavage fluid.
NOAEC	Guinea pig	26 mg/m3, 3 weeks No evidence of significant inflammation in respiratory tract.
<i>Oral</i>		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
<b>Subchronic</b>		
<i>Inhalation</i>		
LOEC	Rat	3.2 - 20 mg/m3, 8 min Accumulation of TiO2 in macrophages and evidence of pulmonary inflammation.

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Health injuries are not known or expected under normal use.

**Irritation Corrosion - Skin**  
TITANIUM DIOXIDE

Acute dermal irritation; OECD 404, Literature data  
Result: Non-irritant  
Species: Rabbit  
Literature data  
Result: Non-irritant  
Species: Guinea pig  
Literature data  
Result: Non-irritant  
Species: Human

**Serious eye damage/eye irritation**

Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Eye**

TITANIUM DIOXIDE

OECD 405, Literature data  
Result: Mild irritant  
Species: Rabbit

**Respiratory or skin sensitization**

**Respiratory sensitization**

Not available.

**Skin sensitization**

Health injuries are not known or expected under normal use.

**Sensitization**

TITANIUM DIOXIDE

5 % Optimisation Test, Literature data - Vehicle: petrolatum  
Result: Negative  
Species: Guinea pig  
Test Duration: 48 hour exposure  
Patch test, Literature data  
Result: Negative  
Species: Human

**Germ cell mutagenicity**

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Mutagenicity**

TITANIUM DIOXIDE

Ames, Literature data  
Result: Negative  
Micronucleus Assay in vitro, CHO cells, Literature data  
Result: Negative  
Micronucleus Assay in vitro, cultured human peripheral lymphocytes, Literature data  
Result: Positive  
Syrian Hamster Embryo (SHE) cell transformation assay  
Result: Negative  
WIL2-NS HPRT/ t-Thioguanidine - Human B-Cell lymphoblastoid, Literature data  
Result: Positive

**Carcinogenicity**

Health injuries are not known or expected under normal use. Contains a material (titanium dioxide) classified as a carcinogen by external agencies. High concentrations or doses administered over an extended period of time were required to produce adverse effects.

TITANIUM DIOXIDE

0.5 mg/m<sup>3</sup>, Literature data  
Result: Negative  
Species: Rat  
Test Duration: 24 months  
0.72 - 14.8 mg/m<sup>3</sup>, Literature data  
Result: Negative  
Species: Mouse  
10 - 250 mg/m<sup>3</sup>, Dietary study - Literature data.  
Result: Inflammation at all doses with alveolar/bronchiolar adenoma at the highest concentration.  
Species: Rat  
Test Duration: 24 months  
25000 - 50000 ppm, Dietary study  
Result: Negative  
Species: Mouse  
25000 - 50000 ppm, Dietary study - Literature data.  
Result: Negative  
Species: Rat

**Carcinogenicity**

TITANIUM DIOXIDE

7.2 - 14.8 mg/m<sup>3</sup>, Literature data

Result: Lung tumour

Species: Rat

Test Duration: 24 months

**IARC Monographs. Overall Evaluation of Carcinogenicity**

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity** Contains no ingredient listed as toxic to reproduction**Specific target organ toxicity - single exposure** None known.**Specific target organ toxicity - repeated exposure** None known.**Aspiration hazard** Not likely, due to the form of the product.**Further information** None known.**12. Ecological information****Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
<b>CITRIC ACID ANHYDROUS (CAS 77-92-9)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) 120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus) 1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus) 440 - 760 mg/l, 96 hours Static test
Microtox	EC50	Microtox 14 mg/l, 15 minutes
<b>METHYL CELLULOSE (CAS 9004-67-5)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Fish	EC50	Orange-red killfish (Adult Oryzias latipes) > 1000 mg/L, 48 hours Static test
<b>TITANIUM DIOXIDE (CAS 13463-67-7)</b>		
<b>Aquatic</b>		
<i>Acute</i>		
Crustacea	EC50	Water flea (Daphnia magna) > 1000 mg/l, 48 hours Static test

\* Estimates for product may be based on additional component data not shown.

**Persistence and degradability** No data is available on the degradability of this product.**Biodegradability****Percent degradation (Aerobic biodegradation-inherent)**

CITRIC ACID ANHYDROUS

98 %, 2 days Modified Zahn-Wellens, Activated sludge

SUCROSE

69 % BOD5

**Bioaccumulative potential** No data available.**Partition coefficient n-octanol / water (log Kow)**

SUCROSE

-3

**Mobility in soil** No data available.**Mobility in general****Volatility****Henry's law**

CITRIC ACID ANHYDROUS

< 0 atm m<sup>3</sup>/mol Calculated, 25 °C

SUCROSE

< 0 atm m<sup>3</sup>/mol Estimated**Other adverse effects** Not available.

### 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

### 14. Transport information

<b>DOT</b>	Not regulated as a dangerous good.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

### 15. Regulatory information

#### US federal regulations

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

#### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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**SARA 302 Extremely hazardous substance**

Not listed.

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Not regulated.

#### Other federal regulations

**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

**Safe Drinking Water Act (SDWA)** Not regulated.

#### US state regulations

**US. Massachusetts RTK - Substance List**

SUCROSE (CAS 57-50-1)

TITANIUM DIOXIDE (CAS 13463-67-7)

**US. New Jersey Worker and Community Right-to-Know Act**

TITANIUM DIOXIDE (CAS 13463-67-7)

**US. Pennsylvania Worker and Community Right-to-Know Law**

SUCROSE (CAS 57-50-1)

TITANIUM DIOXIDE (CAS 13463-67-7)

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

WARNING: This product contains a chemical known to the State of California to cause cancer.

**US - California Proposition 65 - CRT: Listed date/Carcinogenic substance**

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	08-08-2014
<b>Revision date</b>	08-08-2014
<b>Version #</b>	09
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1* Flammability: 1 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 1 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States GHS: Classification