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 of the chemical and restrictions on use

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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
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-PROPANETRICARBOXYLIC ACID CITIRIC ACID	77-92-9	3 - 5
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

4. First-aid measures

Description of necessary first aid measures

Inhalation	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.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without medical advice.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	Direct contact with eyes may cause temporary irritation.
Medical attention and special treatment	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water fog. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO2).
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for fire fighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.

Hazchem Code	Not available.
General fire hazards	Assume that this product is capable of sustaining combustion.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	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. Wear a dust mask if dust is generated above exposure limits. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
Methods and materials for containment and cleaning up	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. Minimise 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.

7. Handling and storage

Precautions for safe handling	Provide appropriate exhaust ventilation at places where dust is formed. Minimise dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes. 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 and personal protection

Control parameters Follow standard monitoring procedures.

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
	OHC	1
METHYL CELLULOSE (CAS 9004-67-5)	OHC	1

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Inhalable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inhalable dust.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	TWA	10 mg/m3	Inspirable dust.
Titanium dioxide (CAS 13463-67-7)	TWA	10 mg/m3	Inspirable 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

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Sucrose (CAS 57-50-1)	STEL	20 mg/m3	
	TWA	10 mg/m3	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
Titanium dioxide (CAS 13463-67-7)	TWA	4 mg/m3	Respirable.
		10 mg/m3	Inhalable

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, for example personal protective equipment (PPE)

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

Skin protection

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

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

Respiratory protection No personal respiratory protective equipment normally required. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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

Physical state Solid.

Form Powder.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Explosive limit - lower (%) Not available.

Explosive limit – upper (%) Not available.

Vapour pressure Not available.

Vapour density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient (n-octanol/water) Not available.

Auto-ignition temperature Not available.

Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

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

11. Toxicological information

Information on possible routes of exposure

Ingestion	Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Symptoms related to exposure	None known.
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)		
Acute		
Dermal		
LD50	Rabbit	> 7940 mg/kg
Oral		
LD50	Rat	> 10 g/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
MALTODEXTRIN (CAS 9050-36-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
Titanium dioxide (CAS 13463-67-7)		
Acute		
Inhalation		
LC50	Rat	6820 mcg/m3
Oral		
LD50	Rat	> 24 g/kg
Chronic		
Inhalation		
LOEC	Rat	8.6 mg/m3, 1 years TiO2 accumulated in interstitial macrophages, aggregated interstitial cells and particle laden macrophrages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose
		5 mg/m3, 24 months

Components	Species	Test results
Subacute		
Inhalation		
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.
Oral		
NOAEL	Rat	100000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Inhalation		
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/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 sensitisation

Skin sensitisation Health injuries are not known or expected under normal use.

Sensitisation

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/m3, Literature data
Result: negative
Species: Rat
Test Duration: 24 months
0.72 - 14.8 mg/m3, Literature data
Result: negative
Species: Mouse
10 - 250 mg/m3, 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
7.2 - 14.8 mg/m3, Literature data
Result: Lung tumour
Species: Rat
Test Duration: 24 months

ACGIH Carcinogens

SUCROSE (CAS 57-50-1) A4 Not classifiable as a human carcinogen.
TITANIUM DIOXIDE (CAS 13463-67-7) A4 Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

TITANIUM DIOXIDE (CAS 13463-67-7) 2B Possibly carcinogenic to humans.

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.

Other 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
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
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
METHYL CELLULOSE (CAS 9004-67-5)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	> 1000 mg/l, 48 hours Static test

Components		Species	Test results
Titanium dioxide (CAS 13463-67-7)			
Aquatic			
Acute			
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 Not available.

Volatility

Henry's law

CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C
Sucrose	< 0 atm m^3/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

Disposal methods Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Residual waste 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).

Contaminated packaging 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

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

CITRIC ACID ANHYDROUS (CAS 77-92-9)	1000 - 9999 TONNES See the regulation for additional information.
TITANIUM DIOXIDE (CAS 13463-67-7)	100000 - 999999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Issue date 08-August-2014

Revision date 08-August-2014

References GSK Hazard Determination

Disclaimer 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.

Revision Information 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