SAFETY DATA SHEET

1. Identification

Product identifier **THERAFLU MAX STRENGTH FLU RELIEF - NIGHTTIME**

Other means of identification

Product code WH-2166-0001

Synonyms WH-2166-0001

Recommended use Consumer Healthcare Product

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

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Serious eye damage/eye irritation	Category 2
	Sensitization, skin	Category 1
Environmental hazards	Hazardous to the aquatic environment, long-term hazard	Category 3
OSHA defined hazards	Combustible dust	

Label elements

Signal word Warning

Hazard statement May form combustible dust concentrations in air. May cause an allergic skin reaction. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

Precautionary statement

Prevention	Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Avoid breathing dust. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Avoid release to the environment. Wear eye protection/face protection. Wear protective gloves.
Response	If on skin: Wash with plenty of water/. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Specific treatment (see on this label). If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. In case of fire: Use appropriate media to extinguish.
Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	6.15% of the mixture consists of component(s) of unknown acute oral toxicity. 90.65% of the mixture consists of component(s) of unknown acute dermal toxicity. 90.65% of the mixture consists of component(s) of unknown acute inhalation toxicity. 81.75% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 79.15% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

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	67.4
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- N-(4-HYDROXYPHENYL) ACETAMIDE ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PARACETAMOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE	103-90-2	8.9
MALTODEXTRIN	MALTRIN MALTRIN M 100 OHS13581 MALTODEXTRIN	9050-36-6	4.3
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACI D ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARB OXYLIC ACID CITIRIC ACID	77-92-9	3.9
NAT LEMON WONF DURAROME, 860098 TD1091		Unassigned	2.6
NAT WHITE TEA WONF DURAROME, 858233 TD7594		Unassigned	0.9
SODIUM CITRATE DIHYDRATE	1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRISODIUM SALT, DIHYDRATE CITRIC ACID, TRISODIUM SALT, DIHYDRATE SODIUM CITRATE, DIHYDRATE SODIUM CITRATE TRISODIUM CITRATE DIHYDRATE TRISODIUM CITRATE SODIUM CITRATE DIHYDRATE	6132-04-3	0.72

Chemical name	Common name and synonyms	CAS number	%
NAT LEMON DURAROME, 860202 TD0991		Unassigned	0.65
CALCIUM PHOSPHATE, TRIBASIC	CALCIUM ORTHOPHOSPHATE CALCIUM PHOSPHATE TRIBASIC CALCIUM PHOSPHATE TRICALCIUM DIPHOSPHATE TRICALCIUM ORTHOPHOSPHATE TRICALCIUM PHOSPHATE ALPHA-TRICALCIUM PHOSPHATE BETA-TRICALCIUM PHOSPHATE	7758-87-4	0.31
DEXTROMETHORPHAN HYDROBROMIDE	9ALPHA,13ALPHA,14ALPHA-MORPHINAN, 3-METHOXY-17-METHYL-, HYDROBROMIDE DEXTROMETHORPHAN BROMIDE METHORATE HYDROBROMIDE C18H25NO.HBr	125-69-9	0.3
ACESULFAME K	1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) ACESULFAM ACESULFAME POTASSIUM	55589-62-3	0.2
ASPARTAME	L-PHENYLALANINE, N-L-ALPHA-ASPARTYL-1-METHYL ESTER N-L-ALPHA-ASPARTYL-1-METHYL ESTER L-PHENYLALANINE SUCCINAMIC ACID, 3-AMINO-N-(ALPHA-CARBOXYPHENETHYL)-, ASPARTYLPHENYLALANINE METHYL ESTER METHYL ASPARTYLPHENYLALANATE NUTRASWEET	22839-47-0	0.2
SILICON DIOXIDE	SILICA SILICA GEL AMORPHOUS SILICA DIATOMACEOUS EARTH INFUSORIAL EARTH SIDENT COLLOIDAL SILICON DIOXIDE SILICON DIOXIDE, CRYSTALLINE SILICON DIOXIDE, AMORPHOUS SILICA, AMORPHOUS HYDRATED	7631-86-9	0.11
CHLORPHENIRAMINE MALEATE	2-PYRIDINEPROPANAMINE, GAMMA-(4-CHLOROPHENYL)-N,N-DIMETHYL-, (Z)-2-BUTENEDIOATE (1:1) 2-(P-CHLORO-ALPHA-(2-(DIMETHYLAMINO)ETHYL)BENZYL)PYRIDINE CARBINOXAMIDE MALEATE CHLOROPROPHENPYRIDAMINE MALEATE	113-92-8	0.04
FD&C RED NO. 40	DISODIUM 6-HYDROXY-5-((2-METHOXY-5-METHYL-4-SULFOPHENYL)AZO) DISODIUM 6-HYDROXY-5-((2-METHOXY-4-SULPHONATO-M-TOLYL)AZO)NAPHTHALENE-2-SULPHONATE DISODIUM 6-HYDROXY-5-((2-METHOXY-4-SULPHONATO-META-TOLYL)AZO)NAPHTHALENE-2-SULPHONATE FDC RED 40 FDC RED 40 DYE ALLURA RED ALLURA RED 40 RED 40 AND LAKE	25956-17-6	0.001

Chemical name	Common name and synonyms	CAS number	%
FD&C BLUE NO. 1	ALPHAZURINE BRILLIANT BLUE FCF, DISODIUM SALT ERIOGLAUCINE ACID BLUE 9	3844-45-9	0.0001
Other components below reportable levels			9.4689

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes. Coughing. May cause an allergic skin reaction. Dermatitis. Rash.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. Water fog. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting equipment/instructions In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent product from entering drains. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Form
ACESULFAME K (CAS 55589-62-3)	OHC	1	>1000 - </=5000 mcg/m3
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
CALCIUM PHOSPHATE, TRIBASIC (CAS 7758-87-4)	OHC	1	
CHLORPHENIRAMINE MALEATE (CAS 113-92-8)	8 HR TWA	20 mcg/m3	SKIN
	OHC	3	SKIN
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)	8 HR TWA	150 mcg/m3	SKIN
	OHC	2	SKIN
FD&C BLUE NO. 1 (CAS 3844-45-9)	OHC	3	
FD&C RED NO. 40 (CAS 25956-17-6)	OHC	1	
MALTODEXTRIN (CAS 9050-36-6)	OHC	1	>1000 - </=5000 mcg/m3
PARACETAMOL (CAS 103-90-2)	8 HR TWA	3000 mcg/m3	
	OHC	1	
SODIUM CITRATE DIHYDRATE (CAS 6132-04-3)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL

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	Respirable fraction.
		15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

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

Appropriate engineering controls Explosion-proof general and local exhaust ventilation. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Use only appropriately classified electrical equipment and powered industrial trucks. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

Respiratory protection If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations When using, do not eat, drink or smoke. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Powder.

Color Off-white White. Yellow. Beige Brown.

Odor Not available.

Odor 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.
Vapor pressure	Not available.
Vapor 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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimize dust generation and accumulation.
Incompatible materials	Alkaline metals.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Dust or powder may irritate the skin. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes. Coughing. May cause an allergic skin reaction.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
ACESULFAME K (CAS 55589-62-3)		
Acute		
Dermal		
LD50	Rabbit	2000
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
CHLORPHENIRAMINE MALEATE (CAS 113-92-8)		
Acute		
Oral		
LD50	Guinea pig	198 mg/kg
	Mouse	130 mg/kg
	Rat	306 - 351 mg/kg
Chronic		
Oral		
LD	Monkey	15 mg/kg/day, 106 weeks Cardiac failure.
Subchronic		
Oral		
NOEL	Mouse	100 mg/kg/day, 13 weeks Hyperactivity.
	Rat	7.5 mg/kg/day, 13 weeks Reduced bodyweight, piloerection, hyperactivity and lethargy.
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	11700 mg/kg
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)		
Acute		
Oral		
LD50	Rat	350 mg/kg
FD&C BLUE NO. 1 (CAS 3844-45-9)		
Acute		
Oral		
LD50	Rat	11.3 g/kg
FD&C RED NO. 40 (CAS 25956-17-6)		
Acute		
Dermal		
LD50	Rabbit	> 10 g/kg
Oral		
LD50	Rat	> 10 g/kg
MALTODEXTRIN (CAS 9050-36-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous

Components	Species	Test Results
Other		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin

CHLORPHENIRAMINE MALEATE	Acute dermal irritation; OECD 404 Result: Slightly irritating Species: Rabbit Notes: GSK data

Irritation Corrosion - Skin: P.I.I. value

CITRIC ACID ANHYDROUS	OECD 404 Result: Mild to moderate irritant. Species: Rabbit
PARACETAMOL	OECD 404, Literature data Result: Slight irritant Species: Rabbit

Serious eye damage/eye irritation Causes serious eye irritation.

Eye

CHLORPHENIRAMINE MALEATE	Acute ocular irritation; OECD 405 Result: Irreversible damage to eyes. Species: Rabbit Notes: GSK data
CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit

Eye / Initial pain reaction score

PARACETAMOL	0, Literature data

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization May cause an allergic skin reaction.

Sensitization

CHLORPHENIRAMINE MALEATE	OECD 406 - Maximisation test Result: Negative Species: Guinea pig Notes: GSK data
DEXTROMETHORPHAN HYDROBROMIDE	SAR, DEREK, Lhasa, UK Result: Positive

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

Mutagenicity

DEXTROMETHORPHAN HYDROBROMIDE	Ames Result: Negative Notes: Global Safety Datasheet.
PARACETAMOL	Ames, Literature data Result: Negative Chromosomal Aberration Assay In Vitro, Literature data Result: Positive HPRT gene mutation in human lymphocytes, Literature data Result: Negative
DEXTROMETHORPHAN HYDROBROMIDE	In vitro cytogenetics assay Result: Negative Notes: Aardema A et al, Reg Tox Pharm.

Mutagenicity

PARACETAMOL	In vivo Micronucleus, Literature data Result: Negative Species: Mouse

Carcinogenicity Not classifiable as to carcinogenicity to humans.

PARACETAMOL	0, Literature data Result: Equivocal. Increase in ademomas at toxic dose. Species: Mouse 0, Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat 0, Literature data Result: Negative Species: Mouse 0, Literature data Result: Negative Species: Rat
CHLORPHENIRAMINE MALEATE	1000 ppm, Dietary study Result: Negative Species: Rat Test Duration: 106 weeks Notes: NTP study report. 15 - 30 mg/kg/day, Oral gavage Result: Negative Species: Rat Test Duration: 103 weeks Notes: NTP study report. 25 - 50 mg/kg/day, oral gavage Result: Negative Species: Mouse Test Duration: 103 weeks Notes: NTP study report.

IARC Monographs. Overall Evaluation of Carcinogenicity

FD&C BLUE NO. 1 (CAS 3844-45-9)	3 Not classifiable as to carcinogenicity to humans.
PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

PARACETAMOL	<= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
DEXTROMETHORPHAN HYDROBROMIDE	<= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rabbit Notes: Global Safety Datasheet. <= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rat Notes: Global Safety Datasheet.
CHLORPHENIRAMINE MALEATE	2 - 20 mg/kg/day Peri- and Post-natal development Result: Reduced post-natal survivor. Notes: Literature reference
PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat
CHLORPHENIRAMINE MALEATE	3 - 15 mg/kg/day Embryo-foetal development Result: No developmental effects observed. Species: Rabbit
PARACETAMOL	387 mg/kg/day Embryofetal Development, Literature data Result: Negative Species: Mouse

Reproductivity

CHLORPHENIRAMINE MALEATE	5 - 20 mg/kg/day Embryo-foetal development Result: Decreased birthweight and reduced pup survival during lactation. Species: Rat Notes: Literature reference 5 - 20 mg/kg/day Reproduction/Fertility Study Result: No adverse effects on fertility. Species: Rat Notes: Literature reference
PARACETAMOL	750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weght, minor skeletal abnormalities. Species: Rat Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human

Specific target organ toxicity - single exposure Not classified.

CHLORPHENIRAMINE MALEATE	Organ: Central Nervous System.
DEXTROMETHORPHAN HYDROBROMIDE	Organ: Central Nervous System.
PARACETAMOL	Species: Human Organ: Liver

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects.

Components		Species	Test Results
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
Acute			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 10000 mg/l
CHLORPHENIRAMINE MALEATE (CAS 113-92-8)			
Aquatic			
Acute			
Algae	EC50	Algae	0.1 - 1 mg/l, 96 hours QSAR Estimate
Crustacea	EC50	Daphnia	0.1 - 1 mg/l, 48 hours QSAR Estimate
Fish	EC50	Fish	1 - 10 mg/l, 96 hours QSAR Estimate
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
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

Components		Species	Test Results
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)			
Aquatic			
Acute			
Algae	EC50	Algae	2.28 mg/l, 72 hours
	NOEC	Algae	0.35 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	13.78 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	< 5.51 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.66 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 100 mg/l, 3 hours
FD&C BLUE NO. 1 (CAS 3844-45-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 97 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 96 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 96 mg/l, 96 hours Static test
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

Persistence and degradability

Hydrolysis

Half-life (Hydrolysis-basic)

ASPARTAME	< 1 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACESULFAME K	0 - 8 %, 25 days Batch activated sludge (BAS), Activated sludge
CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge
DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
	0 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge
SUCROSE	69 % BOD5

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME	60 - 90 %, 5 days
DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

CHLORPHENIRAMINE MALEATE	3.38 (measured)
PARACETAMOL	0.36
SUCROSE	-3

Bioconcentration factor (BCF)

ASPARTAME	1 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

ASPARTAME	1.78 Estimated

Mobility in general

Volatility

Henry's law

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

Distribution

Octanol/water distribution coefficient log DOW

CHLORPHENIRAMINE MALEATE	1.15 (calculated)

Octanol/water distribution coefficient pH

CHLORPHENIRAMINE MALEATE	7

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Incinerate the material under controlled conditions in an approved incinerator. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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 Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

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 applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes
Classified hazard categories	Combustible dust Serious eye damage or eye irritation Respiratory or skin sensitization

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

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Issue date	12-02-2021
Version #	01

Further information	Refer to: OSHA 3371-08 2009, Hazard Communication Guidance for Combustible Dusts NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids
HMIS® ratings	Health: 2 Flammability: 2 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 2 Instability: 0
Disclaimer	GlaxoSmithKline cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.

SAFETY DATA SHEET

1. Identification

Product identifier **THERAFLU MAX STRENGTH FLU RELIEF - DAYTIME**

Other means of identification

Product code WH-2165-0001

Synonyms WH-2165-0001

Recommended use Consumer Healthcare Product

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

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards

Serious eye damage/eye irritation	Category 2
Sensitization, skin	Category 1

Environmental hazards Not classified.

OSHA defined hazards Combustible dust

Label elements

Signal word Warning

Hazard statement May form combustible dust concentrations in air. May cause an allergic skin reaction. Causes serious eye irritation.

Precautionary statement

Prevention	Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Avoid breathing dust. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear eye protection/face protection. Wear protective gloves.
Response	If on skin: Wash with plenty of water/. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Specific treatment (see on this label). If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. In case of fire: Use appropriate media to extinguish.
Storage	Not available.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	13.6% of the mixture consists of component(s) of unknown acute oral toxicity. 92.27% of the mixture consists of component(s) of unknown acute dermal toxicity. 84.01% of the mixture consists of component(s) of unknown acute inhalation toxicity. 83.37% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 81.81% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

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	62.1
PARACETAMOL	ACETAMIDE, N-(4-HYDROXYPHENYL)- N-(4-HYDROXYPHENYL) ACETAMIDE ACETANILIDE, 4'-HYDROXY- 4'-HYDROXYACETANILIDE PARACETAMOL PARA-ACETAMIDOPHENOL 4-ACETAMINOPHENOL PARA-HYDROXYACETANILIDE	103-90-2	8.9
MALTODEXTRIN	MALTRIN MALTRIN M 100 OHS13581 MALTODEXTRIN	9050-36-6	4.33
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACI D ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARB OXYLIC ACID CITIRIC ACID	77-92-9	3.34
NAT LEMON DURAROME, 860202 TD0991		Unassigned	1.56
SODIUM CITRATE DIHYDRATE	1,2,3-PROPANETRICARBOXYLIC ACID, 2-HYDROXY-, TRISODIUM SALT, DIHYDRATE CITRIC ACID, TRISODIUM SALT, DIHYDRATE SODIUM CITRATE, DIHYDRATE SODIUM CITRATE TRISODIUM CITRATE DIHYDRATE TRISODIUM CITRATE SODIUM CITRATE DIHYDRATE	6132-04-3	0.71
NAT LEMON WONF DURAROME, 860098 TD1091		Unassigned	0.4

Chemical name	Common name and synonyms	CAS number	%
ACESULFAME K	1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) ACESULFAM ACESULFAME POTASSIUM	55589-62-3	0.31
ASPARTAME	L-PHENYLALANINE, N-L-ALPHA-ASPARTYL-1-METHYL ESTER N-L-ALPHA-ASPARTYL-1-METHYL ESTER L-PHENYLALANINE SUCCINAMIC ACID, 3-AMINO-N-(ALPHA-CARBOXYPHENETHYL)-, ASPARTYLPHENYLALANINE METHYL ESTER METHYL ASPARTYLPHENYLALANATE NUTRASWEET	22839-47-0	0.31
CALCIUM PHOSPHATE, TRIBASIC	CALCIUM ORTHOPHOSPHATE CALCIUM PHOSPHATE TRIBASIC CALCIUM PHOSPHATE TRICALCIUM DIPHOSPHATE TRICALCIUM ORTHOPHOSPHATE TRICALCIUM PHOSPHATE ALPHA-TRICALCIUM PHOSPHATE BETA-TRICALCIUM PHOSPHATE	7758-87-4	0.3
DEXTROMETHORPHAN HYDROBROMIDE	9ALPHA,13ALPHA,14ALPHA-MORPHINAN, 3-METHOXY-17-METHYL-, HYDROBROMIDE DEXTROMETHORPHAN BROMIDE METHORATE HYDROBROMIDE C18H25NO.HBr	125-69-9	0.3
SILICON DIOXIDE	SILICA SILICA GEL AMORPHOUS SILICA DIATOMACEOUS EARTH INFUSORIAL EARTH SIDENT COLLOIDAL SILICON DIOXIDE SILICON DIOXIDE, CRYSTALLINE SILICON DIOXIDE, AMORPHOUS SILICA, AMORPHOUS HYDRATED	7631-86-9	0.11
FD&C RED NO. 40	DISODIUM 6-HYDROXY-5-((2-METHOXY-5-METHYL-4-SULFOPHENYL)AZO) DISODIUM 6-HYDROXY-5-((2-METHOXY-4-SULPHONATO-M-TOLYL)AZO)NAPHTHALENE-2-SULPHONATE DISODIUM 6-HYDROXY-5-((2-METHOXY-4-SULPHONATO-META-TOLYL)AZO)NAPHTHALENE-2-SULPHONATE FDC RED 40 FDC RED 40 DYE ALLURA RED ALLURA RED 40 RED 40 AND LAKE	25956-17-6	0.004
FD&C BLUE NO. 1	ALPHAZURINE BRILLIANT BLUE FCF, DISODIUM SALT ERIOGLAUCINE ACID BLUE 9	3844-45-9	0.001
Other components below reportable levels			17.325

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact	Do not rub eyes. Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes. Coughing. May cause an allergic skin reaction. Dermatitis. Rash.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture. Water fog. Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2). Apply extinguishing media carefully to avoid creating airborne dust.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	May form combustible dust concentrations in air.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Minimize dust generation and accumulation. Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk. Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water. Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. 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	Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value	Form
ACESULFAME K (CAS 55589-62-3)	OHC	1	>1000 - </=5000 mcg/m3
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
CALCIUM PHOSPHATE, TRIBASIC (CAS 7758-87-4)	OHC	1	
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	
	OHC	1	
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)	8 HR TWA	150 mcg/m3	SKIN
	OHC	2	SKIN
FD&C BLUE NO. 1 (CAS 3844-45-9)	OHC	3	
FD&C RED NO. 40 (CAS 25956-17-6)	OHC	1	
MALTODEXTRIN (CAS 9050-36-6)	OHC	1	>1000 - </=5000 mcg/m3
PARACETAMOL (CAS 103-90-2)	8 HR TWA	3000 mcg/m3	
	OHC	1	
SODIUM CITRATE DIHYDRATE (CAS 6132-04-3)	OHC	1	>1000 - </=5000 mcg/m3 PROVISIONAL

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	Respirable fraction.
		15 mg/m3	Total dust.

US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value
SILICON DIOXIDE (CAS 7631-86-9)	TWA	0.8 mg/m3
		20 mppcf

US. ACGIH Threshold Limit Values

Components	Type	Value
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SILICON DIOXIDE (CAS 7631-86-9)	TWA	6 mg/m3	
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total

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

Appropriate engineering controls	Explosion-proof general and local exhaust ventilation. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling of this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. Use only appropriately classified electrical equipment and powered industrial trucks. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.
Respiratory protection	If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	When using, do not eat, drink or smoke. 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. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.
Color	Off-white White. Yellow. Beige Brown.
Odor	Not available.
Odor 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.
Vapor pressure	Not available.
Vapor 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.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

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	Keep away from heat, sparks and open flame. Contact with incompatible materials. Minimize dust generation and accumulation.
Incompatible materials	Alkaline metals.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
Skin contact	Dust or powder may irritate the skin. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Dusts may irritate the respiratory tract, skin and eyes. Coughing. May cause an allergic skin reaction.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
ACESULFAME K (CAS 55589-62-3)		
Acute		
Dermal		
LD50	Rabbit	2000
Oral		
LD50	Rat	> 2000 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	11700 mg/kg
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)		
Acute		
Oral		
LD50	Rat	350 mg/kg
FD&C BLUE NO. 1 (CAS 3844-45-9)		
Acute		
Oral		
LD50	Rat	11.3 g/kg
FD&C RED NO. 40 (CAS 25956-17-6)		
Acute		
Dermal		
LD50	Rabbit	> 10 g/kg

Components	Species	Test Results
Oral		
LD50	Rat	> 10 g/kg
MALTODEXTRIN (CAS 9050-36-6)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
PARACETAMOL (CAS 103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg
TD	Human	>= 150 mg/kg
Subacute		
Oral		
NOAEL	Rat	12500 ppm, 14 Day dietary, continuous
Subchronic		
Oral		
NOAEL	Rat	6200 ppm, 13 weeks dietary, continuous
TD	Rat	>= 12500 ppm, 13 weeks dietary, continuous
Other		
LOAEL	Mouse	130 ppm, 61 weeks dietary, continuous
NOAEL	Mouse	3200 ppm, 13 weeks dietary, continuous
		0.3 %, 41 weeks dietary, continuous
TD	Mouse	6100 ppm, 13 weeks dietary, continuous
		1.25 %, 41 weeks dietary, continuous

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Irritation Corrosion - Skin: P.I.I. value

CITRIC ACID ANHYDROUS	OECD 404 Result: Mild to moderate irritant. Species: Rabbit
PARACETAMOL	OECD 404, Literature data Result: Slight irritant Species: Rabbit

Serious eye damage/eye irritation Causes serious eye irritation.

Eye

CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
PARACETAMOL	OECD 405 Result: Slight irritant Species: Rabbit

Eye / Initial pain reaction score

PARACETAMOL	0, Literature data

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization May cause an allergic skin reaction.

Sensitization

DEXTROMETHORPHAN HYDROBROMIDE	SAR, DEREK, Lhasa, UK Result: Positive

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

Mutagenicity

DEXTROMETHORPHAN HYDROBROMIDE	Ames Result: Negative Notes: Global Safety Datasheet.
PARACETAMOL	Ames, Literature data Result: Negative Chromosomal Aberration Assay In Vitro, Literature data Result: Positive HPRT gene mutation in human lymphocytes, Literature data Result: Negative
DEXTROMETHORPHAN HYDROBROMIDE	In vitro cytogenetics assay Result: Negative Notes: Aardema A et al, Reg Tox Pharm.
PARACETAMOL	In vivo Micronucleus, Literature data Result: Negative Species: Mouse

Carcinogenicity Not classifiable as to carcinogenicity to humans.

PARACETAMOL	0, Literature data Result: Equivocal. Increase in ademomas at toxic dose. Species: Mouse 0, Literature data Result: Equivocal. Liver and bladder neoplasms at toxic doses. Species: Rat 0, Literature data Result: Negative Species: Mouse 0, Literature data Result: Negative Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

FD&C BLUE NO. 1 (CAS 3844-45-9)	3 Not classifiable as to carcinogenicity to humans.
PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.
SILICON DIOXIDE (CAS 7631-86-9)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

PARACETAMOL	<= 1400 mg/kg/day Pre- and Post-natal development, Literature data Result: reduced weight gain during nursing. Species: Rat
DEXTROMETHORPHAN HYDROBROMIDE	<= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rabbit Notes: Global Safety Datasheet. <= 50 mg/kg/day Fertility Result: No adverse effects on fertility, or development. Species: Rat Notes: Global Safety Datasheet.
PARACETAMOL	250 mg/kg/day Embryofetal Development, Literature data Result: Foetal NOAEL Species: Rat 387 mg/kg/day Embryofetal Development, Literature data Result: Negative Species: Mouse 750 mg/kg/day Embryofetal Development, Literature data Result: decrease in foetal weght, minor skeletal abnormalities. Species: Rat Epidemiology, Literature data Result: No clear association with therapeutic use. Species: Human

Specific target organ toxicity - single exposure Not classified.

DEXTROMETHORPHAN HYDROBROMIDE	Organ: Central Nervous System.
PARACETAMOL	Species: Human Organ: Liver

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

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
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
Acute			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 10000 mg/l
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
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
DEXTROMETHORPHAN HYDROBROMIDE (CAS 125-69-9)			
Aquatic			
Acute			
Algae	EC50	Algae	2.28 mg/l, 72 hours
	NOEC	Algae	0.35 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	13.78 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna)	< 5.51 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	4.66 mg/l, 96 hours
Chronic			
Other	LC50	Bacteria	> 100 mg/l, 3 hours
FD&C BLUE NO. 1 (CAS 3844-45-9)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 97 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	> 96 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 96 mg/l, 96 hours Static test

Components		Species	Test Results
PARACETAMOL (CAS 103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	50 mg/l, 48 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours Flow-through test
SILICON DIOXIDE (CAS 7631-86-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours Static test
Fish	EC50	Common carp (Juvenile Cyprinus carpio)	> 10000 mg/l, 72 hours
		Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	8700 mg/l, 15 minutes

Persistence and degradability

Hydrolysis

Half-life (Hydrolysis-basic)

ASPARTAME	< 1 Days Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ACESULFAME K	0 - 8 %, 25 days Batch activated sludge (BAS), Activated sludge
CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge
DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge
	0 %, 28 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
PARACETAMOL	99 %, 5 days Modified Zahn-Wellens, Activated sludge
SUCROSE	69 % BOD5

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME	60 - 90 %, 5 days
DEXTROMETHORPHAN HYDROBROMIDE	0 %, 28 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PARACETAMOL	0.36
SUCROSE	-3

Bioconcentration factor (BCF)

ASPARTAME	1 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

ASPARTAME	1.78 Estimated

Mobility in general

Volatility

Henry's law

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

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Incinerate the material under controlled conditions in an approved incinerator. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	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	Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

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 applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes
Classified hazard categories	Combustible dust Serious eye damage or eye irritation Respiratory or skin sensitization

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

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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

Issue date 12-02-2021

Version # 01

Further information Refer to:
OSHA 3371-08 2009, Hazard Communication Guidance for Combustible Dusts
NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids

HMIS® ratings Health: 2
Flammability: 2
Physical hazard: 0

NFPA ratings Health: 2
Flammability: 2
Instability: 0

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