SAFETY DATA SHEET



1. Identification

Product identifier TUMS ULTRA STRENGTH ASSORTED BERRIES 3001111-0038 (MIXED BERRY)

Other means of identification

TUMS ULTRA STRENGTH ASSORTED BERRIES (MIXED BERRY) * TUMS ULTRA STRENGTH **Synonyms**

ASSORTED BERRIES (MIXED BERRY) (CANADA) * FORMULATION NUMBER: 3001111-0038 *

CALCIUM CARBONATE, 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.

No other uses are advised. Recommended restrictions

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive

Research Triangle Park, NC 27709 USA

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

Email: msds@gsk.com Website: www.gsk.com

EMERGENCY CONTACTS

CHEMTREC EMERGENCY NUMBERS

Telephone: +(1) 703 527 3887 (International)

24/7; multi-language response

CCN9484 **Contract Number:**

VERISK 3E GLOBAL INCIDENT RESPONSE

+(1) 760 476 3971 (In country) Telephone:

+(1) 760 476 3962 or +(1) 866 519 4752 (International)

24/7; multi-language response

Contract Number: 334878

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	%
CALCIUM CARBONATE	CARBONIC ACID, CALCIUM SALT CALCIUM MONOCARBONATE PRECIPITATED CALCIUM CARBONATE CHALK	471-34-1	39.52
STARCH	ARROWROOT STARCH CORN STARCH POTATO STARCH RICE STARCH	9005-25-8	5.42

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Chemical name	Common name and synonyms	CAS number	%
TALC	TALCUM, NON-ASBESTOS FORM TALC HYDROUS MAGNESIUM SILICATE	14807-96-6	2.1
LIGHT MINERAL OIL	OHS12791 RTECS PY8047000	8042-47-5	1.15
ADIPIC ACID	HEXANEDIOIC ACID 1,4-BUTANEDICARBOXYLIC ACID 1,6-HEXANEDIOIC ACID ADIPINIC ACID	124-04-9	0.8
SODIUM HEXAMETAPHOSPHATE	METAPHOSPHORIC ACID, HEXASODIUM SALT CALGON CHEMI-CHARL GILTEX HAGAN PHOSPHATE HEXASODIUM HEXAMETAPHOSPHATE HEXASODIUM METAPHOSPHATE RTECS OY3675000	10124-56-8	0.35
FD&C RED NO. 40	DISODIUM 6-HYDROXY-5-((2-METHOXY-5-METHY L-4-SULFOPHENYL)AZO) DISODIUM 6-HYDROXY-5-((2-METHOXY-4-SULPH ONATO-M-TOLYL)AZO)NAPHTHALENE-2-SULPHONATE DISODIUM 6-HYDROXY-5-((2-METHOXY-4-SULPH ONATO-META-TOLYL)AZO)NAPHTHAL ENE-2-SULPHONATE FDC RED 40 FDC RED 40 DYE ALLURA RED ALLURA RED 40 RED 40 AND LAKE	25956-17-6	0.13
Other components below reportable	lovole		> 50

Other components below reportable levels

> 50

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, remove to fresh air and keep at rest in a position

comfortable for breathing. Call a physician if symptoms develop or persist. Call a POISON

CENTER or doctor/physician if you feel unwell.

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Skin contact

Get medical attention if symptoms occur.

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Eye contact

If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting Ingestion

without advice from poison control center.

Most important

General information

symptoms/effects, acute and delayed

Indication of immediate

medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For

additional guidance, refer to the local poison control information centre.

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. Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media

Dry chemical powder. Carbon dioxide (CO2). Water. Foam.

Unsuitable extinguishing media

None known.

Irritant effects.

Specific hazards arising from the chemical

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.

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Fire fighting

equipment/instructions

Use water spray to cool unopened containers.

Expected to be non-combustible.

Specific methods

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

General fire hazards

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. 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

Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Avoid contact with clothing. Provide adequate ventilation. Wear appropriate personal protective equipment.

Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Туре	Value	
FD&C RED NO. 40 (CAS 25956-17-6)	OHC	1	
SODIUM HEXAMETAPHOSPHATE (CAS 10124-56-8)	OHC	1	
US. OSHA Table Z-1 Limits for Air	Contaminants (29 CFR 1910.	1000)	
Components	Туре `	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
LIGHT MINERAL OIL (CAS 8042-47-5)	PEL	5 mg/m3	Mist.
STARCH (CAS 9005-25-8)	PEL	5 mg/m3	Respirable fraction.
•		15 mg/m3	Total dust.
US. OSHA Table Z-3 (29 CFR 1910.	1000)	-	
Components	Туре	Value	Form
TALC (CAS 14807-96-6)	TWA	0.3 mg/m3	Total dust.
		0.1 mg/m3	Respirable.
		20 mppcf	
		2.4 mppcf	Respirable.
US. ACGIH Threshold Limit Values	•		
Components	Туре	Value	Form
ADIPIC ACID (CAS 124-04-9)	TWA	5 mg/m3	
LIGHT MÍNERAL OIL (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.
US. NIOSH: Pocket Guide to Chem	ical Hazards		
Components	Туре	Value	Form
CALCIUM CARBONATE (CAS 471-34-1)	TWA	5 mg/m3	Respirable.
` '		10 mg/m3	Total

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Components	Туре	Value	Form
LIGHT MINERAL OIL (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
·	TWA	5 mg/m3	Mist.
STARCH (CAS 9005-25-8)	TWA	5 mg/m3	Respirable.
		10 mg/m3	Total
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable.

Biological limit values

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

Appropriate engineering controls

General ventilation normally adequate. 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.

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.

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.

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved Respiratory protection

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

Solid. Physical state Tablet. **Form**

Color Not available. Odor Not available. **Odor threshold** Not available. Not available. Hq Not available. Melting point/freezing point Initial boiling point and boiling Not available.

range

Flash point Not available. **Evaporation rate** Not available. Not available. Flammability (solid, gas)

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%)

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available. Not available. Explosive limit - upper (%)

Vapor pressure Not available. Not available. Vapor density Relative density Not available.

Solubility(ies)

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

Not available.

Not available. **Auto-ignition temperature Decomposition temperature** Not available. Not available. **Viscosity**

10. Stability and reactivity

Not available. Reactivity

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.

Incompatible materials Acids. Fluorine.

Hazardous decomposition None known. Irritating and/or toxic fumes and gases may be emitted upon the products

decomposition. products

11. Toxicological information

Information on likely routes of exposure

Inhalation Health injuries are not known or expected under normal use. Inhalation of dusts may cause

respiratory irritation.

Health injuries are not known or expected under normal use. Dust or powder may irritate the skin. Skin contact

Eye contact Health injuries are not known or expected under normal use. Dust or powder may irritate eye

Health injuries are not known or expected under normal use. Ingestion

Symptoms related to the physical, chemical and toxicological characteristics Irritant effects.

Information on toxicological effects

Health injuries are not known or expected under normal use. Acute toxicity

Components	Species	Test Results

ADIPIC ACID (CAS 124-04-9)

Acute Oral

LD50 Rat > 11 g/kg

CALCIUM CARBONATE (CAS 471-34-1)

Acute Oral

LD50 Rat 6450 mg/kg

FD&C RED NO. 40 (CAS 25956-17-6)

Acute Dermal

LD50 Rabbit > 10 g/kg

Oral

LD50 Rat > 10 g/kg

LIGHT MINERAL OIL (CAS 8042-47-5)

Acute Oral

LD50 Rat > 2000 mg/kg

SODIUM HEXAMETAPHOSPHATE (CAS 10124-56-8)

Acute

Oral

LD50 Rat 6200 mg/kg

^{*} 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. Prolonged skin contact may cause

temporary irritation.

Serious eye damage/eye

irritation

Health injuries are not known or expected under normal use. Dust or powder may irritate eye

tissue.

Respiratory or skin sensitization

Respiratory sensitization Not applicable.

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

Germ cell mutagenicity

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

mutagenic or genotoxic.

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure. Contains a material

(talc) classified as a carcinogen by external agencies. These effects are linked only to high doses

of this substance; lower doses did not cause this adverse effect.

IARC Monographs. Overall Evaluation of Carcinogenicity

LIGHT MINERAL OIL (CAS 8042-47-5)

3 Not classifiable as to carcinogenicity to humans.

TALC (CAS 14807-96-6) 2B Possibly carcinogenic to humans.

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Health injuries are not known or expected under normal use. 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 hazardDue to partial or complete lack of data the classification is not possible.

Further information Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

TALC (CAS 14807-96-6)

Aquatic

Acute

Fish

EcotoxicityThe 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
ADIPIC ACID (CAS 1	24-04-9)		
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	31.3 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	85.7 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	97 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	230 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 48 hours Static renewal test
CALCIUM CARBONA	TE (CAS 471-34-1)		
Aquatic			
Fish	LC50	Western mosquitofish (Gambusia affinis	s) > 56000 mg/l, 24 hours

Zebra fish (Adult Brachydanio rerio)

EC50

Persistence and degradability No data is available on the degradability of this product.

> 100 g/l, 24 hours Static renewal test

^{*} Estimates for product may be based on additional component data not shown.

Photolysis

Half-life (Photolysis-atmospheric)

ADIPIC ACID

LIGHT MINERAL OIL

2.9 Days Estimated

< 1 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ADIPIC ACID 100 %, 28 days Modified Sturm test., Activated sludge LIGHT MINERAL OIL 24 %, 28 days Modified Sturm test., Activated sludge

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

ADIPIC ACID 0.08

Bioconcentration factor (BCF)

ADIPIC ACID 0.68 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ADIPIC ACID 1.4 Estimated

Mobility in general

Volatility

Henry's law

ADIPIC ACID 0 atm m^3/mol Estimated

Other adverse effects Not available.

13. Disposal considerations

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

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

15. Regulatory information

US federal regulationsOne or more components are not listed on TSCA.

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

ADIPIC ACID (CAS 124-04-9) Listed. SODIUM HEXAMETAPHOSPHATE (CAS 10124-56-8) Listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

No

chemical

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

Not regulated.

Inventory name

(SDWA)

Australia

US state regulations

US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd.

Australian Inventory of Chemical Substances (AICS)

(a))

TALC (CAS 14807-96-6)

International Inventories

Country(s) or region

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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	No

⁽PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

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

Issue date 04-16-2018

Version # 01

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 1

Flammability: 0 Physical hazard: 0

NFPA ratings Health: 1

Flammability: 0 Instability: 0

References GSK Hazard Determination

Material name: TUMS ULTRA STRENGTH ASSORTED BERRIES 3001111-0038 (MIXED BERRY) 137317 Version #: 01 Issue date: 04-16-2018

On inventory (yes/no)*

No

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).

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.