



SAFETY DATA SHEET

1. Identification

Product identifier

GAVISCON ANTACID LIQUID REGULAR STRENGTH

Other means of identification

Synonyms

FORMULA NO: 3014-101-0002 * GAVISCON ANTACID LIQUID REGULAR STRENGTH COOL MINT * ALUMINUM HYDROXIDE, MAGNESIUM CARBONATE AND SODIUM ALGINATE, FORMULATED PRODUCT

Recommended use

Medicinal Product.

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

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com

Website: www.gsk.com

EMERGENCY PHONE NUMBERS -

TRANSPORT EMERGENCIES:

US / International toll call +1 703 527 3887

available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHIDROXYPROPANE 1,2,3-TRIHIDROXYPROPANE OSMOGLYN	56-81-5	9.4

Chemical name	Common name and synonyms	CAS number	%
ALUMINUM HYDROXIDE DRIED GEL, F-2200		21645-51-2	1 - < 3
MAGNESIUM CARBONATE HYDRATE	CARBONIC ACID, MAGNESIUM SALT (1:1), HYDRATE MAGNESIUM CARBONATE, N-HYDRATE MAGNESIUM (II) CARBONATE, HYDRATE MAGNESIUM CARBONATE MAGNESIUM CARBONATE, LIGHT OHS13342	23389-33-5	1 - < 3
SODIUM ALGINATE	ALGINIC ACID, SODIUM SALT ALGIN SODIUM POLYMANNURONATE	9005-38-3	1 - < 3
TITANIUM DIOXIDE	TITANIUM OXIDE TITANIUM(IV) OXIDE TITANIUM PEROXIDE (TiO2) PIGMENT WHITE 6	13463-67-7	0.2
Other components below reportable levels			>90

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

4. 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 center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation.
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 current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
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.
Fire fighting equipment/instructions	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	This product is non-flammable.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
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Methods and materials for containment and cleaning up

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). 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. Avoid discharge into drains, water courses or onto the ground.

Environmental precautions**7. Handling and storage****Precautions for safe handling**

Avoid prolonged exposure. Observe good industrial hygiene practices.

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**

Not established

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

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
MAGNESIUM CARBONATE HYDRATE (CAS 23389-33-5)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
TITANIUM DIOXIDE (CAS 13463-67-7)	PEL	15 mg/m ³	Total dust.
		15 mg/m ³	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
ALUMINUM HYDROXIDE DRIED GEL, F-2200 (CAS 21645-51-2)	TWA	1 mg/m ³	Respirable fraction.
TITANIUM DIOXIDE (CAS 13463-67-7)	TWA	10 mg/m ³	

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MAGNESIUM CARBONATE HYDRATE (CAS 23389-33-5)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

Biological limit values

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

Exposure guidelines**Appropriate engineering controls**

General ventilation normally adequate.

Individual protection measures, such as personal protective equipment**Eye/face protection**

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

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. 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

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 Liquid.
Form Solution.
Color Not available.

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 applicable.

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 Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

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

11. Toxicological information**Information on likely routes of 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.

Ingestion Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

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

Components	Species	Test Results
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
SODIUM ALGINATE (CAS 9005-38-3)		
Acute		
Oral		
LD50	Rat	> 5000 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 macrophages in lymphoid tissue.
NOAEC	Rat	250 mg/m3, 2 years Highest dose 5 mg/m3, 24 months
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

0, Literature data
Result: Non-irritant
Species: Guinea pig

Irritation Corrosion - Skin
TITANIUM DIOXIDE

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

Serious eye damage/eye irritation

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

Eye

TITANIUM DIOXIDE

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

Respiratory or skin sensitization

Respiratory sensitization

No studies have been conducted.

Skin sensitization

None known. This product is not expected to cause skin sensitization.

Sensitization

TITANIUM DIOXIDE

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

Germ cell mutagenicity

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

Mutagenicity

TITANIUM DIOXIDE

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

Carcinogenicity

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

IARC Monographs. Overall Evaluation of Carcinogenicity

TITANIUM DIOXIDE (CAS 13463-67-7)

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity	Contains no ingredient listed as toxic to reproduction
Specific target organ toxicity - single exposure	Not assigned.
Specific target organ toxicity - repeated exposure	Not assigned.
Aspiration hazard	Not established.
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

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	
TITANIUM DIOXIDE (CAS 13463-67-7)			
Aquatic			
Fish	LC50	Mummichog (<i>Fundulus heteroclitus</i>)	> 1000 mg/l, 96 hours
Acute			
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	> 1000 mg/l, 48 hours Static test

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

Persistence and degradability Not available.

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

GLYCERIN -1.76

Mobility in soil Not available.

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

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.

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 established.

15. Regulatory information

US federal regulations

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

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

Not regulated.

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

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

FEMA Priority Substances Respiratory Health and Safety in the Flavor Manufacturing Workplace

GLYCERIN (CAS 56-81-5)

Other Flavoring Substances with OSHA PEL's

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

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

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Massachusetts RTK - Substance List

GLYCERIN (CAS 56-81-5)

MAGNESIUM CARBONATE HYDRATE (CAS 23389-33-5)

TITANIUM DIOXIDE (CAS 13463-67-7)

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

GLYCERIN (CAS 56-81-5)

MAGNESIUM CARBONATE HYDRATE (CAS 23389-33-5)

TITANIUM DIOXIDE (CAS 13463-67-7)

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

GLYCERIN (CAS 56-81-5)

TITANIUM DIOXIDE (CAS 13463-67-7)

US. Rhode Island RTK

Not regulated.

US. 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.

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

TITANIUM DIOXIDE (CAS 13463-67-7)

Listed: September 2, 2011

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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	10-29-2015
Revision date	10-29-2015
Version #	13
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 0 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 0 Flammability: 0 Instability: 0
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 Regulatory Information: United States Material Attributes & Uses; Experimental Data: Product Uses