SAFETY DATA SHEET



1. Identification

Product identifier MAALOX ADVANCED MAXIMUM STRENGTH LIQUID

Other means of identification

Synonyms MAALOX ADVANCED MAXIMUM STRENGTH ANTACID ANTIGAS LIQUID MINT * MAALOX

ADVANCED MAXIMUM STRENGTH WILDBERRY * MAALOX ADVANCED MAX STRENGTH +

GAS CHERRY * MAALOX ADVANCED MAX STRENGTH + GAS MINT * NOVARTIS

FORMULATION NUMBER 1318 * NOVARTIS FORMULATION NUMBER 1319 * NOVARTIS

FORMULATION NUMBER 1321 * ALUMINUM OXIDE, MAGNESIUM HYDROXIDE,

SIMETHICONE, FORMULATED PRODUCT

Medicinal Product. Recommended use

> 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 Canada Canadian Head Office 7333 Mississauga Road Mississauga, Ontario L5N 6L4

Canada

General Information Phone Number (normal business hours): 905-819-3000 Consumer Healthcare Product Inquiries (toll free): 1-800-250-8866 Pharmaceutical, Stiefel, and Vaccine Inquiries (toll free): 1-800-387-7374

CHEMTREC TRANSPORTATION EMERGENCY NUMBERS

Customer Number: CCN9484

(available 24hrs/7days: multi-language response)

International Toll Call +(1) 703 527 3887 Email Address: msds@gsk.com Website: www.qsk.com

Supplier Not available.

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. 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	%
Aluminum oxide	ALUMINA OXIDE ALUMINA ALUMINUM TRIOXIDE ALUMINIUM OXIDE ALUMINIUM OXIDE	1344-28-1	10

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Chemical name	Common name and synonyms	CAS number	%	
MAGNESIUM HYDROXIDE	MAGNESIA HYDRATE MILK OF MAGNESIA	1309-42-8	9	
SIMETHICONE	DIMETHYL POLYSILOXANE DIMETHICONE ACTIVATED DIMETHICONE ACTIVATED POLYMETHYLSILOXANE ANTIFOAM A MYLICON MAZU(R) DF 200SP DIMETICON OHS76398 RTECS VW6200000	8050-81-5	0.8	
Other components below reports	ahla lavals		< 85.0	

Other components below reportable levels

< 85.0

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

Indication of immediate medical attention and special treatment needed

General information

Not established.

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.

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

Unsuitable extinguishing

media

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

None known.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Fire fighting

General fire hazards

equipment/instructions

Specific methods

Move containers from fire area if you can do so without risk.

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

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. 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. For waste disposal, see section 13 of the SDS.

Never return spills in original containers for re-use.

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

7. Handling and storage

Precautions for safe handling Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect

material from direct sunlight. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with

eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation.

Conditions for safe storage, including any incompatibilities Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight.

Store in a closed container away from incompatible materials.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Not established

US. ACGIH	Threshold	Limit Values
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Components	Туре	Value	Form	
Aluminum oxide (CAS 1344-28-1)	TWA	1 mg/m3	Respirable fraction.	_

Canada, Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components	Туре	Value	
Aluminum oxide (CAS 1344-28-1)	TWA	10 mg/m3	

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components	Туре	Value	Form	
Aluminum oxide (CAS	TWA	1 mg/m3	Respirable.	
1344-28-1)				

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components	Туре	Value	Form	
Aluminum oxide (CAS 1344-28-1)	TWA	1 mg/m3	Respirable fraction.	

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components	Туре	Value	Form	
Aluminum oxide (CAS 1344-28-1)	TWA	1 mg/m3	Respirable fraction.	

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment) Components Type Value **Form**

Aluminum oxide (CAS **TWA** 10 mg/m3 Total dust. 1344-28-1)

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

Exposure guidelines

General ventilation normally adequate. Appropriate engineering

controls

Individual protection measures, such as personal protective equipment

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

Skin protection

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

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.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

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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

Liquid. **Physical state** Suspension. **Form** Color Not available. Odor Not available. **Odor threshold** Not available. Not available. Ηq Melting point/freezing point Not available. Not available. Initial boiling point and boiling

range

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 Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Explosive properties Not explosive.

10. Stability and reactivity

Reactivity Not available.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Heat, flames and sparks. Contact with incompatible materials.

Incompatible materials Not available.

Hazardous decomposition

products

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.

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Ingestion Health injuries are not known or expected under normal use. May be harmful if swallowed.

Symptoms related to the physical, chemical and toxicological

Not established.

Information on toxicological effects

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

Components **Test Results**

MAGNESIUM HYDROXIDE (CAS 1309-42-8)

Acute Oral

characteristics

LD50 Rat 8500 mg/kg

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

Serious eve damage/eve

irritation

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

temporary irritation.

Respiratory or skin sensitization

Respiratory sensitization Based on available data, the classification criteria are not met.

Skin sensitization Due to partial or complete lack of data the classification is not possible.

Germ cell mutagenicity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Carcinogenicity

ACGIH Carcinogens

Aluminum oxide (CAS 1344-28-1) A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

ALUMINUM METAL AND INSOLUBLE COMPOUNDS. Not classifiable as a human carcinogen.

RESPIRABLE FRACTION (CAS 1344-28-1)

Reproductive toxicity Based on available data, the classification criteria are not met.

Specific target organ

toxicity - single exposure

Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated

exposure

Based on available data, the classification criteria are not met.

Not likely, due to the form of the product. **Aspiration hazard**

Chronic effects Not available.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause

adverse effects.

12. Ecological information

There is insufficient information to determine the scope of the environmental effects this material **Ecotoxicity**

may cause. Avoid contaminating soil or water and entry into drainage or sewer systems. It should

not be released into the environment.

Persistence and degradability

Not available. Not available. Bioaccumulative potential Mobility in soil Not available. Not available. Mobility in general Not available. Other adverse effects

13. Disposal considerations

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not **Disposal instructions**

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.

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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

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Not available.

Annex II of MARPOL 73/78 and the IBC Code

15. Regulatory information

Canadian regulations

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

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

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

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

16. Other information

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References **GSK Hazard Determination**

The information and recommendations in this safety data sheet are, to the best of our knowledge, Disclaimer

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.

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