SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	GAVISCON TABLETS
Registration number	-
Synonyms	ALGINIC ACID 200 MG AND ALUMINUM HYDROXIDE 80 MG CHEWABLE TABLETS * ALGINIC ACID, PANADOL, MAGNESIUM SILICATE, AND ALUMINUM HYDROXIDE, FORMULATED PRODUCT
Issue date	18-November-1998
Version number	13
Revision date	27-April-2012
Supersedes date	19-April-2012

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES (by country / geographic region):

Africa / EU / Israel / Middle East (English / European languages):	+44 (0) 1235 239 670
Asia Pacific (except China):	+65 3158 1074
China:	+86 10 5100 3039
Middle East / Africa (Arabic-speaking countries):	+44 (0) 1235 239 671
United States:	+1 703 527 3887

available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards Expected to be non-combustible.
Handling this product in its final form presents minimal risk from occupational exposure.
Health effects information is based on hazards of components.
No information is available about the potential of this product to produce adverse environmental effects.

SECTION 3: Composition/information on ingredients

3.1. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
ALGINIC ACID	12.5	9005-32-7 232-680-1	-	-	
Classification: **DSD:** -					
CLP: -					
ALUMINUM HYDROXIDE DRIED GEL, F-2200	5	Unassigned -	-	-	
Classification: **DSD:** Xi;R36					
CLP: Eye Irrit. 2;H319					
PARACETAMOL	1.26	103-90-2 203-157-5	-	-	
Classification: **DSD:** Xn;R22, N;R51/53					
CLP: Acute Tox. 4;H302, Aquatic Chronic 2;H411					
MAGNESIUM SILICATE	1.25	14987-04-3 239-076-7	-	-	
Classification: **DSD:** -					
CLP: -					

Components below reportable levels >79.0

SECTION 4: First aid measures

General information 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.

4.1. Description of first aid measures

Inhalation Physical form suggests that risk of inhalation exposure is negligible.

Skin contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Eye contact Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed None known.

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media

Suitable extinguishing media Water or foam extinguishers are recommended.

Unsuitable extinguishing media Carbon dioxide or dry powder extinguishers may be ineffective.

5.2. Special hazards arising from the substance or mixture Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

5.3. Advice for firefighters

Special protective equipment for firefighters	Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.
Special fire fighting procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Wear protective clothing and equipment consistent with the degree of hazard.
For emergency responders	Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
6.3. Methods and material for containment and cleaning up	Collect and place it in a suitable, properly labelled container for recovery or disposal. No specific decontamination or detoxification procedures have been identified for this product.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid breaking or crushing tablets.
7.2. Conditions for safe storage, including any incompatibilities	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value
ALGINIC ACID (9005-32-7)	OHC	1
PARACETAMOL (103-90-2)	8 HR TWA	4000 mcg/m3
	OHC	1
SODIUM BICARBONATE (144-55-8)	8 HR TWA	5000 mcg/m3
	OHC	1
Sucrose (57-50-1)	OHC	1

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
PARACETAMOL (103-90-2)	TWA	10 mg/m3	Inhalable dust.

United Kingdom

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

Biological limit values

EU

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

United Kingdom

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

Recommended monitoring procedures	Not available.
Derived No Effect Level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	Not available.

Individual protection measures, such as personal protective equipment

General information	An eye wash station should be available.
Eye/face protection	Wear approved safety glasses with side shields if eye contact is possible.
Skin protection	
- Hand protection	None required for the normal handling of this material.
- Other	Not available.
Respiratory protection	Not available.
Thermal hazards	Not available.
Hygiene measures	None required for normal handling. Wash hands and arms thoroughly after handling.
Environmental exposure controls	
Hazard guidance and control recommendations	Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical state	Solid.
Form	Tablet.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not applicable.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not applicable.
Evaporation rate	Not applicable.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not applicable.
Vapour density	Not applicable.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Decomposition temperature	Not available.
Viscosity	Not applicable.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	Not available.
10.2. Chemical stability	This product is expected to be stable.
10.3. Possibility of hazardous reactions	Not available.
10.4. Conditions to avoid	None for normal handling of this product.
10.5. Incompatible materials	Not available.
10.6. Hazardous decomposition products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

SECTION 11: Toxicological information

General information Not available.

Information on likely routes of exposure

Ingestion Exposure from ingestion may occur. Not expected to be toxic following ingestion.

Inhalation Not expected to occur during normal handling of this product.

Skin contact Direct contact may occur. Irritation is not expected following direct contact.

Eye contact Direct contact may occur. Irritation is not expected following direct contact with eyes.

Symptoms Not available.

11.1. Information on toxicological effects

Acute toxicity No studies have been conducted. Not expected to be toxic following ingestion. Assessment based upon effects of individual components.

Components	Species	Test results
ALGINIC ACID (9005-32-7)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
PARACETAMOL (103-90-2)		
Acute		
Oral		
LD50	Rat	1944 mg/kg

Skin corrosion/irritation No studies have been conducted. Irritation is not expected following direct contact.

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

PARACETAMOL	0.3

Serious eye damage/eye irritation No studies have been conducted. Irritation is not expected following direct contact with eyes. Assessment based upon effects of individual components.

Respiratory sensitisation No studies have been conducted.

Skin sensitisation Sensitisation (allergic skin reaction) is not expected. Assessment based upon effects of individual components.

Germ cell mutagenicity Not expected to be genotoxic, based on effects of individual components.

Carcinogenicity No studies have been conducted.

IARC Monographs. Overall Evaluation of Carcinogenicity

PARACETAMOL (CAS 103-90-2)	3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Specific target organ toxicity - single exposure No specific target organ effects have been identified.

Specific target organ toxicity - repeated exposure No specific target organ effects have been identified.

Aspiration hazard No studies have been conducted.

Mixture versus substance information No studies have been conducted.

Other information None known for occupational exposure.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

Components		Species	Test results
PARACETAMOL (103-90-2)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	134 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	9.2 mg/l, 48 hours, Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	814 mg/l, 96 hours, Flow-through test

Components		Species	Test results
Microtox	EC50	Microtox	1000 mg/l, 30 minutes

12.2. Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

PARACETAMOL 99 %, 5 days Modified Zahn-Wellens, Activated sludge

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow)

PARACETAMOL 0.36

12.4. Mobility in soil

Mobility in general

Volatility

Henry's law

PARACETAMOL 0 atm m^3/mol Estimated

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste Not available.

Contaminated packaging Not available.

EU waste code Not available.

Disposal methods/information Observe all local and national regulations when disposing of this product. Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

SECTION 14: Transport information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 on persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 143/2011 Annex XIV Substances Subject to Authorisation

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

National regulations	Not available.
15.2. Chemical safety assessment	Not available.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	Not available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R22 Harmful if swallowed. R36 Irritating to eyes. R51/53 Toxic to aquatic organisms, May cause long-term adverse effects in the aquatic environment. H302 - Harmful if swallowed. H319 - Causes serious eye irritation. H411 - Toxic to aquatic life with long lasting effects.
Revision information	Not available.
Training information	Not available.
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.
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