

1. Identification

Product identifier

EX LAX MAXIMUM STRENGTH PILLS 25MG

Other means of identification

Synonyms

EXLAX MAXIMUM STRENGTH PILLS 25 MG * EX-LAX EXTRA STRENGTH PILLS * EX-LAX 25 MG GRAGEAS * SENNOSIDES A+B, CALCIUM SALT (USP), 25 MG * MFC0016 * SENNOSIDES AND CALCIUM SALT, 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 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.gsk.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	%
MAGNESIUM STEARATE	STEARIC ACID, MAGNESIUM SALT MAGNESIUM DISTEARATE DIBASIC MAGNESIUM STEARATE MAGNESIUM DISTEARATE, PURE	557-04-0	10 - 25

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CRYSTALLINE CELLULOSE	9004-34-6	10 - 25
SUCROSE	SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR ALPHA-D-GLUCOPYRANOSIDE, BETA-D- FRUCTOFURANOSYL GRANULATED SUGAR SUCRALOX	57-50-1	10 - 25
PREGELATINIZED STARCH		9005-25-8	2.5 - 10
TALC	ASBESTINE BEAVER WHITE 200 BEAVER WHITE 325 CIMFLEX 606 AGALITE CIRCRO MP CRYSTALITE CRS 6002 CROWN TALC W 83 CROWN TALC Z CUBIC MASTER DESERTALC 57 EMTAL 500 EMTAL 549 EMTAL 596 EMTAL 599 FIBRENE C 400 FINNTALC PF IT EXTRA MICRO ACE K1 MICRO ACE L1 MICRON WHITE 5000A MICRON WHITE 5000P MICRON WHITE 5000S MICROTALCO IT EXTRA MISTRON FROST P MISTRON STAR MISTRON SUPER FROST MISTRON VAPOR MUSSOLINITE NYTAL 200 NYTAL 400 POLYTAL 4641 POLYTAL 4725 SILICATE: TALC, CONTAINING NO ASBESTOS (OSHA) STEAWHITE SUPREME SUPREME DENSE TALC (ACGIH) TALCAN PK-P TALCRON CP 44-31 TALCUM TALC, (MG3H2(SIO3)4) TALC - NON-ASBESTOS FORM TALCO (SIN FIBRAS DE ASBESTO)	14807-96-6	<2.5

Chemical name	Common name and synonyms	CAS number	%
ALGINIC ACID	KELACID NORGINE POLYMANNUROIC ACID	9005-32-7	<2.0
SENNOSIDES A + B, CALCIUM SALT (USP)	HYDROXYANTHRACENE GLYCOSIDES SENNA SENNOSIDE SENNA LEAVE DERIVATIVE	N/A	25 MG

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	Not established.
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	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.
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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

Components	Type	Value
ALGINIC ACID (CAS 9005-32-7)	OHC	1

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

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

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable particles.

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

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	3 mg/m3	Respirable fraction.
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3 3 mg/m3	Total dust. Respirable fraction.
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3 3 mg/m3	Total dust. Respirable fraction.
TALC (CAS 14807-96-6)	TWA	10 mg/m3 2 mg/m3	Total dust. Respirable.

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

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 mg/m3	Respirable fraction.

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

Components	Type	Value	Form
MAGNESIUM STEARATE (CAS 557-04-0)	TWA	10 mg/m3	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	2 fibers/ml 2 mg/m3	Respirable particles.

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3	Total dust.
PREGELATINIZED STARCH (CAS 9005-25-8)	TWA	10 mg/m3	Total dust.
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3	
TALC (CAS 14807-96-6)	TWA	3 mg/m3	Respirable dust.

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 Solid.
Form Tablet.
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 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.

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.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Not established.

Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
ALGINIC ACID (CAS 9005-32-7)		
<u>Acute</u>		
Oral		
LD50	Rat	> 5000 mg/kg
MAGNESIUM STEARATE (CAS 557-04-0)		
<u>Acute</u>		
Oral		
LD50	Rat	> 2000 mg/kg
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
<u>Acute</u>		
Dermal		
LD50	Rabbit	> 2000 mg/kg

Components	Species	Test Results
Oral LD50	Rat	> 2000 mg/kg
TALC (CAS 14807-96-6)		
Acute Inhalation NOAEL	Rat	10.8 mg/m3
Skin corrosion/irritation	Health injuries are not known or expected under normal use.	
Irritation Corrosion - Skin: P.I.I. value MAGNESIUM STEARATE	0	
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.	
Eye / Kay and Calandra class - Intact MAGNESIUM STEARATE	4	Recovery Period: 2 days
Respiratory or skin sensitization		
Canada - Alberta OELs: Irritant		
MAGNESIUM STEARATE (CAS 557-04-0)	Irritant	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	Irritant	
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.	
Carcinogenicity	Based on available data, the classification criteria are not met.	
ACGIH Carcinogens		
MAGNESIUM STEARATE (CAS 557-04-0)	A4 Not classifiable as a human carcinogen.	
PREGELATINIZED STARCH (CAS 9005-25-8)	A4 Not classifiable as a human carcinogen.	
SUCROSE (CAS 57-50-1)	A4 Not classifiable as a human carcinogen.	
TALC (CAS 14807-96-6)	A4 Not classifiable as a human carcinogen.	
Canada - Manitoba OELs: carcinogenicity		
STARCH (CAS 9005-25-8)	Not classifiable as a human carcinogen.	
STEARATES (EXCEPT STEARATES OF TOXIC METALS) (CAS 557-04-0)	Not classifiable as a human carcinogen.	
SUCROSE (CAS 57-50-1)	Not classifiable as a human carcinogen.	
TALC, CONTAINING NO ASBESTOS FIBERS, RESPIRABLE FRACTION (CAS 14807-96-6)	Not classifiable as a human carcinogen.	
IARC Monographs. Overall Evaluation of Carcinogenicity		
TALC (CAS 14807-96-6)	2B Possibly carcinogenic to humans. 3 Not classifiable as to carcinogenicity to humans.	
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.	
Aspiration hazard	Not likely, due to the form of the product.	
Chronic effects	Not available.	
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.	

12. Ecological information

Ecotoxicity	There is insufficient information to determine the scope of the environmental effects this material may cause. Avoid contaminating soil or water and entry into drainage or sewer systems. It should not be released into the environment.
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Components	Species		Test Results
MAGNESIUM STEARATE (CAS 557-04-0)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	130 mg/l, 96 hours
TALC (CAS 14807-96-6)			
Aquatic			
Acute			
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 100 g/l, 24 hours Static renewal test
Persistence and degradability	Not available.		
Photolysis			
Half-life (Photolysis-atmospheric)			
MAGNESIUM STEARATE			17 Hours Estimated
UV/visible spectrum wavelength			
MAGNESIUM STEARATE			210 nm
Biodegradability			
Percent degradation (Aerobic biodegradation-inherent)			
MAGNESIUM STEARATE			77 %, 28 days BOD
SUCROSE			69 % BOD5
Percent degradation (Aerobic biodegradation-ready)			
MAGNESIUM STEARATE			95 %, 22 days Sturm test
Percent degradation (Aerobic biodegradation-soil)			
MAGNESIUM STEARATE			50 %, 13 days
Bioaccumulative potential	Not available.		
Partition coefficient n-octanol / water (log Kow)			
SUCROSE			-3
Bioconcentration factor (BCF)			
MAGNESIUM STEARATE			> 9999 Estimated
Mobility in soil	Not available.		
Adsorption			
Soil/sediment sorption - log Koc			
MAGNESIUM STEARATE			5.86 Estimated
Mobility in general	Not available.		
Volatility			
Henry's law			
SUCROSE			< 0 atm m^3/mol Estimated
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

TDG

Not regulated as dangerous goods.

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 available.

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)	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
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

Issue date	09-15-2016
Version #	01
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.