SAFETY DATA SHEET

HALEON

1. Identification

Product identifier **PREPARATION H RAPID RELIEF CREAM WITH PHENYLEPHRINE + LIDOCAINE**

Other means of identification

Product code WH-1875-0002

Synonyms WH-1875-0002 * PREPARATION H RAPID RELIEF CREAM WITH PHENYLEPHRINE + LIDOCAINE * H000015011

Recommended use Consumer Healthcare 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

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

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

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 335879

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

OSHA defined hazards Not classified.

Label elements

Signal word Warning

Hazard statement May cause an allergic skin reaction. Causes serious eye irritation. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.

Precautionary statement

Prevention	Avoid breathing dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Avoid release to the environment. Wear eye protection/face protection. Wear protective gloves.
Response	If on skin: Wash with plenty of water/. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Specific treatment (see on this label). If skin irritation or rash occurs: Get medical advice/attention. If eye irritation persists: Get medical advice/attention. Wash contaminated clothing before reuse.
Storage	Not available.
Disposal	Not available.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	6% of the mixture consists of component(s) of unknown acute oral toxicity. 13% of the mixture consists of component(s) of unknown acute dermal toxicity. 27.45% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 27.45% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

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 TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE OSMOGLYN	56-81-5	10 - < 20
PHARMACEUTICAL GRADE PETROLATUM	PETROLEUM JELLY VASELINE WHITE PETROLEUM JELLY WHITE PETROLEUM USP PETROLATO (PETROLIO) PETROLATUM PRETOLATO PÉTROLATUM VASELIN WHITE PETROLATUM USP YELLOW PETROLATUM SOFT PARAFFIN	8009-03-8	10 - < 20
LIDOCAINE	2-(DIETHYLAMINO)-N-(2,6-DIMETHYLPHENYL)ACETAMIDE ACETAMIDE, 2-(DIETHYLAMINO)-N-(2,6-DIMETHYLPHENYL)- 2-(DIETHYLAMINO)-2',6'-ACETOXYLIDIDE DUNCAINE LIGNOCAINE XYLOCAIN XYLOCAINE 2',6'-ACETOXYLIDIDE, 2-(DIETHYLAMINO)-	137-58-6	5 - < 10
STEARYL ALCOHOL	1-OCTADECANOL 1-HYDROXYOCTADECANE OCTADECANOL N-OCTADECANOL OCTADECYL ALCOHOL N-OCTADECYL ALCOHOL C18H38O OHS21876 RTECS RG2010000	112-92-5	5 - < 10

Chemical name	Common name and synonyms	CAS number	%
CETYL ALCOHOL	1-HEXADECANOL HEXADECYL ALCOHOL N-1-HEXADECANOL N-CETYL ALCOHOL 1-HEXADECYL ALCOHOL CETEARYL ALCOHOL PALMITYL ALCOHOL	36653-82-4	3 - < 5
GLYCERYL MONOSTEARATE	OCTADECANOIC ACID, MONOESTER WITH 1,2,3-PROPANETRIOL GLYCERIN MONOSTEARATE GLYCEROL MONOSTEARATE STEARIC ACID MONOGLYCERIDE STEARIC MONOGLYCERIDE CEFATIN	31566-31-1	3 - < 5
POLYETHYLENE GLYCOL STEARYL ETHER	POLY(OXY-1,2-ETHANEDIYL), ALPHA-OCTADECYL-OMEGA-HYDROX XL ALPHA-OCTADECYL-OMEGA-HYDROX Y-POLY(OXY-1,2-ETHANEDIYL) GLYCOLS, POLYETHYLENE, MONOOCTADECYL ETHER POLY(OXYETHYLENE) STEARYL ETHE R ETHOXYLATED STEARYL ALCOHOL STEARYL ALCOHOL ETHOXYLATE STEARYL POLYOXYETHYLENE ETHER POLYOXYL STEARYL ETHER STEARETH-2 OCTADECAN-1-OL, ETHOXYLATED PEG STEARYL ETHER	9005-00-9	1 - < 3
POLYOXYETHYLENE (23) LAURYL ETHER	BRIJ 35 GLYCOLS, POLYETHYLENE, MONODODODECYL ETHER DODECYL POLY(OXYETHYLENE) ETHER POLYOXYL LAURYL ETHER POLYOXYL 4 LAURYL ETHER POLY(OXYETHYLENE) LAURYL ETHER POLYETHYOXYLATED DODECANOL POLYETHYLENE GLYCOL LAURYL ETHER POLY(ETHYLENE OXIDE) DODECYL ETHER POLYETHYLENE OXIDE LAURYL ETHE R POLY(OXYETHYLENE) DODECYL ETHER LAURYL ALCOHOL ETHOXYLATE LAURYL POLYETHYLENE GLYCOL ETHER LAURYL POLY(OXYETHYLENE) ETHER LAURETH-4	9002-92-0	1 - < 3
TOCOPHEROL	ALPHA-TOCOPHEROL TOCOFEROL	1406-66-2	< 1
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARB OXYLIC ACID, MONOHYDRATE CITRIC ACID MONOHYDRATE	5949-29-1	< 0.3
PHENYLEPHRINE HYDROCHLORIDE	(-)-M-HYDROXY-ALPHA-((METHYLAMIN O)METHYL)BENZYL ISOPHRIN HYDROCHLORIDE LEVOPHENYLEPHRINE HYDROCHLORIDE METAOXEDRINE HYDROCHLORIDE META-SYNEPHRINE HYDROCHLORIDE NEOPHRYN NEO-SYNEPHRINE HYDROCHLORIDE L-PHENYLEPHRINE HYDROCHLORIDE BENZENEMETHANOL, 3-HYDROXY-ALPHA-(METHYLAMINO)M ETHYL)-, HYDROCHLORIDE, (R)-	61-76-7	< 0.3

Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL 1,2-DIHYDROXYPROPANE 2-HYDROXYPROPANOL ISOPROPYLENE GLYCOL METHYLETHYLENE GLYCOL METHYLETHYL GLYCOL MONOPROPYLENE GLYCOL 2,3-PROPANEDIOL ALPHA-PROPYLENE GLYCOL 1,2-PROPYLENE GLYCOL (RS)-1,2-PROPANEDIOL 1,2-(RS)-PROPANEDIOL 1,2-PROPANDIOL DL-1,2-PROPANEDIOL DL-PROPYLENE GLYCOL PROPANE-1,2-DIOL (PROPYLENE GLYCOL) PROPANE-1-2-DIOL PROPANEDIOL,1,2-	57-55-6	< 0.3
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODUIM BENZOIC ACID	532-32-1	< 0.3
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID ANHYDROUS CITRIC ACID 2-HYDROXY-1,2,3-PROPANETRICARBOXYLIC ACID CITIRIC ACID	77-92-9	< 0.2
PROPYL GALLATE	BENZOIC ACID, 3,4,5-TRIHYDROXY-, PROPYL ESTER NIPA 49 NIPAGALLIN P PROGALLIN P PROPYLESTER KYSELINY GALLOVE (CZECH) N-PROPYL ESTER OF 3,4,5-TRIHYDROXYBENZOIC ACID PROPYL GALLATE N-PROPYL GALLATE PROPYL 3,4,5-TRIHYDROXYBENZOATE N-PROPYL 3,4,5-TRIHYDROXYBENZOATE TENOX PG 3,4,5-TRIHYDROXYBENZENE-1-PROPYLCARBOXYLATE 3,4,5-TRIHYDROXYBENZOIC ACID N-PROPYL ESTER	121-79-9	< 0.2
VITAMIN E	(+)-ALPHA-TOCOPHEROL VITAMIN E, 1000 I.U./g (DISTILLED FROM VEGETABLE OIL) (2R,4'R,8'R)-ALPHA-TOCOPHEROL ALPHA TOCOPHEROL ANTISTERILITY VITAMIN D-VITAMIN E EMIPHEROL VITAMIN E	59-02-9	< 0.2

Chemical name	Common name and synonyms	CAS number	%
XANTHAN GUM	ACTIGUM CX 9 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 GALAXY XB KELFLO KELTROL (GUM) KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 XANFLOOD XANTHOMONAS GUM	11138-66-2	< 0.2
BUTYLATED HYDROXYANISOLE	BHA TENOX BHA (1,1-DIMETHYLETHYL)-4-METHOXYPH ENOL ANTIOXYNE B BUTYLHYDROXYANISOLE TERT-BUTYLHYDROXYANISOLE EMBANOX PROTEX SUSTANE 1F SUSTAN 1F OHS03640 RTECS SL1945000 BUTYLHYDROXYANISOLE (BHA) T-BUTYL HYDROXY ANISOLE (BHA) TERT.-BUTYL-4-METHOXYPHENOL	25013-16-5	< 0.1
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	(ETHYLENEDIAMINETETRAACETIC ACID), DISODIUM SALT ACETIC ACID, (ETHYLENEDINITRILO)TETRA-, DISODIUM SALT CHELAPLEX DISODIUM EDETATE DISODIUM EDTA DISODIUM ETHYLENEDIAMINE TETRAACETATE DISODIUM SEQUESTRENE DISODIUM VERSENATE DISODIUM VERSENE EDETATE DISODIUM EDTA DISODIUM SALT ENDRATE DISODIUM N,N'-1,2-ETHYLENEDIYLBIS(N-(CARBOXYMETHYL)GLYCINE, DISODIUM SALT SELEKTON B2 SODIUM (DI) ETHYLENEDIAMINE TETRAACETATE TETRACEMATE DISODIUM	139-33-3	< 0.1
MINERAL OIL U.S.P.	WHITE MINERAL OIL WHITE MINERAL OIL, (PETROLEUM) WHITE OIL(REFINED PETROLEUM OIL) LIQUID PARAFFIN BP MINERAL OIL, WHITE PARAFFIN OIL	8042-47-5	< 0.1
Other components below reportable levels			40 - < 50

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause an allergic skin reaction. Dermatitis. Rash. May be irritating to eyes. May be irritating to the skin.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media	Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
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. 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	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. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with eyes, skin, and clothing. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK Components	Type	Value	Form
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)	OHC	2	
CETYL ALCOHOL (CAS 36653-82-4)	OHC	2	>5 - </=50 ppm
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3	

GSK

Components	Type	Value	Form
	OHC	1	
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT (CAS 139-33-3)	8 HR TWA	3000 mcg/m3	
	OHC	1	
HYDROUS CITRIC ACID (CAS 5949-29-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	
LIDOCAINE (CAS 137-58-6)	8 HR TWA	200 mcg/m3	SKIN
	OHC	2	SKIN
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)	8 HR TWA	40 mcg/m3	SKIN
	OHC	3	SKIN
SODIUM BENZOATE (CAS 532-32-1)	8 HR TWA	5000 mcg/m3	
STEARYL ALCOHOL (CAS 112-92-5)	8 HR TWA	5000 mcg/m3	
	OHC	1	
TOCOPHEROL (CAS 1406-66-2)	OHC	1	>1000 - ≤5000 mcg/m3
VITAMIN E (CAS 59-02-9)	OHC	1	>1000 - ≤5000 mcg/m3
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

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/m3	Respirable fraction.
		15 mg/m3	Total dust.
MINERAL OIL U.S.P. (CAS 8042-47-5)	PEL	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
GLYCERYL MONOSTEARATE (CAS 31566-31-1)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.
MINERAL OIL U.S.P. (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MINERAL OIL U.S.P. (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

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

Exposure guidelines Occupational Exposure Limits are not relevant to the current physical form of the product.

US ACGIH Threshold Limit Values: Skin designation

SODIUM BENZOATE (CAS 532-32-1) Danger of cutaneous absorption

Appropriate engineering controls Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles). Face shield is recommended.

Skin protection

Hand protection Suitable gloves can be recommended by the glove supplier.

Other Wear appropriate chemical resistant clothing. Use of an impervious apron is recommended.

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 Not applicable. 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. Contaminated work clothing should not be allowed out of the workplace. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance Cream.

Physical state Not available.

Form Paste.

Color White.

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

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	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	No adverse effects due to inhalation are expected.
Skin contact	Causes mild skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. May cause an allergic skin reaction. Dermatitis. Rash. May be irritating to eyes. May be irritating to the skin.

Information on toxicological effects

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

Components	Species	Test Results
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)		
Acute		
Oral		
LD50	Rat	2 g/kg
CETYL ALCOHOL (CAS 36653-82-4)		
Acute		
Dermal		
LD50	Rabbit	8000 mg/kg, 24 Hours
Oral		
LD50	Rat	> 2000 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg, 24 Hours
Oral		
LD50	Rat	11700 mg/kg
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT (CAS 139-33-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
LIDOCAINE (CAS 137-58-6)		
Acute		
Oral		
LD50	Rat	317 mg/kg
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
		> 15 g/kg
Chronic		
Oral		
NOAEL	Rat	>= 3000 mg/kg, 2 years
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)		
Acute		
Oral		
LD50	Rat	350 mg/kg
Subacute		
Oral		
NOAEL	Mouse	2000 ppm, 14 Day Dietary study, highest dose tested.
	Rat	2000 ppm, 14 Day Dietary study, highest dose tested.
Subchronic		
Oral		
LD	Mouse	5000 - 20000 ppm, 12 weeks dietary study
	Rat	5000 - 20000 ppm, 12 weeks dietary study
LOAEL	Mouse	1250 ppm, 12 weeks dietary study
	Rat	1250 ppm, 12 weeks dietary study
POLYETHYLENE GLYCOL STEARYL ETHER (CAS 9005-00-9)		
Acute		
Dermal		
LD50	Rabbit	2000 mg/kg, 24 Hours
Oral		
LD50	Rat	> 21000 mg/kg
POLYOXYETHYLENE (23) LAURYL ETHER (CAS 9002-92-0)		
Acute		
Oral		
		< 2000 mcg/kg/day
PROPYL GALLATE (CAS 121-79-9)		
Acute		
Oral		
LD50	Rat	2100 mg/kg
SODIUM BENZOATE (CAS 532-32-1)		
Acute		
Oral		
LD50	Rat	2000 mg/kg

Components	Species	Test Results
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
LD50	Rat	> 5000 mg/kg

Skin corrosion/irritation Causes mild skin irritation.

Corrosivity

PHENYLEPHRINE HYDROCHLORIDE	0, Supplier SDS Result: Non-irritant Species: Rabbit Notes: US Pharmacopeia
POLYOXYETHYLENE (23) LAURYL ETHER	Literature search Result: Moderate Irritant
SODIUM BENZOATE	OECD 404 Result: Negative Species: Rabbit

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

CITRIC ACID ANHYDROUS	OECD 404 Result: Mild to moderate irritant. Species: Rabbit

Serious eye damage/eye irritation Causes serious eye irritation.

Eye

PHENYLEPHRINE HYDROCHLORIDE	0, Supplier SDS Result: Irritant
SODIUM BENZOATE	Acute ocular irritation; OECD 405 Result: Mild irritant Species: Rabbit
CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit
PHENYLEPHRINE HYDROCHLORIDE	Clinical use Result: Pharmacological, cardiovascular effects. Species: Human
POLYOXYETHYLENE (23) LAURYL ETHER	Literature search Result: Severe Irritant

Respiratory or skin sensitization

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

Skin sensitization May cause an allergic skin reaction.

Sensitization

PHENYLEPHRINE HYDROCHLORIDE	Clinical use - Opthalmology Result: Low incidence of contact hypersensitivity. Species: Human
SODIUM BENZOATE	Local lymph node assay Result: Negative Species: Mouse

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

Mutagenicity

SODIUM BENZOATE	Ames Result: Negative
PHENYLEPHRINE HYDROCHLORIDE	Ames Result: Negative Notes: NTP Study report - Phenylephrine. Chromosomal Aberration Assay In Vitro, CHO cells Result: Negative Notes: NTP Study report - Phenylephrine.
SODIUM BENZOATE	Chromosomal aberration assay Result: Negative Species: Rat

Mutagenicity

PHENYLEPHRINE HYDROCHLORIDE	L5178Y mouse lymphoma thymidine kinase locus assay Result: Equivocal Notes: NTP Study report - Phenylephrine. sister chromatid exchange Result: Positive Notes: NTP Study report - Phenylephrine.

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

PHARMACEUTICAL GRADE PETROLATUM	>= 3000 mg/kg/day 2 year bioassay, oral administration Result: NOAEL Species: Rat
PHENYLEPHRINE HYDROCHLORIDE	133 - 270 mg/kg/day Result: Negative Species: Mouse Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.
SODIUM BENZOATE	2 year study, Male + Female Result: Negative - dietary Species: Rat
PHENYLEPHRINE HYDROCHLORIDE	24 - 50 mg/kg/day Result: Negative Species: Rat Test Duration: 103 weeks Notes: NTP Report - Tox and carc studies with phenylephrine hydrochloride.
PHARMACEUTICAL GRADE PETROLATUM	Dermal application Result: Negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)	2B Possibly carcinogenic to humans.
MINERAL OIL U.S.P. (CAS 8042-47-5)	3 Not classifiable as to carcinogenicity to humans.
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)	3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)	Reasonably Anticipated to be a Human Carcinogen.

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

Reproductivity

SODIUM BENZOATE	Embryofetal Development Result: Negative
PHENYLEPHRINE HYDROCHLORIDE	Epidemiology Result: Equivocal, evidence of malformations, or other adverse foetal effects from clinical use. Other studies show no such association. Species: Human
SODIUM BENZOATE	Reproduction/Fertility Study Result: Negative Species: Rat
PHENYLEPHRINE HYDROCHLORIDE	Result: Foetal growth retardation and onset of early delivery at doses equivalent to clinical exposure. Species: Rabbit

Specific target organ toxicity - single exposure Based on available data, the classification criteria are not met.

PHENYLEPHRINE HYDROCHLORIDE	Clinical use Organ: Cardiovascular effects, some marked.

Specific target organ toxicity - repeated exposure Based on available data, the classification criteria are not met.

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

12. Ecological information

Ecotoxicity There is insufficient information to determine the scope of the environmental effects this material may cause. Harmful to aquatic life with long lasting effects.

Components		Species	Test Results
BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	> 2.5 to < 5.3 mg/L, 48 hours Static test
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test
		Golden ide/orfe (Adult Leuciscus idus)	> 440 to < 760 mg/l, 96 hours Static test
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT (CAS 139-33-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	19.6 mg/l, 48 hours Static test
	NOEC	Water flea (Daphnia magna)	3.7 mg/l, 48 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	47.5 mg/l, 96 hours Static test
		Channel catfish (Adult Ictalurus punctatus)	148.4 mg/l, 96 hours Static test
		Fathead minnow (Adult Pimephales promelas)	68.8 mg/l, 96 hours Static test
PHENYLEPHRINE HYDROCHLORIDE (CAS 61-76-7)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 124 mg/l, 72 hours Measured
	NOEC	Algae	31 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	0.86 mg/l, 48 hours Measured
	NOEC	Daphnia	0.21 mg/l, 48 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 100 mg/l, 96 hours Measured
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	100 mg/l, 96 hours
PROPYLENE GLYCOL (CAS 57-55-6)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test

Components		Species	Test Results
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
SODIUM BENZOATE (CAS 532-32-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/L, 96 hours Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	484 mg/L, 96 hours Flow-through test
STEARYL ALCOHOL (CAS 112-92-5)			
Aquatic			
Acute			
Algae	EC50	Green algae (Scenedesmus subspicatus)	235 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	1666 mg/l, 48 hours Static test
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 10000 mg/l, 96 hours
VITAMIN E (CAS 59-02-9)			
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	> 25.5 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	25.5 mg/l, 72 hours
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 91.1 mg/l, 96 hours
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	91.1 mg/l, 96 hours
XANTHAN GUM (CAS 11138-66-2)			
Aquatic			
Acute			
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	420 mg/l, 96 hours Static test

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

Photolysis

Half-life (Photolysis-aqueous)

PROPYLENE GLYCOL	1.3 - 2.3 Years Estimated

Half-life (Photolysis-atmospheric)

BUTYLATED HYDROXYANISOLE	10.7 Hours Estimated
CETYL ALCOHOL	16.7 Hours Estimated
PROPYLENE GLYCOL	32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CETYL ALCOHOL	0.4 %, < 1 day Other degradation test system, Activated sludge 30 - 60 %, 5 days BOD5
CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	37 %, 14 days Zahn-Wellens, Activated sludge
PHENYLEPHRINE HYDROCHLORIDE	81 %, 28 days Modified Zahn-Wellens, DOC removal., Activated sludge 99 %, 7 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
PROPYLENE GLYCOL	62 %, 5 days BOD5, Activated sludge 79 %, 20 Days BOD20, Activated sludge
VITAMIN E	84 %, 28 days Modified MITI (II) Test.

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	28 %, 28 days Sturm test
SODIUM BENZOATE	100 %, 28 days Modified OECD Screening Test (OECD 301E), Sea water 90 %, 7 days Modified Sturm test., Activated sludge
STEARYL ALCOHOL	69 %, 28 days Closed bottle test, Mixed Residential/Industrial
VITAMIN E	17 %, 28 days Manometric Respirometry Test

Percent degradation (Aerobic biodegradation-soil)

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	13 - 45 %, 15 weeks

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL	100 %, 9 days
SODIUM BENZOATE	93 %, 7 days Other degradation test system, Mixed Residential/Industrial

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

CETYL ALCOHOL	6.7, (LogPow)
CITRIC ACID ANHYDROUS	-1.64
GLYCERIN	-1.76
LIDOCAINE	2.26
PHENYLEPHRINE HYDROCHLORIDE	0.49 (Measured).
PROPYL GALLATE	1.8
PROPYLENE GLYCOL	-1.35
SODIUM BENZOATE	1.89 -2.27

Bioconcentration factor (BCF)

CETYL ALCOHOL	> 9999 Measured
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	0.8 - 1.8 Measured, Lepomis macrochirus, bluegill sunfish
PROPYLENE GLYCOL	< 1 Estimated
STEARYL ALCOHOL	> 2000 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

BUTYLATED HYDROXYANISOLE	3.14 Calculated
CETYL ALCOHOL	3.58 - 4.67 Estimated
LIDOCAINE	2.06
SODIUM BENZOATE	1.16 Calculated
STEARYL ALCOHOL	5.27 Estimated

Mobility in general

Volatility

Henry's law

BUTYLATED HYDROXYANISOLE	0.000001 atm m3/mol Calculated
CETYL ALCOHOL	0.000073 atm m^3/mol Estimated
CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C
LIDOCAINE	0 atm m^3/mol Estimated
PROPYL GALLATE	0 atm m^3/mol, 25 C Estimated
PROPYLENE GLYCOL	0 atm m^3/mol Estimated
STEARYL ALCOHOL	0.00084 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

LIDOCAINE	-0.05, pH 5 1.76, pH 7 2.77, pH 9

Other adverse effects None known.

13. Disposal considerations

Disposal instructions Collect 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	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.

Read safety instructions, SDS and emergency procedures before handling.

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 applicable. Not established.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	Yes
Classified hazard categories	Serious eye damage or eye irritation Respiratory or skin sensitization

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)	Contains component(s) regulated under the Safe Drinking Water Act.

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

BUTYLATED HYDROXYANISOLE (CAS 25013-16-5)
MINERAL OIL U.S.P. (CAS 8042-47-5)
PHARMACEUTICAL GRADE PETROLATUM (CAS 8009-03-8)

California Proposition 65

WARNING: This product can expose you to BUTYLATED HYDROXYANISOLE, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Carcinogenic substance

BUTYLATED HYDROXYANISOLE (CAS 25013-16-5) Listed: January 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	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, including date of preparation or last revision

Issue date 04-11-2023

Version # 01

HMIS® ratings Health: 2
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 2
Flammability: 0
Instability: 0

Disclaimer Haleon cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.