SAFETY DATA SHEET

HALEON

1. Identification

Product identifier **ADVIL TOPICAL CREAM**

Other means of identification

Product code WH-2313-0001

Synonyms ADVIL TOPICAL CREAM * WH-2313-0001

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 1
Specific target organ toxicity, single exposure	Category 2 (lungs)

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement Causes serious eye damage. May cause damage to organs (lungs).

Precautionary statement

Prevention Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye protection/face protection.

Response If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center/doctor/.

Storage Store locked up.

Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	15.6998% of the mixture consists of component(s) of unknown acute oral toxicity. 18.7998% of the mixture consists of component(s) of unknown acute dermal toxicity. 18.7998% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 18.7998% 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	%
METHYL SALICYLATE	2-(METHOXYCARBONYL)PHENOL ANTHRAPOLE ND BENZOIC ACID, 2-HYDROXY-, METHYL ESTER METHYL 2-HYDROXYBENZOATE METHYL O-HYDROXYBENZOATE OIL OF WINTERGREEN SALICYLIC ACID, METHYL ESTER WINTERGREEN OIL	119-36-8	10 - < 20
MENTHOL	HEXAHYDROTHYMOL MENTHACAMPHOR MENTHOMENTHOL PEPPERMINT CAMPHOR NATURAL MENTHOL Racementhol MENTHOL RACEMIC	89-78-1	5 - < 10
CAMPHOR	1,7,7-TRIMETHYL-BICYCLO(2.2.1)HEPTAN-2-ONE ROOT BARK SPIRIT 1,7,7-TRIMETHYLNORCAMPHOR SYNTHETIC CAMPHOR GUM CAMPHOR ROOT BARK OIL SPIRIT OF CAMPHOR	76-22-2	3 - < 5
STEARIC ACID	1-HEPTADECANECARBOXYLIC ACID OCTADECANOIC ACID STEAROPHANIC ACID N-OCTADECANOIC ACID	57-11-4	3 - < 5
CARBOMER 980		139637-85-7	< 1
CETYL ALCOHOL	1-HEXADECANOL HEXADECYL ALCOHOL N-1-HEXADECANOL N-CETYL ALCOHOL 1-HEXADECYL ALCOHOL CETEARYL ALCOHOL PALMITYL ALCOHOL	36653-82-4	< 1
SODIUM HYDROXIDE	CAUSTIC SODA LYE SODIUM HYDRATE HIDROXIDO SODICO HIDRÓXIDO DE SÓDIO CAUSTIC SODA SOLUTION Caustic soda (as NaOH) Soda lye Soda, caustic	1310-73-2	< 0.2
Other components below reportable levels			60 - < 70

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and water. Get medical attention if irritation develops and persists.
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 immediately.
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. Permanent eye damage including blindness could result.
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	If you feel unwell, seek medical advice (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	Alcohol resistant foam. 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	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 discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not get this material in contact with eyes. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store locked up. 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
CAMPHOR (CAS 76-22-2)	OHC	1	SKIN
CARBOMER 980 (CAS 139637-85-7)	OHC	3	>10 - </=100 mcg/m3
CETYL ALCOHOL (CAS 36653-82-4)	OHC	2	>5 - </=50 ppm
MENTHOL (CAS 89-78-1)	OHC	1	>1000 - </=5000 mcg/m3 SKIN
METHYL SALICYLATE (CAS 119-36-8)	8 HR TWA	3000 mcg/m3	
	OHC	1	

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

Components	Type	Value
CAMPHOR (CAS 76-22-2)	PEL	2 mg/m3
SODIUM HYDROXIDE (CAS 1310-73-2)	PEL	2 mg/m3

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
CAMPHOR (CAS 76-22-2)	STEL	3 ppm	
	TWA	2 ppm	
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3	
STEARIC ACID (CAS 57-11-4)	TWA	3 mg/m3	Respirable fraction.
		10 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value
CAMPHOR (CAS 76-22-2)	TWA	2 mg/m3
SODIUM HYDROXIDE (CAS 1310-73-2)	Ceiling	2 mg/m3

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
MENTHOL (CAS 89-78-1)	STEL	3 ppm
	TWA	1 ppm

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.

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. Provide eyewash station.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection

Hand protection Wear appropriate chemical resistant gloves.

Other Wear suitable protective clothing. Use of an impervious apron is recommended.

Respiratory protection In case of insufficient ventilation, wear suitable respiratory equipment.

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.

9. Physical and chemical properties

Appearance

Physical state Not available.

Form Cream.

Color White. Off-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	No adverse effects due to skin contact are expected.
Eye contact	Causes serious eye damage.
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. Permanent eye damage including blindness could result.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
CAMPHOR (CAS 76-22-2)		
Acute		
Inhalation		
LC50	Rat	500 mg/m3
Oral		
LD50	Mouse	1310 mg/kg
	Rat	3688 mg/kg
CETYL ALCOHOL (CAS 36653-82-4)		
Acute		
Dermal		
LD50	Rabbit	8000 mg/kg, 24 Hours
Oral		
LD50	Rat	> 2000 mg/kg

Components	Species	Test Results
MENTHOL (CAS 89-78-1)		
Acute		
Oral		
LD50	Rat	3200 mg/kg
		3180 mg/kg
METHYL SALICYLATE (CAS 119-36-8)		
Acute		
Oral		
LD50	Rat	887 mg/kg
STEARIC ACID (CAS 57-11-4)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg, 24 Hours
Oral		
LD50	Rat	> 6000 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity

SODIUM HYDROXIDE
Literature search
Result: Causes severe burns.

Irritation Corrosion - Skin

MENTHOL
0, Literature data
Result: Irritating to skin
Species: Rabbit
Notes: IUCLID data

Serious eye damage/eye irritation Causes serious eye damage.

Eye

MENTHOL
0, Literature data
Result: MIld-moderate
Species: Rabbit

SODIUM HYDROXIDE
Literature search
Result: Causes severe burns.

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

Skin sensitization This product is not expected to cause skin sensitization.

Sensitization

MENTHOL
Buehler assay, Literature data
Result: Negative
Species: Guinea pig
Notes: IUCLID data
Epidemiology, Literature data
Result: Low incidence of contact hypersensitivity.
Notes: IUCLID data
Modified Draize, Literature data
Result: Positive
Species: Guinea pig
Notes: IUCLID data
Open repetitive dermal test, Literature data
Result: Negative
Species: Guinea pig
Notes: IUCLID data

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

Mutagenicity

MENTHOL
725 mg/kg In vivo-In vitro Replicative DNA synthesis
Result: Positive
Species: Rat
Alkaline Elution Assay In Vitro, Literature data
Result: Negative
Notes: IUCLID data

Mutagenicity

MENTHOL

Ames, Literature dataLiterature data
Result: Negative
Notes: IUCLID data
BlueScreen mammalian cell mutation assay, Literature data
Result: Negative
Notes: IUCLID data
Chromosomal Aberration Assay In Vitro, CHO cells, Literature data
Result: Negative
Notes: IUCLID data
Chromosomal Aberration Assay In Vitro, human lymphocytes, Literature data
Result: Negative
Notes: IUCLID data
GreenScreen mammalian cell mutation assay, Literature dat a Result: Negative
Notes: IUCLID data
L5178Y mouse lymphoma thymidine kinase locus assay, Literature data
Result: Negative
Notes: IUCLID data
Micronucleus Test, Literature data
Result: Negative
Species: Mouse
Notes: IUCLID data
Mutation in Drosophila melanogaster, Literature data
Result: Negative
Notes: IUCLID data
sister chromatid exchange, Literature data
Result: Negative
Notes: IUCLID data

Carcinogenicity Not classifiable as to carcinogenicity to humans.

MENTHOL

<= 1000 mg/kg/day, Literature data, dietary study.
Result: Negative
Species: Rat
Test Duration: 103 weeks
Notes: IUCLID data
<= 2143 mg/kg/day, Literature data, dietary study.
Result: Negative
Species: Mouse
Notes: IUCLID data

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

MENTHOL

185 mg/kg/day Embryo-foetal development, Literature data
Result: NOAEL-Highest dose.
Species: Mouse
Notes: IUCLID data
218 mg/kg/day Embryo-foetal development - Oral, Literature data
Result: NOAEL-Highest dose.
Species: Rat
Notes: IUCLID data
405 mg/kg/day Embryo-foetal development - Oral, Literature data
Result: NOAEL-Highest dose.
Species: Hamster
Notes: IUCLID data

Reproductivity

MENTHOL — 475 mg/kg/day Embryo-foetal development - Oral, Literature data
Result: NOAEL-Highest dose.
Species: Rabbit
Notes: IUCLID data

Specific target organ toxicity - single exposure May cause damage to organs (lungs).

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not an aspiration hazard.

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
CAMPHOR (CAS 76-22-2)			
Aquatic			
Acute			
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	110 mg/l, 96 hours
SODIUM HYDROXIDE (CAS 1310-73-2)			
Aquatic			
Acute			
Fish	EC50	Mosquito fish (Adult Gambusia affinis)	125 mg/l, 96 hours Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	45.4 mg/l, 96 hours Static test

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

Photolysis

Half-life (Photolysis-aqueous)

METHYL SALICYLATE — 48 Minutes Measured

Half-life (Photolysis-atmospheric)

CETYL ALCOHOL — 16.7 Hours Estimated
METHYL SALICYLATE — 5.7 Days Estimated
STEARIC ACID — 17 Hours Estimated

UV/visible spectrum wavelength

STEARIC ACID — 210 nm

Hydrolysis

Half-life (Hydrolysis-basic)

METHYL SALICYLATE — 3 - 12 Hours Measured

Half-life (Hydrolysis-neutral)

METHYL SALICYLATE — 14 - 22 Days Calculated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CETYL ALCOHOL — 0.4 %, < 1 day Other degradation test system, Activated sludge
30 - 60 %, 5 days BOD5

METHYL SALICYLATE — 100 %, 7 days
65 %, 5 days BOD5

STEARIC ACID — 77 %, 28 days BOD

Percent degradation (Aerobic biodegradation-ready)

STEARIC ACID — 95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

METHYL SALICYLATE — 90 %, 9 days BOD
STEARIC ACID — 50 %, 13 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

CETYL ALCOHOL — 6.7, (LogPow)
MENTHOL — 3.4
METHYL SALICYLATE — 2.55

Partition coefficient n-octanol / water (log Kow)

STEARIC ACID	8.23, (LogPow)

Bioconcentration factor (BCF)

CETYL ALCOHOL	> 9999 Measured
METHYL SALICYLATE	4 Estimated
STEARIC ACID	> 9999 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

CETYL ALCOHOL	3.58 - 4.67 Estimated
METHYL SALICYLATE	2.1 Estimated
STEARIC ACID	5.86 Estimated

Mobility in general

Volatility

Henry's law

CETYL ALCOHOL	0.000073 atm m^3/mol Estimated
MENTHOL	0.000015 atm m^3/mol, 25 C Estimated
METHYL SALICYLATE	0.000098 atm m^3/mol, 25 C Estimated
STEARIC ACID	0.000051 Estimated

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. 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)

SODIUM HYDROXIDE (CAS 1310-73-2) 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 Specific target organ toxicity (single or repeated exposure)

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.

US state regulations

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

SODIUM HYDROXIDE (CAS 1310-73-2)

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. For more information go to www.P65Warnings.ca.gov.

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	No
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	02-13-2023
Version #	01
HMIS® ratings	Health: 3 Flammability: 0 Physical hazard: 0
NFPA ratings	Health: 3 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.