SAFETY DATA SHEET

HALEON

1. Identification

Product identifier **ABREVA**

Other means of identification

Product code 10718-001-0001

Synonyms ABREVA TUBE * ABREVA PUMP * abreva Docosanol 10 Percent Cream Cold Sore Treatment * 10718-001-0001 * DOCOSONAL 10% CREAM * DOCOSONAL, FORMULATED PRODUCT

Recommended use This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Consumer Healthcare Product

Medicinal Product.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME Haleon PLC

Address: 184 Liberty Corner Road, Suite 200
Warren, NJ 07059 USA

Telephone: +1-908-293-4000 (General Inquiries)

Email: msds@haleon.com

Website: www.haleon.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 Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC) None known.

Supplemental information 13% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 13% 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	%
N-DOCOSANOL	BEHENYL ALCOHOL BEHENIC ALCOHOL DOCOSYL ALCOHOL DOCOSANOL	661-19-8	10 - < 20
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	5 - < 10
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	5 - < 10
BENZYL ALCOHOL	BENZENEMETHANOL BENZENECARBINOL (HYDROXYMETHYL)BENZENE ALPHA-HYDROXYTOLUENE PHENYLCARBINOL PHENYLMETHANOL PHENYLMETHYL ALCOHOL ALPHA-TOLUENOL OHS02800 RTECS DN3150000	100-51-6	1 - < 3
Other components below reportable levels			70 - < 80

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 Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed Direct contact with eyes may cause temporary irritation.

Indication of immediate medical attention and special treatment needed Treat symptomatically.

General information 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 fog. 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. 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	Avoid prolonged exposure. 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.

Haleon Exposure Limits

Components	Type	Value	Form
N-DOCOSANOL (CAS 661-19-8)	OHC	1	>1000 - ≤5000 mcg/m3

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

Components	Type	Value	Form
MINERAL OIL U.S.P. (CAS 8042-47-5)	PEL	5 mg/m3	Mist.

US. ACGIH Threshold Limit Values (TLV)

Components	Type	Value	Form
MINERAL OIL U.S.P. (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards Recommended Exposure Limits (REL)

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

US. OARS. Workplace Environmental Exposure Level (WEEL) Guide

Components	Type	Value	Form
BENZYL ALCOHOL (CAS 100-51-6)	TWA	44.2 mg/m3	
		10 ppm	
PROPYLENE GLYCOL (CAS 57-55-6)	TWA	10 mg/m3	Aerosol.

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

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.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Skin protection	
Hand protection	Wear appropriate chemical resistant gloves.
Other	Wear suitable protective clothing.
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	Liquid.
Form	Cream.
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	>203 °F (>95 °C) Closed Cup (Estimation based on components).
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
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	Avoid temperatures exceeding the flash point. 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	Prolonged inhalation may be harmful.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.
Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation.

Information on toxicological effects

Acute toxicity Not known.

Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
Acute		
Inhalation		
LC50	Rat	1000 ppm
Oral		
LD50	Rat	1230 mg/kg
N-DOCOSANOL (CAS 661-19-8)		
Acute		
Oral		
LD50	Rat	> 10000 mg/kg
Other		
LD50	Mouse	> 800 mg/kg
Chronic		
Oral		
NOAEL	Dog	2000 mg/kg/day, 26 weeks
	Rat	2000 mg/kg/day, 26 weeks

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

Irritation Corrosion - Skin

N-DOCOSANOL
Acute dermal irritation; OECD 404, Literature data
Result: Non-irritant
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

N-DOCOSANOL
Acute ocular irritation; OECD 405, Literature data
Result: Mild irritant
Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Not a respiratory sensitizer.

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

Sensitization

N-DOCOSANOL
SAR / QSAR, DEREK, Lhasa, UK
Result: No structural alerts identified.

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

Mutagenicity

N-DOCOSANOL
Ames Assay, Literature data
Result: Negative
Chromosomal Aberration Assay In Vitro, Literature data
Result: Negative
Micronucleus Test, Literature data
Result: Negative
Species: Mouse

Carcinogenicity Not classifiable as to carcinogenicity to humans.

Carcinogenicity

N-DOCOSANOL — SAR / QSAR, DEREK, Lhasa, UK
Result: No structual alerts identified.

IARC Monographs. Overall Evaluation of Carcinogenicity

MINERAL OIL U.S.P. (CAS 8042-47-5) — 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

Not listed.

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

Reproductivity

N-DOCOSANOL

Embryo-foetal development - Oral
Result: Foetal NOAEL = 1000 mg/kgday (maximum dose)
Species: Rat

Embryo-foetal development - Oral
Result: Foetal NOAEL = 2000 mg/kgday (maximum dose)
Species: Rabbit

Fertility
Result: NOAEL / male & female fertility = 1000 mg/kg/day (maximum dose)
Species: Rat

Specific target organ toxicity - single exposure — Not classified.

Specific target organ toxicity - repeated exposure — Not classified.

Aspiration hazard — Not an aspiration hazard.

Chronic effects — Prolonged inhalation may be harmful.

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
BENZYL ALCOHOL (CAS 100-51-6)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Mixed industrial/residential sludge.	2100 mg/l, 49 hours
Algae	EC50	Green algae (Scenedesmus quadricauda)	640 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna)	360 mg/l, 48 hours
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	10 mg/l, 96 hours Static test
		Fathead minnow (Adult Pimephales promelas)	460 mg/l, 96 hours Static test
Microtox	EC50	Microtox	63.7 mg/l, 15 minutes
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

Components		Species	Test Results
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours Static test
	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

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)

BENZYL ALCOHOL 2 Days Estimated

PROPYLENE GLYCOL 32 Hours Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

PROPYLENE GLYCOL 62 %, 5 days BOD5, Activated sludge
79 %, 20 Days BOD20, Activated sludge

Percent degradation (Aerobic biodegradation-ready)

BENZYL ALCOHOL > 90 %, 30 days Closed bottle test, Activated sludge

Percent degradation (Anaerobic biodegradation)

BENZYL ALCOHOL 100 %, 14 days Serum Bottle, Anaerobic sludge

PROPYLENE GLYCOL 100 %, 9 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

BENZYL ALCOHOL 1.1

PROPYLENE GLYCOL -1.35

Bioconcentration factor (BCF)

BENZYL ALCOHOL 4 Estimated

PROPYLENE GLYCOL < 1 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

BENZYL ALCOHOL < 0.7 Measured

Mobility in general

Volatility

Henry's law

BENZYL ALCOHOL 0 atm m^3/mol, 25 C Estimated

PROPYLENE GLYCOL 0 atm m^3/mol 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.

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 established.

15. Regulatory information

US federal regulations This product is not known to be 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 No

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))

MINERAL OIL U.S.P. (CAS 8042-47-5)

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)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
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)	Yes

Country(s) or region	Inventory name	On inventory (yes/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 05-22-2018

Revision date 04-08-2025

Version # 13

HMIS® ratings
Health: 1
Flammability: 1
Physical hazard: 0

NFPA ratings
Health: 1
Flammability: 1
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.

Revision information
Product and Company Identification: Synonyms
Composition / Information on Ingredients: Disclosure Overrides
Toxicological information: Acute toxicity
Toxicological information: Aspiration hazard
Toxicological information: Carcinogenicity
Toxicological information: Corrosivity
Toxicological information: Eye contact
Toxicological information: Mutagenicity
Toxicological information: Reproductivity
Toxicological information: Skin contact
Toxicological information: Specific target organ toxicity - repeated exposure
Toxicological information: Specific target organ toxicity - single exposure