

1. Identification

Product identifier

ABREVA

Other means of identification

Synonyms

ABREVA TUBE * ABREVA PUMP * MFC 50508 * DOCOSONAL 10% CREAM * DOCOSONAL, 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 US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

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.

Hazard(s) not otherwise classified (HNOC)

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	%
N-DOCOSANOL	BEHENYL ALCOHOL * BEHENIC ALCOHOL * DOCOSYL ALCOHOL	661-19-8	10
LIGHT MINERAL OIL	OHS12791 * RTECS PY8047000	8042-47-5	7.89

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	4.93
BENZYL ALCOHOL	BENZENEMETHANOL * BENZENECARBINOL * (HYDROXYMETHYL)BENZENE * ALPHA-HYDROXYTOLUENE * PHENYLCARBINOL * PHENYLMETHANOL * PHENYLMETHYL ALCOHOL * ALPHA-TOLUENOL * C7H8O * OHS02800 * RTECS DN3150000	100-51-6	2.7
Other components below reportable levels			74.48

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
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.
Most important symptoms/effects, acute and delayed	None known.
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 local poison control information centre.
General information	Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2). Water.
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	This product will support combustion at elevated temperatures.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. 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

Extinguish all flames in the vicinity.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent entry into waterways, sewer, basements or confined areas. 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

Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Type

Value

N-DOCOSANOL (CAS
661-19-8)

8 HR TWA

5000 mcg/m3

OHC

1

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

Components

Type

Value

Form

LIGHT MINERAL OIL (CAS
8042-47-5)

PEL

5 mg/m3

Mist.

US. ACGIH Threshold Limit Values

Components

Type

Value

Form

LIGHT MINERAL OIL (CAS
8042-47-5)

TWA

5 mg/m3

Inhalable fraction.

US. NIOSH: Pocket Guide to Chemical Hazards

Components

Type

Value

Form

LIGHT MINERAL OIL (CAS
8042-47-5)

STEL

10 mg/m3

Mist.

TWA

5 mg/m3

Mist.

US. AIHA Workplace Environmental Exposure Level (WEEL) Guides

Components

Type

Value

Form

BENZYL ALCOHOL (CAS
100-51-6)

TWA

44.2 mg/m3

PROPYLENE GLYCOL
(CAS 57-55-6)

TWA

10 ppm

10 mg/m3

Aerosol.

Biological limit values

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

Appropriate engineering controls

An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Good general ventilation (typically 10 air changes per hour) 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	Eye wash fountain is recommended. If contact is likely, safety glasses with side shields are recommended.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Skin protection	
Other	Not normally needed.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. 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	Tube.
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) (Estimation based on components).
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.

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	Strong oxidizing agents.

Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information**Information on likely routes of exposure**

Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics

None known.

Information on toxicological effects**Acute toxicity** Health injuries are not known or expected under normal use.

Components	Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)		
Acute		
<i>Inhalation</i>		
LC50	Rat	1000 ppm
<i>Oral</i>		
LD50	Rat	1230 mg/kg
LIGHT MINERAL OIL (CAS 8042-47-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.**Irritation Corrosion - Skin**

N-DOCOSANOL

Acute dermal irritation; OECD 404, Literature data
Result: Non-irritant
Species: Rabbit**Serious eye damage/eye irritation** Health injuries are not known or expected under normal use. 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 available.**Skin sensitization** Health injuries are not known or expected under normal use.**Sensitization**

N-DOCOSANOL

SAR / QSAR, DEREK, Lhasa, UK
Result: No structural alerts identified.**Germ cell mutagenicity** Health injuries are not known or expected under normal use. 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

Health injuries are not known or expected under normal use. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Contains a material (light mineral oil) classified as a carcinogen by external agencies. These effects are suspected to be due to impurities that are not expected to be present in purified material used in this product.

N-DOCOSANOL

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

IARC Monographs. Overall Evaluation of Carcinogenicity

LIGHT MINERAL OIL (CAS 8042-47-5)

3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity

Health injuries are not known or expected under normal use.

Reproductivity

N-DOCOSANOL

Embryo-foetal development - Oral
Result: Foetal NOAEL = 1000 mg/kg/day (maximum dose)
Species: Rat
Embryo-foetal development - Oral
Result: Foetal NOAEL = 2000 mg/kg/day (maximum dose)
Species: Rabbit
Fertility
Result: NOAEL / male & female fertility = 1000 mg/kg/day (maximum dose)
Species: Rat

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

None known.

Aspiration hazard

Not available.

12. Ecological information**Ecotoxicity**

Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
BENZYL ALCOHOL (CAS 100-51-6)			
Aquatic			
<i>Acute</i>			
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)			
<i>Acute</i>			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
<i>Acute</i>			
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 Oncorhynchus mykiss)	51600 mg/l, 96 hours Static test
NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours Static test
	Rainbow trout (Adult Oncorhynchus mykiss)	42000 mg/l, 96 hours Static test
Microtox	EC50 Microtox	51400 mg/l, 30 minutes

Persistence and degradability

Photolysis

Half-life (Photolysis-aqueous)

PROPYLENE GLYCOL

1.3 - 2.3 Years Estimated

Half-life (Photolysis-atmospheric)

BENZYL ALCOHOL

2 Days Estimated

LIGHT MINERAL OIL

< 1 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 (Anaerobic biodegradation)

BENZYL ALCOHOL

100 %, 14 days Serum Bottle, Anaerobic sludge

PROPYLENE GLYCOL

100 %, 9 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

BENZYL ALCOHOL

1.1

PROPYLENE GLYCOL

-0.92

-1.35

Bioconcentration factor (BCF)

BENZYL ALCOHOL

4 Estimated

PROPYLENE GLYCOL

< 1 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

BENZYL ALCOHOL

< 0.7 Measured

Mobility in general

Volatility

Henry's law

BENZYL ALCOHOL

0 atm m³/mol, 25 C Estimated

PROPYLENE GLYCOL

0 atm m³/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.

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

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

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

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

One or more components are not listed on 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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

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. Massachusetts RTK - Substance List

BENZYL ALCOHOL (CAS 100-51-6)
LIGHT MINERAL OIL (CAS 8042-47-5)

US. New Jersey Worker and Community Right-to-Know Act

PROPYLENE GLYCOL (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

BENZYL ALCOHOL (CAS 100-51-6)
LIGHT MINERAL OIL (CAS 8042-47-5)
PROPYLENE GLYCOL (CAS 57-55-6)

US. Rhode Island RTK

Not regulated.

US. 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.

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, including date of preparation or last revision

Issue date	07-04-2014
Revision date	07-04-2014
Version #	10
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 1 Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 1 Flammability: 1 Instability: 0
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.
Revision Information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Toxicological Information: Irritation Corrosion Regulatory Information: United States GHS: Classification