Safety Data Sheet



Section 1: Identification

Product identifier

Product Name

• Salex Shampoo

• NDC 13548-012-06

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Skin care product. For Dermatologic Use: Salex® is a topical aid in the removal of

excessive keratin in hyperkeratotic skin disorders.

Restrictions on use• Use in accordance with product literature.

Details of the supplier of the safety data sheet

• Valeant Pharmaceuticals North America, LLC

400 Somerset Corporate Blvd.

Bridgewater, NJ 08807

United States valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

• +1 352-323-3500 - International - Infotrac

Consumer 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 consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS• Eye Irritation 2
Skin Irritation 2

Label elements

UN GHS

WARNING



Hazard statements • Causes serious eye irritation Causes skin irritation

Precautionary statements

Prevention • Wash thoroughly after handling.

Wear eye/face protection,.

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Response • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Storage/Disposal · Dispose of content and/or container in accordance with local, regional, national, and/or

international regulations.

Other hazards

UN GHS · No data available

Section 3 - Composition/Information on Ingredients

Substances

Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

	Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive	
Acrylates copolymer	CAS:25133-97-5	N/A	UN GHS: NDA	
Behentrimonium methosulfate	CAS:81646-13-1 EINECS:279-791- 1	N/A	UN GHS: NDA	
Cetearyl alcohol	CAS:67762-27-0 EINECS:267-008-	N/A	UN GHS: NDA	
Chamomile Tea Fragrance	NDA	N/A	UN GHS: NDA	
Cocamidopropyl betaine	CAS:61789-40-0 EINECS:263-058- 8	N/A	UN GHS: NDA	
Edetate disodium	CAS:6381-92-6	N/A	UN GHS: NDA	
Glycerin	CAS:56-81-5 EINECS:200-289- 5	N/A	UN GHS: Skin Irrit. 3; Eye Irrit. 2	
Methylparaben	CAS:99-76-3 EINECS:202-785- 7	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2A	
Propylene glycol	CAS:57-55-6 EINECS:200-338- 0	N/A	UN GHS: Skin Irrit. 2; Eye Irrit. 2B	
Propylparaben	CAS:94-13-3 EINECS:202-307- 7	N/A	UN GHS: NDA	
Quaternium-26	CAS:68953-64-0 EINECS:273-222- 0	N/A	UN GHS: NDA	
Salicylic acid	CAS:69-72-7 EINECS:200-712- 3	6%	UN GHS: Skin Corr. 1; Skin Irrit. 2; Eye Dam. 1; Eye Irrit. 2A	
Sodium laureth sulfate	CAS:9004-82-4	N/A	UN GHS: NDA	

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Inhalation

Skin

Eye

Trolamine	CAS :102-71-6 EINECS :203-049-8	N/A	UN GHS: Skin Irrit. 3; Eye Irrit. 2A; Skin Sens. 1B; Acute Tox. Oral 5; STOT SE 3: Resp. Irrit.
Water	CAS:7732-18-5 EINECS:231-791- 2	N/A	UN GHS: Classification criteria not met

N/A - Designates that the chemical percentage of composition is not available as it is considered proprietary information.

Section 4: First-Aid Measures

Description of first aid measures

 No adverse effects anticipated by breathing small amounts. If large amounts are inhaled, remove to fresh air.

 For accidental and non-therapeutic exposures, immediately flush skin with large amounts of water. Remove contaminated clothing. If irritation (redness, rash,

blistering) develops, get medical attention. If skin irritation occurs: Get medical

advice/attention.

 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses. if present and easy to do. Continue rinsing. If eye irritation persists: Get medical

advice/attention.

Ingestion If swallowed, wash out mouth with water provided person is conscious. Seek medical

attention.

Most important symptoms and effects, both acute and delayed

No data available

Indication of any immediate medical attention and special treatment needed Other information

 Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Carbon dioxide, dry chemical powder, appropriate foam or water fog.

Unsuitable Extinguishing Media

No data available

Firefighting Procedures

• As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion **Hazards**

No data available

Hazardous Combustion Products

No data available

Advice for firefighters

· No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

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Personal Precautions

No special controls or personal protection required under conditions of intended use.
 In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures

For bulk material spills: Contain spilled product. For small spills, add suitable
absorbent material. Scoop up and place in an appropriate liquid-tight container
equipped with a tight cover for disposal. For large spills, dike spilled material or
otherwise contain material to ensure runoff does not reach a waterway. Place spilled
material in an appropriate, liquid-tight container equipped with a tight cover for
disposal.

Environmental precautions

 Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

· Cover with absorbent or contain. Collect and dispose.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

 Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area, away from all sources of ignition. Keep container closed. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities

Storage

Keep tightly closed and store in upright position. Store at room temperature 20-25°C (68-77°F).

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

 Refer to the occupational exposure limits / guidelines for the individual product components.

	Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	OSHA	Other Agency Information	
Propylene glycol (57-55-6)	TWAs	Not established	Not established	Not established	10 mg/m3 TWA	
Glycerin (56-81-5)	TWAs	Not established	10 mg/m3 TWAEV (mist)	15 mg/m3 TWA (mist, total particulate); 5 mg/m3 TWA (mist, respirable fraction)	Not established	
Trolamine (102-71-6)	TWAs	5 mg/m3 TWA	5 mg/m3 TWAEV	Not established	Not established	

Exposure controls

Engineering Measures/Controls

 No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Pictograms



Respiratory

In the event of a bulk spill, and where risk assessment shows that air-purifying

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respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

• Wear eye/face protection , .

• Wear protective gloves .

• No special personal protection required under conditions of intended use. In the event

Handle in accordance with good industrial hygiene and safety practice.

of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

Environmental Exposure

Controls

· No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Semi-Solid	Appearance/Description	Not relevant
Color	White	Odor	No odor.
Odor Threshold	Not relevant		
General Properties		•	-
Boiling Point	> 37.7 °C(> 99.86 °F)	Melting Point/Freezing Point	No data available
Decomposition Temperature	Not relevant	рН	4 to 5
Specific Gravity/Relative Density	No data available	Water Solubility	Soluble
Viscosity	No data available		
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

No dangerous reactions known.

Chemical stability

Stable under normal temperatures and pressures.

Possibility of hazardous reactions

No data available

Conditions to avoid

Extreme heat or cold. Do not freeze.

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Incompatible materials

· No data available

Hazardous decomposition products

· No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Salicylic acid (6%)	69-72-7	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 480 mg/kg

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Irritation 2
Serious eye damage/Irritation	UN GHS • Eye Irritation 2
Skin sensitization	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)

Under normal conditions of use, no health effects are expected.

Chronic (Delayed)

· Under normal conditions of use, no health effects are expected.

Skin

Acute (Immediate)

· Causes skin irritation.

Chronic (Delayed)

Repeated and prolonged exposure may cause sensitization.

Eye

Acute (Immediate)

· Causes serious eye irritation.

Chronic (Delayed)

· Under normal conditions of use, no health effects are expected.

Ingestion

Acute (Immediate)

· May be harmful if swallowed.

Chronic (Delayed)

Under normal conditions of use, no health effects are expected.

Carcinogenic Effects				
	CAS IARC NTP			
Trolamine	102-71-6	Group 3-Not Classifiable	Evidence of Carcinogenicity	
Salicylic acid	69-72-7	Not Listed	Evidence of Carcinogenicity	

Reproductive Effects

· Salicylic acid has been shown to be teratogenic in rats and monkeys. It is difficult to

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extrapolate from oral doses of acetylsalicylic acid used in these studies to topical administration as the oral dose to monkeys may represent six times the maximal daily human dose of salicylic acid when applied topically over a large body surface. There are no adequate and well-controlled studies in pregnant women.

Section 12 - Ecological Information

Toxicity

• This material has not been tested for environmental effects.

Persistence and degradability

· No data available

Bioaccumulative potential

No data available

Mobility in Soil

No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

 Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user

No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Cetearyl alcohol	67762-27-0	Yes	Yes	Yes

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Quaternium-26	68953-64-0	Yes	Yes	Yes
Edetate disodium	6381-92-6	Yes	No	No
Acrylates copolymer	25133-97-5	Yes	No	Yes
Behentrimonium methosulfate	81646-13-1	Yes	Yes	No
Methylparaben	99-76-3	Yes	Yes	Yes
Propylparaben	94-13-3	Yes	Yes	Yes
Glycerin	56-81-5	Yes	Yes	Yes
Propylene glycol	57-55-6	Yes	Yes	Yes
Cocamidopropyl betaine	61789-40-0	Yes	Yes	Yes
Salicylic acid	69-72-7	Yes	Yes	Yes
Sodium laureth sulfate	9004-82-4	Yes	No	Yes
Trolamine	102-71-6	Yes	Yes	Yes

Canada

abor		
anada - WHMIS - Classifications of Substances		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
		Uncontrolled product
Acrylates copolymer	25133-97-5	according to WHMIS
		classification criteria
Sodium laureth sulfate	9004-82-4	Not Listed
Cocamidopropyl betaine	61789-40-0	Not Listed
		Uncontrolled product
Propylene glycol	57-55-6	according to WHMIS
		classification criteria
		Uncontrolled product
Trolamine	102-71-6	according to WHMIS
		classification criteria
Observator	50.04.5	Uncontrolled product
• Glycerin	56-81-5	according to WHMIS classification criteria
Salicylic acid	69-72-7	D2A
• Salicylic acid	09-72-7	
Edetate disodium	6381-92-6	Uncontrolled product according to WHMIS
Luctate disoulding	0301-92-0	classification criteria
Cetearyl alcohol	67762-27-0	Not Listed
• Quaternium-26	68953-64-0	Not Listed
Behentrimonium methosulfate	81646-13-1	Not Listed
Deficitation in the allocations	01010101	Not Elotod
anada - WHMIS - Ingredient Disclosure List		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Acrylates copolymer	25133-97-5	Not Listed
Sodium laureth sulfate	9004-82-4	Not Listed
Cocamidopropyl betaine	61789-40-0	Not Listed
Propylene glycol	57-55-6	1 %

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• Glycerin	56-81-5 Not Listed
Salicylic acid	69-72-7 0.1 %
Edetate disodium	6381-92-6 Not Listed
Cetearyl alcohol	67762-27-0 Not Listed
Quaternium-26	68953-64-0 Not Listed
Behentrimonium methosulfate	81646-13-1 Not Listed

United States - California

Environment J.S California - Proposition 65 - Carcinogens List		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Acrylates copolymer	25133-97-5	Not Listed
Sodium laureth sulfate	9004-82-4	Not Listed
Cocamidopropyl betaine	61789-40-0	Not Listed
Propylene glycol	57-55-6	Not Listed
• Trolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
Salicylic acid	69-72-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Cetearyl alcohol	67762-27-0	Not Listed
• Quaternium-26	68953-64-0	Not Listed
Behentrimonium methosulfate	81646-13-1	Not Listed
	0.0.0	
J.S California - Proposition 65 - Developmental Toxicity		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Acrylates copolymer	25133-97-5	Not Listed
Sodium laureth sulfate	9004-82-4	Not Listed
Cocamidopropyl betaine	61789-40-0	Not Listed
Propylene glycol	57-55-6	Not Listed
Trolamine	102-71-6	Not Listed
Glycerin	56-81-5	Not Listed
Salicylic acid	69-72-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Cetearyl alcohol	67762-27-0	Not Listed
Quaternium-26	68953-64-0	Not Listed
Behentrimonium methosulfate	81646-13-1	Not Listed
J.S California - Proposition 65 - Reproductive Toxicity - Female		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Acrylates copolymer	25133-97-5	Not Listed
Sodium laureth sulfate	9004-82-4	Not Listed
Cocamidopropyl betaine	61789-40-0	Not Listed
Propylene glycol	57-55-6	Not Listed
Trolamine	102-71-6	Not Listed
• Glycerin	56-81-5	Not Listed
Salicylic acid	69-72-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Cetearyl alcohol	67762-27-0	Not Listed
• Quaternium-26	68953-64-0	Not Listed
Behentrimonium methosulfate	81646-13-1	Not Listed

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U.S California - Proposition 65 - Reproductive Toxicity - Male		
Methylparaben	99-76-3	Not Listed
Propylparaben	94-13-3	Not Listed
Acrylates copolymer	25133-97-5	Not Listed
Sodium laureth sulfate	9004-82-4	Not Listed
Cocamidopropyl betaine	61789-40-0	Not Listed
Propylene glycol	57-55-6	Not Listed
Trolamine	102-71-6	Not Listed
Glycerin	56-81-5	Not Listed
Salicylic acid	69-72-7	Not Listed
Edetate disodium	6381-92-6	Not Listed
Cetearyl alcohol	67762-27-0	Not Listed
Quaternium-26	68953-64-0	Not Listed
Behentrimonium methosulfate	81646-13-1	Not Listed

Section 16 - Other Information

Revision Date
Last Revision Date
Preparation Date
Disclaimer/Statement of
Liability

- 27/January/2016
- 27/January/2016
- 27/January/2016
- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.

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