SWEDISH DREAM SEA SALT HAND SANITIZER- ethyl alcohol formulation liquid
Kala Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Swedish Dream® Sea Salt Hand Sanitizer

Active Ingredient

Ethyl Alcohol 65%

Purpose

Antiseptic

Uses

Sanitizer to help reduce bacteria on skin. For use when soap and water not available.

Warnings

For external use only. Keep away from heat or flame.

When using this product

Keep out of eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if

Keep out of reach of children

If swallowed get medical help or contact a poison control center right away.

Directions:

Apply on hands and rub until dry.

Other Information

Store between 15-30C(59-86F) - Avoid freezing and excess heat over 40C(104F)

Inactive Ingredients

Deionized Water, Glycerine, Sea Salt Essence (Fragrance Oil)

Sea Salt Hand Sanitizer Label

SWEDISH DREAM SEA SALT HAND SANITIZER

ethyl alcohol formulation liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79655-606
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	38.35 mL in 59 mL

Inactive Ingredients	
Ingredient Name	**Strength**
LINALOOL, (+/-)- (UNII: D81QY6I88E)	0.05 mL in 59 mL
WATER (UNII: 059QF0KO0R)	18.88 mL in 59 mL
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	0.05 mL in 59 mL
3-(3,4-METHYLENEDIOXYPHENYL)-2-METHYLPROPANAL (UNII: L65EG8H6PA)	0.05 mL in 59 mL
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.04 mL in 59 mL
ABIES SIBIRICA LEAF OIL (UNII: XRY0V4VZKZ)	0.01 mL in 59 mL
.ALPHA.-AMYLCINNAMALDEHYDE DIMETHYL ACETAL (UNII: M2X8F8W2U8)	0.03 mL in 59 mL
METHYL BENZODIOXEPINONE (UNII: 0NQ136C313)	0.05 mL in 59 mL
8-(N-INDOLYL)-2,6-DIMETHYL-7-OCTEN-2-OL (UNII: 00NG926C95)	0.1 mL in 59 mL
HYDROXYCITRONELLAL (UNII: 8SQ0VA4YUR)	0.05 mL in 59 mL
CYCLAMEN ALDEHYDE (UNII: 4U37UX0E1E)	0.05 mL in 59 mL
2,6,10-TRIMETHYL-9-UNDECENAL (UNII: JNM5JFE28J)	0.05 mL in 59 mL
2-METHYLUNDECANAL (UNII: S94QNS2VY5)	0.05 mL in 59 mL
2-ISOBUTYL-4-METHYLTETRAHYDROPYRAN-4-OL (UNII: VK5ZHH2T3F)	0.05 mL in 59 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.885 mL in 59 mL
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	0.05 mL in 59 mL

.ALPHA.-TERPINEOL (UNII: 21334LVV8W)	0.05 mL in 59 mL
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	0.05 mL in 59 mL
ISOAMYL SALICYLATE (UNII: M25E4ZMR0N)	0.05 mL in 59 mL
3-HEXENYL SALICYLATE, CIS- (UNII: C78Y9OR6YH)	0.05 mL in 59 mL
METHYL 2-NONYNOATE (UNII: 8RN66UR57V)	0.005 mL in 59 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79655-606-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/08/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/08/2020	

Labeler - Kala Corporation (623014826)

Registrant - Kala Corporation (623014826)

Establishment

Name	Address	ID/FEI	Business Operations
Kala Corporation		623014826	manufacture(79655-606)

Revised: 1/2022 Kala Corporation