SWEDISH DREAM SEAWEED HAND SANITIZER- hand sanitizer spray
SWEDISH DREAM SEA ASTER HAND SANITIZER- ethyl alcohol solution spray
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® Seaweed and Sea Aster Hand Sanitizer

Drug Facts

Active Ingredient[s]

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

irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply on hands, rub until dry.

Other information:

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

Inactive Ingredients

Deionized water, Glycerine, Fragrance Oil

Seaweed Hand Sanitizer & Sea Aster Hand Sanitizer Label

SWEDISH DREAM SEAWEED HAND SANITIZER

hand sanitizer spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79655-607
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**
WATER (UNII: 059QF0KO0R)	19.65 mL in 59 mL
PARA-CRESOL (UNII: 1MXY2UM8NV)	0.08 mL in 59 mL
ACETOPHENONE (UNII: RK493WHV10)	0.1 mL in 59 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.8 mL in 59 mL
BENZYL ACETATE (UNII: 0ECG3V79ZJ)	0.1 mL in 59 mL
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	0.1 mL in 59 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:79655-607-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/21/2020	

SWEDISH DREAM SEA ASTER HAND SANITIZER

ethyl alcohol solution spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:79655-608
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**
GLYCERIN (UNII: PDC6A3C0OX)	0.8 mL in 59 mL
ETHYLENE BRASSYLATE (UNII: 9A87HC7ROD)	0.01 mL in 59 mL
COUMARIN (UNII: A4VZ22K1WT)	0.01 mL in 59 mL
3-(3,4-METHYLENEDIOXYPHENYL)-2-METHYLPROPANAL (UNII: L65EG8H6PA)	0.01 mL in 59 mL
GALBANUM OIL (UNII: 211UF7M8N1)	0.2 mL in 59 mL
METHYL BENZODIOXEPINONE (UNII: 0NQ136C313)	0.01 mL in 59 mL
BENZYL SALICYLATE (UNII: WAO5MNK9TU)	0.01 mL in 59 mL
CYCLAMEN ALDEHYDE (UNII: 4U37UX0E1E)	0.01 mL in 59 mL

3-HEXEN-1-OL, (3Z)- (UNII: V14F8G75P4)	0.01 mL in 59 mL
ACETYL CEDRENE (UNII: X6I62755AK)	0.01 mL in 59 mL
PHENYL ACETALDEHYDE DIMETHYL ACETAL (UNII: P8C94L4MUR)	0.01 mL in 59 mL
2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE (UNII: 452GFV2AFS)	0.01 mL in 59 mL
PHENYLACETALDEHYDE (UNII: U8J5PLW9MR)	0.01 mL in 59 mL
ISOCYCLOCITRAL (UNII: 38HRF2I56T)	0.01 mL in 59 mL
WATER (UNII: 059QF0KO0R)	20 mL in 59 mL
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	0.01 mL in 59 mL
EUCALYPTUS GLOBULUS LEAF (UNII: S546YLW6E6)	0.2 mL in 59 mL
8-(N-INDOLYL)-2,6-DIMETHYL-7-OCTEN-2-OL (UNII: 00NG926C95)	0.01 mL in 59 mL
ISOEUGENYL BENZYL ETHER, (Z)- (UNII: 78Q46SZU33)	0.01 mL in 59 mL
LINALYL ACETATE (UNII: 5K47SSQ51G)	0.01 mL in 59 mL
BASIL OIL (UNII: Z129UMU8LE)	0.14 mL in 59 mL
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	0.01 mL in 59 mL
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)	0.01 mL in 59 mL
2-ISOBUTYL-4-METHYLTETRAHYDROPYRAN-4-OL (UNII: VK5ZHH2T3F)	0.01 mL in 59 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79655-608-01	59 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/02/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	11/02/2020	

Labeler - Kala Corporation (623014826)

Registrant - Kala Corporation (623014826)

Establishment

Name	Address	ID/FEI	Business Operations
Kala Corporation		623014826	manufacture(79655-607, 79655-608) , pack(79655-607, 79655-608) , label(79655-607, 79655-608)

Revised: 1/2022 Kala Corporation