SPREAD LOVE NOT GERMS- alcohol liquid TRUE REWARDS HAND SANITIZER- alcohol liquid Damon Industries

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.

Active Ingredient(s)

Alcohol 80% v/v Purpose: Antiseptic

Purpose

Antiseptic Hand Sanitizer

Use(s)

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available

Warnings

For External use only. Flammable. Keep away from heat or flame.

Do not use

on children less than 2 months of age

on open skin wounds

When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask doctor if 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

Place enough product on hands to cover all surfaces. Rub hands until dry.

Supervise children under 6 years of age when using this product to avoid swallowing.

Other Information

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

Inactive Ingredients

Glycerin, Hydrogen Peroxide, Purified Water USP, Fragrance

Package Label - Principal Display Panel

60ml NDC: 74682-003-53



60ml 74682-004-53

	Drug Facts	
	Active Ingredient[s] Purpose Alcohol 80% v/vAntiseptic	
	Use[s] Hand sanitizer to help reduce bacteria that potentially can cause disease For use when soap and water are not available.	
	Warnings For external use only. Flammable. Keep away from heat or flame.	
	Do not use on children less than 2 months of age on open skin wounds 	
	When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water.	
EWARDS	Stop use and ask a doctor if 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.	
f Most Illness Causing Germs	Directions • Place enough product on hands to cover all surfaces. Rub hands together until dry. • Supervise children under 6 years of age when using this product to avoid swallowing.	
	Other Information • Store between 15-30C (59-86F) • Avoid freezing and excessive heat above 40C (104F)	
	Inactive Ingredients Glycerin, Hydrogen Peroxide, Purified Water USP, Fragrance	
OL ANTISEPTIC 80%	Manufactured by Damon Industries • 822 Packer Way, Sparks, NV 894 800-838-2908 • NDC# XXXXXXX	
TED TOPICAL SOLUTION N-STERILE SOLUTION 2 OZ (60 ML)	Ande in the USA	

Inactive Ingredients Strengt Ingredient Name Strengt HYDRO GEN PERO XIDE (UNII: BBX060AN9V) Mater WATER (UNII: 059QF0K00R) Improve LIMO NENE, (+/-) (UNII: 9MC3I34447) Improve DIHYDRO MYRCENOL (UNII: 46L1B02ND9) Methyl DIHYDRO JASMO NATE (SYNTHETIC) (UNII: 3GW44CIE3Y) 2-ACETO XY-1,8-CINEOLE, (+)-ENDO- (UNII: 3J5IV4Q716) GLYCERIN (UNII: PDC6A3C00X)	Basis of Strength	
Num out (source) Rome of Administration TOPICAL TOPICAL Active Ingredient/Active Moiety Lingredient Name Basis of Strength Strength ALCOHOL (UNIE 3K9958 V90M) (ALCOHOL - UNIE3K9958 V90M) ALCOHOL 80 mL in 100 mI Ingredient Name Strength Ingredient Name Strengt HYDRO GEN PERO XIDE (UNIE BBX060 AN9 V) Strengt WATER (UNIE 059QE0K00R) Strengt HYDRO GEN PERO XIDE (UNIE BBX060 AN9 V) Strengt WATER (UNIE 059QE0K00R) Strengt LIMONENE, (+/-) (UNIE 9MC3B4447) Strengt DIHYDRO MYRCENOL (UNIE 461 B02ND9) Strengt METHYL DIHYDRO JASMONATE (SYNTHETIC) (UNIE 3GW44CIE3Y) Strengt Strengt Packaging Marketing Start Date Marketing Start Date Marketing Information Or/28/2020 Strengt Marketing Information	Basis of Strength	Strength 80 mL in 100 mL
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Ingredient Name Basis of Strength Strength ALCOHOL (UNIE 3K9958 V90M) (ALCOHOL - UNIE3K9958 V90M) ALCOHOL 80 mL in 100 mI Inactive Ingredients Ingredient Name Strength Inactive Ingredients Strength Strength WATER (UNIE 059QF0K00R) Image: Strength Image: Strength LIMONENE, (+/-) (UNIE 9B2060AN9V) Image: Strength Image: Strength WATER (UNIE 059QF0K00R) Image: Strength Image: Strength LIMONENE, (+/-) (UNIE 9B2060AN9V) Image: Strength Image: Strength WETHYL DIHYDROMARCEOL (UNIE 46L1B02ND9) Image: Strength Image: Strength Strengt Image: Strength Image: Strength Image: Strength Packaging Image: Strength Image: Strength Image: Strength MDC:74682-003 - 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product 07/28/2020 Image: Strength Marketing Information Product Image: Strength Image: Strength		80 mL in 100 mL
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water (UNE: 059QF0K00R) i <td></td> <td></td>		
Interm Code Package Description Marketing Start Marketing Start Date 07/28/2020		
Aceto XY-1,8-CINEOLE, (+)-ENDO- (UNII: 3GW44CIE3Y) Z-ACETO XY-1,8-CINEOLE, (+)-ENDO- (UNII: 3J5IV4Q716) GLYCERIN (UNII: PDC6A3C00X) Packaging X Item Code Package Description Marketing Start Date Marketing Er J NDC:74682-003- 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product 07/28/2020 Aceto Combination 07/28/2020		
2-ACETOXY-1,8-CINEOLE, (+)-ENDO- (UNII: 3J5IV4Q716) GUYCERIN (UNII: PDC6A3C0OX) Package Description Marketing Start Date Marketing En Date 0 1 NDC:74682-003- 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product 07/28/2020 07/28/2020		
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Item Code Package Description Marketing Start Date Marketing En Date 1 NDC:74682-003- Start Oduct 60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product 07/28/2020 07/28/2020		
Marketing Information		Marketing End Date
	7/28/2020	
Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End D		
OTC monograph not final part333A 07/28		//28/2020

TRUE REWARDS HAND SANITIZER					
alcohol liquid					
Product Information					
Product T ype	HUMAN OTC DRUG	Item Code ((Source)	NDC:74682-004	
Route of Administration	TOPICAL				
Active Ingredient/Active Moiety					
Ingred		Basis of Strengtl	h Strength		

ALCOHOL	(UNII: 3K99)	58 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	80 mL in 100 mL
Inactive I	ngredien	ts		
		Ingredient Name		Strength
HYDRO GEN	N PERO XIDI	E (UNII: BBX060AN9V)		
WATER (UN	III: 059QF0K	COOR)		
L IMO NENE,	, (+/-)- (UNI	: 9MC3I34447)		
DIHYDRO M	YRCENOL	(UNII: 46L1B02ND9)		
METHYL DI	HYDRO JAS	MONATE (SYNTHETIC) (UNII: 3GW44CIE3Y)		
2-ACETOXY	Y-1,8-CINEC	DLE, (+)-ENDO- (UNII: 3J5IV4Q716)		
2-ACETOXY GLYCERIN (
	(UNII: PDC6			
GL YCERIN ((UNII: PDC6		Marketing Start Date	Marketing End Date
GLYCERIN Packaginį	(UNII: PDC6 g Code 32-004- 60	A3C0OX)	•	<u> </u>
GLYCERIN Packaging # Item (1 NDC:7468	(UNII: PDC6 g Code 32-004- 60	A3C0OX) Package Description mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination	Date	<u> </u>
GLYCERIN Packaging # Item (1 NDC:7468	(UNII: PDC6 g Code 32-004- 60	A3C0OX) Package Description mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination	Date	<u> </u>
GLYCERIN Packaging # Item (1 NDC:7468 53	(UNII: PDC6 g Code 32-004- 60 Pro	A3C0OX) Package Description mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination	Date	<u> </u>
GLYCERIN Packaging # Item (1 NDC:7468 53 Marketi	(UNII: PDC6 g Code 32-004- 60 Pro	A3C0OX) Package Description ML in 1 BOTTLE, SPRAY; Type 0: Not a Combination oduct rmation	Date	<u> </u>

Labeler - Damon Industries (034954339)

Establishment

Name	Address	ID/FEI	Business Operations
Damon Industries		034954339	manufacture(74682-003, 74682-004)

Revised: 7/2020

Damon Industries