REBORNCARE HAND SANITIZER (100ML)- ethyl alcohol gel Reborncare

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.

Reborncare hand sanitizer (100mL)

Active ingedient

Ethanol (ethyl alcohol) (70%)

Purpose

Antibacterial

Uses

Hand sanitizer for decreasing bacteria on skin

Warnings

For external use only

Do not use if you are allergic to any of the ingredients

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water. avoid contact with broken, irritated, or itching skin. Do not puncture or incinerate.

Stop use and ask a doctor if irritation or redness develops and the condition persists for more than 72 hours.

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

Apply the adequate amount on hands

Inactive ingredients

Water, Glycerin, Tocopheryl

Reborncare hand sanitizer (100mL)

	1 [Drug Facts		
Reborncare		Active Ingredient Ethyl Alcohol (70%)	why .	Purpose Antiseptic
		Uses Hand Sanitize	er to help reduce bacteria that p	potentially can
			ise when soap and water are r al use only. Flammable. Keep aw	
			Iren less than 2 months of age •	
	Kills		roduct avoid contact with eye	
CLEAN HAND SANIT			th eyes, rinse eyes thoroughly doctor if irritation or rash occ	
			of a serious condition.	medical help on
		contact a Poison Co	of children. If swallowed, get ntrol Center (1-800-222-1222)	right away.
		Rub hands together	enough product on hands to until dry. • Supervise Children product to avoid swallowing.	
		0	Store at temperature between	en 59°F - 86°F
Ethanol		· /	d freezing and excessive heat a	
	o/ *) L	Inactive Ingredien	ts Water, Glycerin, Tocopher	yl.
	70	Manufactured and	Distributed by :	Pump: Other/
		Reborncare Co., Lto		Lable : PP
		Address: 44 Jeong dong-ro, Danwon-g		
Kills 99.9%	6 Germs	Gyeonggi-do, Korea	a.	
			8 " 8099	90 " 212903 ">
3.38 FL.OZ	(100ml)			
REBORNCARE HAND S	ANITIZER (100MI)		
)		
ethyl alcohol gel				
Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:79486-100
Route of Administration	TOPICAL			
Active Ingredient/Active Moi	o t a			
	y			al Carrowal
Ingredient Name			Basis of Streng	
ALCOHOL (UNII: 3K9958V90M) (ALC	COHOL - UNII:3K9958V90M)		ALCOHOL	70 g in 100 mL
Inactive Ingredients				
	Ingredient Name			Strength

GLYCERIN (UNII: PDC6A3C0OX) .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)

WATER (UNII: 059QF0KO0R)

Packaging

#

Package Description

Marketing Start Date Marketing End Date

1 NDC:79486-100-01 100 mL in 1 BOTTLE; Type 0: Not a Combination Product 07/07/2020

Item Code

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	07/07/2020		

Labeler -	Reborncare	(695538808)
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Establishment

Name	Address	ID/FEI	Business Operations
Venice Cosmetic		695047082	manufacture(79486-100)

Establishment

Name	Address	ID/FEI	Business Operations
Reborncare Co., Ltd.		695520618	manufacture(79486-100)

Revised: 7/2020

Reborncare