

HAND SANITIZER- alcohol liquid
Rebel Rebel Personal Care Corp.

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Ethyl Alcohol 65%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Antiseptic (skin) cleanser to help reduce bacteria on skin.

Warnings

Keep out of reach of children. For external use only. Flammable. Keep away from flame and heat. When using this product keep out of eyes, ears and mouth. In case of contact with eyes, rinse eyes thoroughly with water. If swallowed get medical help or contact poison control centre right away.

Do not use

- in 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 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.

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Directions

Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children to avoid swallowing. Store between 15-30°C (59-86°F).

Other information

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

Inactive ingredients

Non Active Ingredients: Purified Water, Aloe Barbadensis Extract, Glycerin, Polysorbate 20, Denatonium Benzoate, Fragrance.

Package Label - Principal Display Panel

60 mL NDC: 82092-001-01





Drug Facts
 Active Medicinal Ingredient.....Purpose
 Ethyl Alcohol 65%.....Antiseptic

Inactive Non-Medicinal Ingredients: Purified Water, Aloe Barbadosis Extract, Glycerin, Polysorbate 20, Denatonium Benzoate, Fragrance

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Discontinue use and consult a health care practitioner if irritation or rash develops. These may be signs of a serious condition.

Do not use

- on children less than 2 years of age
- on open skin wounds

Informations pharmaceutiques
 Ingrédient médicamenteux actifs.....Objectif
 Alcool éthylique 65 %.....Antiseptique

Ingrédients inactifs non médicinaux: Eau purifiée, Extrait d'Aloe Barbadosis, Glycérine, Polysorbate 20, Benzoate de dénatonium, Parfum

Usage recommandé: Nettoyant antiseptique (peau) pour aider à réduire les bactéries sur la peau.

Dose recommandé et mode d'emploi: Frotter vigoureusement les mains pendant au moins 30 secondes. Laisser sécher. Surveiller les enfants pour éviter toute ingestion de produit. Conserver entre 15-30 °C (59-86 °F).

Mises en garde: Tenir hors de portée des enfants. Pour usage externe uniquement. Inflammable. Tenir loin des flammes et des sources de chaleur. Au moment de son utilisation, garder le produit hors des yeux, des oreilles et de la bouche. En cas de contact avec les yeux, rincer abondamment les yeux à l'eau. En cas d'ingestion, obtenir une aide médicale ou contacter immédiatement un centre antipoison.

Cesser toute utilisation et consulter un professionnel de la santé si une irritation ou une éruption cutanée se développe. Il peut s'agir de signes d'un trouble grave.

Contre-indications

- chez les enfants de moins de 2 ans
- sur les plaies cutanées ouvertes

Manufactured by/Fabriqué par:
 ProLab Health and Beauty Ltd.
 Distributed by/Distribué par:
 Rebel Personal Care Corp.
 2305-610 Granville Street
 Vancouver, BC, V6C 3T3 Canada

Made in Canada
 Fabriqué au Canada
 www.heyrebelrebel.com

No Parabens & No Phthalate | Vegan & Cruelty-free

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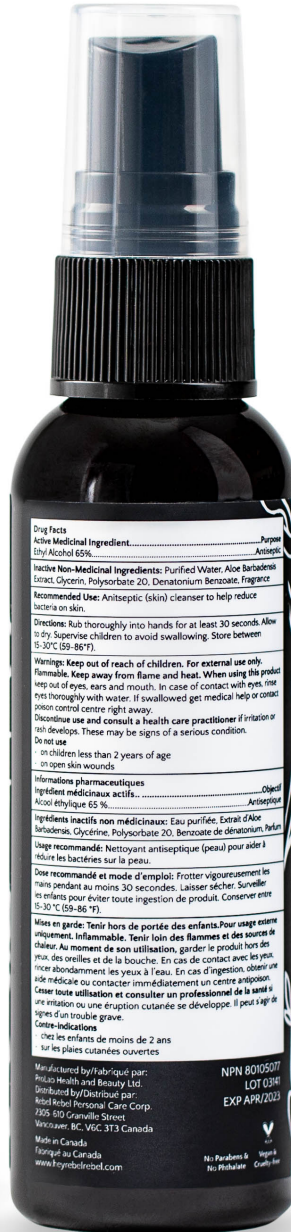
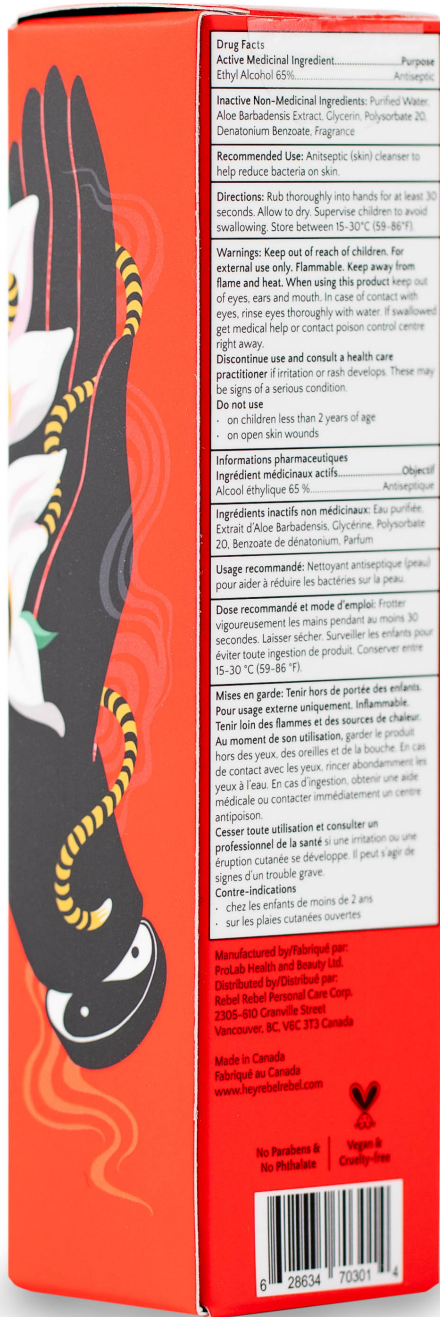
Made in Canada
 Fabriqué au Canada
 www.heyrebelrebel.com

NPN 80105071
 LOT 0313
 EXP APR/2023

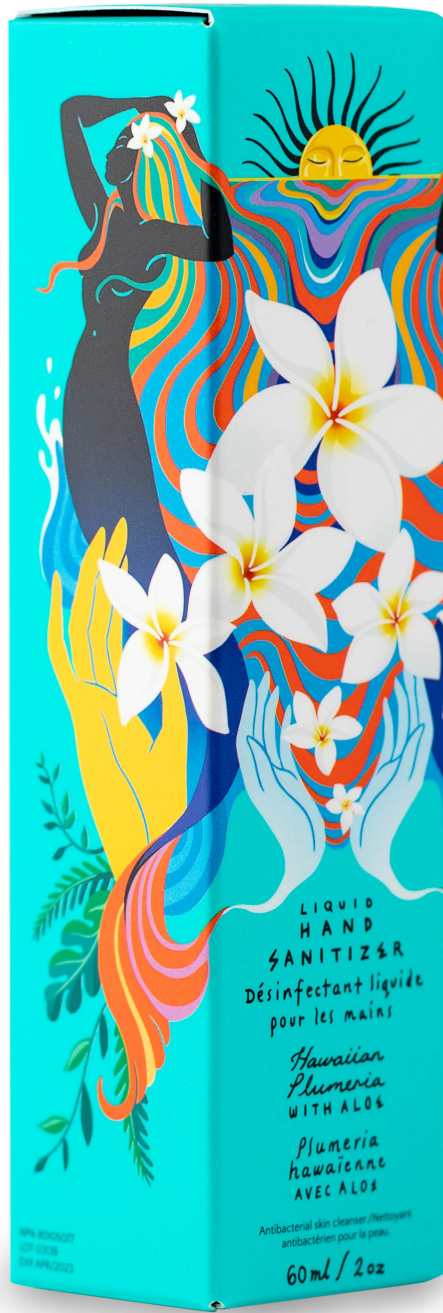
No Parabens & No Phthalate | Vegan & Cruelty-free

60 mL NDC: 82092-002-01





60 mL NDC: 82092-003-01





HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82092-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82092-001-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/01/2021	

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82092-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
2-ACETONAPHTHONE (UNII: 21D49LOP2T)	
ETHYL METHYLPHENYLGLYCIDATE (UNII: UD51D5KR4A)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
WATER (UNII: 059QF0K00R)	

HEXAMETHYLINDANOPYRAN (UNII: 14170060AT)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
METHYL ANTHRANILATE (UNII: 981I0C1E5W)	
GERANIOL (UNII: L837108USY)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
2,4-DIMETHYL-3-CYCLOHEXENE CARBOXALDEHYDE (UNII: 452GFV2AFS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82092-003-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/01/2021	

HAND SANITIZER

alcohol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82092-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
PIPERONAL (UNII: KE109YAK00)	
LINALYL ACETATE (UNII: 5K47SSQ51G)	
GERANYL ACETATE (UNII: 3W81YG7P9R)	
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
PENTADECALACTONE (UNII: OK17S3S98K)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

GLYCERIN (UNII: PDC6A3C00X)		1.45 mL in 100 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82092-002-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2021	
Marketing Information				
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OTC monograph not final	part333A	02/01/2021		

Labeler - Rebel Rebel Personal Care Corp. (204273499)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Rebel Personal Care Corp.		204273499	manufacture(82092-001, 82092-002, 82092-003)

Revised: 1/2023

Rebel Rebel Personal Care Corp.