

RONA-B-GONA SANITIZING HAND GUARD- alcohol spray
Buckler Essentials, LLC

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.

Rona-B-Gona Hand Guard

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 (isopropyl) (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. Aloe Vera Water (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

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

- 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

- Shake well
- 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.

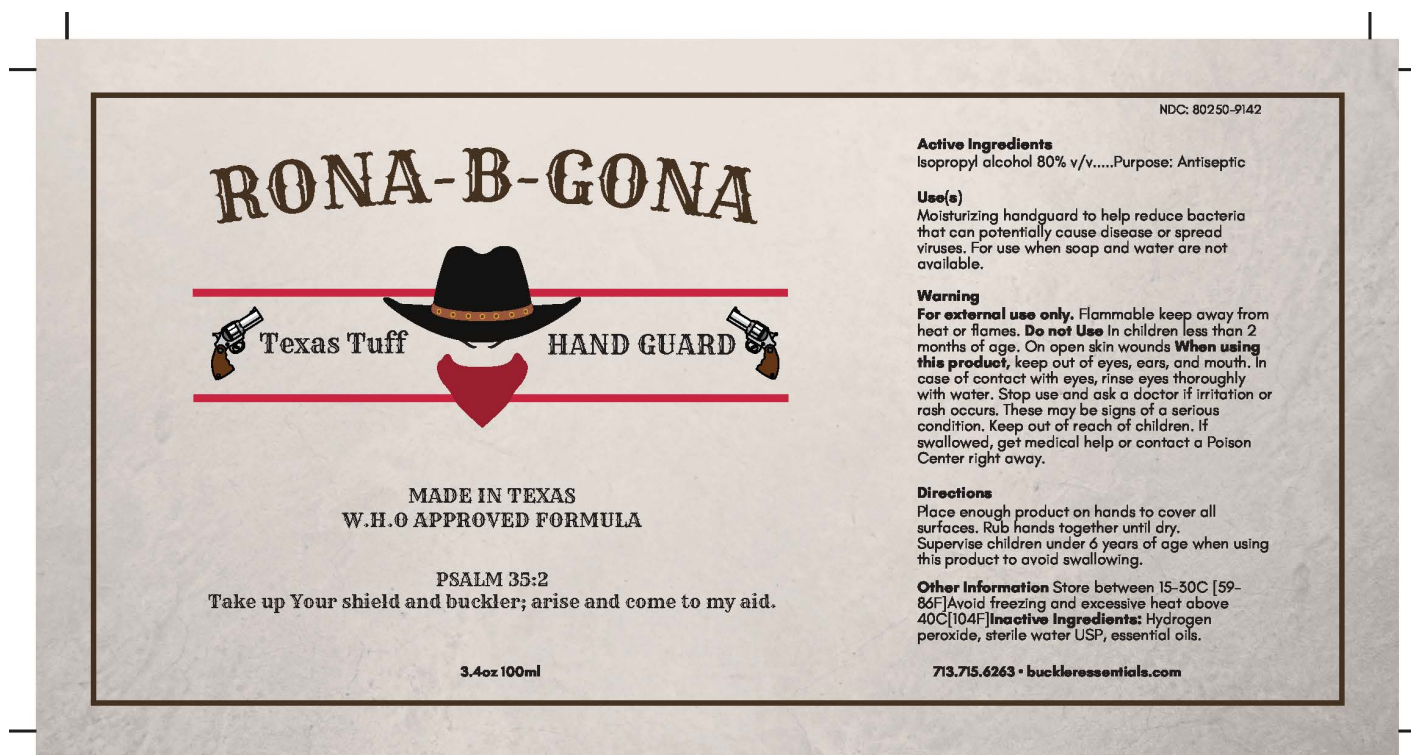
Other information

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

Inactive ingredients

Aloe vera, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



RONA-B-GONA

Texas Tuff HAND GUARD

MADE IN TEXAS
W.H.O APPROVED FORMULA

PSALM 35:2
Take up Your shield and buckler; arise and come to my aid.

3.4oz 100ml

NDC: 80250-9142

Active Ingredients
Isopropyl alcohol 80% v/v.....Purpose: Antiseptic

Use(s)
Moisturizing handguard to help reduce bacteria that can potentially cause disease or spread viruses. For use when soap and water are not available.

Warning
For external use only. Flammable keep away from heat or flames. **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 Center right away.

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:** Hydrogen peroxide, sterile water USP, essential oils.

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100 mL NDC: 80250-3521-3

RONA-B-GONA SANITIZING HAND GUARD

alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80250-3521
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GOSSYPIUM BARBADENSE LEAF (UNII: 251DUP3OSN)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80250-3521-3	1 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	12/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/20/2020	

Labeler - Buckler Essentials, LLC (117607480)

Registrant - Buckler Essentials, LLC (117607480)

Establishment

Name	Address	ID/FEI	Business Operations
Buckler Essentials		117607480	manufacture(80250-3521)

Revised: 12/2020

Buckler Essentials, LLC