

HONEYWELL HAND SANITIZER- alcohol solution
Honeywell International Inc.

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 rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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. Isopropyl Alcohol (75%, 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)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Rub

Use

Health care personnel hand rub to help reduce bacteria that potentially can cause disease.

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

- 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

Package Label - Principal Display Panel

lab-honeywell.com

Cat. 10100-4X1G
Lot No. AA111-US
Mfg No. 10664994
Mfg date: 04/24/2020
Expiry date: 04/24/2023
Country of Origin: USA

Specifications, CoA and SDS available at lab-honeywell.com

Boiling pt: 81 - 83 °C Density(20°C): 0.866 g/cm³
Flash Pt(cc): 22 °C

**Isopropyl Alcohol Antiseptic
75% Topical Solution**

Isopropyl (81-83-0); Water (7732-18-6); Glycerol (58-10-6); Hydrogen peroxide (7722-84-1)

Antiseptic Hand Rub
Non-sterile Solution

3785 ML

In case of Emergency, call (247):
Medical: 1-800-468-5701 or +1-303-388-1414

1953 S. Hanley St., Muskegon, MI 49442, USA +1-231-726-3171
Vianthener Straße 40, D-50928, Soltau, Germany +49-4137-669-0

Danger - Highly Flammable Liquid and Vapor. Causes serious eye irritation. May cause drowsiness or dizziness. Keep away from heat, open flames, hot surfaces. No smoking. Keep container tightly closed. Decanted into container and mixing equipment. Use according to label. Ventilate, spray equipment. Use only non-sparking tools. Take precautions: measure against static charge. Avoid breathing dust, fumes, gas, mist, vapors, smoke. When skin thoroughly wetted, use only solutions of 1% salt-saturated area. When product is under pressure, closing and protection from protection of O2, N2O, or other. Take of immediately and compressed coating. Release air with water shower. If SWALLOWED: Rinse with water for 30 sec and take as soon as possible to a poison control center for treatment. If IN EYES: Flush with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER doctor or your local poison center. If eye irritation persists, get medical advice immediately. In case of the use of hand, do not use in enclosed environment for protection. Keep in a well-ventilated place. Keep container tightly closed. Keep cool. Store locked up. Children or container content to be approved under 18 years old.

Danger - Liquide et vapeurs très inflammables. Provoque une sévère irritation des yeux. Peut provoquer somnolence ou vertige.
Tenir à l'écart de la chaleur, des étincelles, des flammes nues, des surfaces chaudes. Ne pas fumer. Maintenir le récipient fermé de manière étanche. Éloigner de toute source d'allumage ou de chaleur. Éviter de verser. Utiliser du matériel électrique au ventilation: éviter les étincelles. Ne pas utiliser d'outils produisant des étincelles. Prendre des mesures de protection contre les charges électrostatiques. Éviter de respirer les poussières, fumées, gaz, brouillards, vapeurs, fumées. En leur le plus rapidement possible. Lorsque le produit est sous pression, fermer et protéger avec une protection de protection des vêtements de protection et équipement de protection des yeux. En cas de contact avec LA PEAU ou les MUCOSALES: rincer immédiatement avec beaucoup d'eau. Rincer le visage à l'eau ou à l'eau. EN CAS D'IRRITATION: transporter à l'urgence à l'hôpital et le maintenir au repos dans une position où les bras sont complètement étendus. EN CAS DE CONTACT AVEC LES YEUX: rincer avec abondance à l'eau pendant plusieurs minutes. Éviter le contact et le contact à la corne et si elle présente des symptômes graves. Continuer à rincer. Appeler un CENTRE ANTIPOISON ou un médecin en cas de besoin. Si l'irritation oculaire persiste, consulter un médecin. En cas d'irritation, utiliser du selé, etc. de la solution chimique sèche ou de la mousses mousses à l'écou pour l'irritation. Stocker dans un endroit bien ventilé. L'éloigner de la chaleur, des étincelles, des flammes nues, des surfaces chaudes. Tenir au frais. Garder sous pression et contenu récipient dans une installation d'élimination des déchets agréés.

California Prop. 65: This product does not contain any listed chemicals. Prop. 65 de la
California: Ce produit ne contient aucun agent chimique listé.

Drug Facts	
Active ingredient(s) Isopropyl alcohol 75% v/v.	Purpose Antiseptic
Use(s) Health care personnel hand rub to help reduce bacteria that potentially can cause disease.	
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.	
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	

Hand Sanitizer – Contains Isopropyl Alcohol

Catalog Number: **10100-4X1G**
Lot Number: **AA111-US**

HONEYWELL HAND SANITIZER

alcohol solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12728-543
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 L in 100 L	

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 L in 100 L
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 L in 100 L
WATER (UNII: 059QF0K00R)	18.425 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12728-543-01	3.785 L in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/20/2020	

Labeler - Honeywell International Inc. (879085116)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell International Inc.		879085116	manufacture(12728-543)

Revised: 4/2020

Honeywell International Inc.