# INO MED 2 HAND SANITIZER- alcohol gel GROUPE DISSAN, LE

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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#### **INO-MED2**

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)**

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**

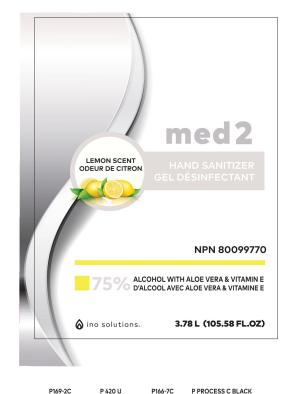
- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

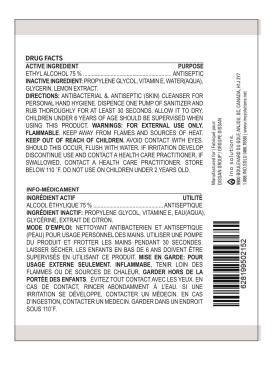
#### Other information

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

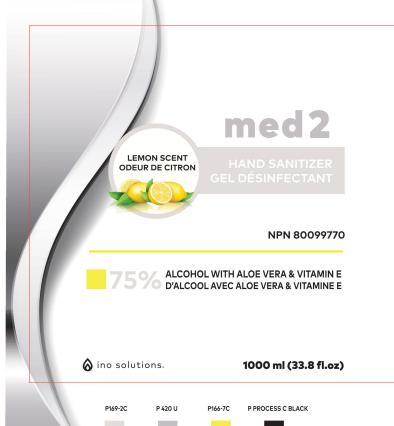
SQUALANE GW89575KF9 IACT
PANTHENOL WV9CM0O67Z IACT
AMINOMETHYLPROPANOL LU49E6626Q IACT
INULIN JOS53KRJ01 IACT
CARBOMER INTERPOLYMER TYPE A (55000 CPS) 59TL3WG5CO IACT
LIMONENE, (+)- GFD7C86Q1W IACT
ALPHA-TOCOPHEROL ACETATE 9E8X80D2L0 IACT
GLYCERIN PDC6A3C0OX IACT
WATER 059QF0KO0R IACT
HYALURONATE SODIUM YSE9PPT4TH IACT
FRUCTOSE, DL- 02T79V874P IACT

Label size: 102W X 135H(mm) 12-05-2020





Label size: 271W X 150H(mm)



DRUG FACTS ACTIVE INGREDIENT ETHYL ALCOHOL 75 % PURPOSE ANTISEPTIC IMACTIVE INGREDIENT: ALOE VERA, VITAMIN E, WATER (AQUA), GLYCERIN, LEMON EXTRACT.

DIRECTIONS: ANTIBACTERIAL & ANTISEPTIC (SKIN) CLEANSER FOR

PERSONAL HAND HYGIENE. DISPENCE ONE PUMP OF SANITIZER AND RUB THOROUGHLY FOR AT LEAST 30 SECONDS. ALLOW IT TO DRY. CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHEN USING THIS PRODUCT WARNINGS: FOR EXTERNAL USE ONLY.
FLAMMABLE. KEEP AWAY FROM FLAMES AND SOURCES OF HEAT.
KEEP OUT OF REACH OF CHILDREN. AVOID CONTACT WITH EYES. SHOULD THIS OCCUR, FLUSH WITH WATER, IF IRRITATION DEVELOP DISCONTINUE USE AND CONTACT A HEALTH CARE PRACTITIONER. IF SWALLOWED, CONTACT A HEALTH CARE PRACTITIONER. STORE BELOW 110 °F. DO NOT USE ON CHILDREN UNDER 2 YEARS OLD.

#### INFO MÉDICAMENT

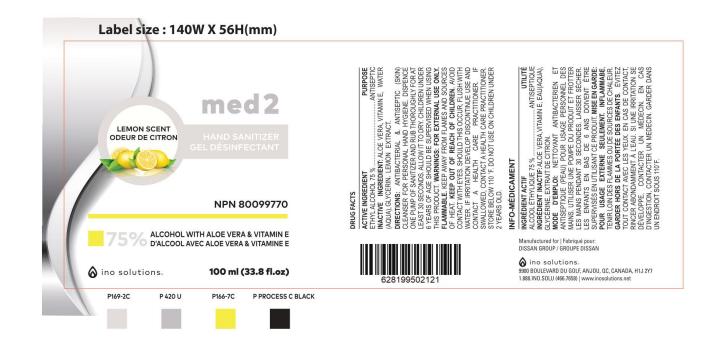
INGRÉDIENT ACTIF UTILITÉ EXTRAIT DE CITRON

MODE D'EMPLOI: NETTOYANT ANTIBACTERIEN ET ANTISEPTIQUE (PEAU) POUR USAGE PERSONNEL DES MAINS. UTILISER UNE POMPE DU PRODUIT ET FROTTER LES MAINS PENDANT 30 SECONDES. LAISSER SÉCHER. LES ENFANTS EN BAS DE 6 ANS DOIVENT ÊTRE SUPERVISÉS EN UTILISANT CE PRODUIT. MISE EN GARDE: POUR USAGE EXTERNE SEULEMENT. INFLAMMABE, TENIR LOIN DES FLAMMES OU DE SOURCES DE CHALEUR. GARDER HORS DE LA PORTÉE DES ENFANTS. ÉVITEZ TOUT CONTACT AVEC LES YEUX. EN CAS DE CONTACT, RINCER ABONDAMMENT À L'EAU. SI UNE IRRITATION SE DÉVELOPPE, CONTACTER UN MÉDECIN. EN CAS D'INGESTION, CONTACTER UN MEDECIN, GARDER DANS UN ENDROIT SOUS 110°F.





PRIG FACTS
ACTIVE ROREDIENT
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ALOE VERA. VITXAMIN E,
MATISEPTIOLE
MACTIVE MOREDIENT ALOE VERA. VITXAMIN E,
MATERIACIDIA, SUCKERIA LEMON EXTRACT.
DIRECTIONS: ANTIBACTERIAL & ANTISEPTIC (SKIN)
CLEANSER FOR PRESONAL HADA PHOREDIENTENCE
ONE PUMP OF SANTIZER AND RUB THOROUGHLY FOR
ATTEBATION PERSONAL HADA PHOREDIENT MARTISEPTIC (SKIN)
LINGER PERSONAL HADA PHOREDIENT MARTISEPTIC (SKIN)
UNDER 9 PEARS OF ACE MADOLUDE SUPERVISED WHEN
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#### **INO MED 2 HAND SANITIZER**

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78306-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
HYALURO NATE SO DIUM (UNII: YSE9 PPT4TH)		
SQUALANE (UNII: GW89575KF9)		
PANTHENOL (UNII: WV9CM0O67Z)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
INULIN (UNII: JOS53KRJ01)		
FRUCTOSE, DL- (UNII: 02T79 V874P)		
LIMO NENE, (+)- (UNII: GFD7C86Q1W)		
GLYCERIN (UNII: PDC6A3C0OX)		
WATER (UNII: 059QF0KO0R)		
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)		
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)		

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78306-501- 12	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/13/2020	
2	NDC:78306-501- 14	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/13/2020	
3	NDC:78306-501- 11	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/13/2020	
4	NDC:78306-501- 15	3800 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	06/13/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/13/2020	

### Labeler - GROUPE DISSAN, LE (248967291)

### **Registrant - Normand Robichaud Services conseils Inc. (242225051)**

Establishment				
Name	Address	ID/FEI	Business Operations	
GROUPE DISSAN, LE		248967291	manufacture (78306-501)	

Revised: 6/2020 GROUPE DISSAN, LE