

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.

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.

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)

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



P169-2C P 420 U P166-7C P PROCESS C BLACK



med2

LEMON SCENT
ODEUR DE CITRON

HAND SANITIZER
GEL DÉSINFECTANT

75% ALCOHOL WITH ALOE VERA & VITAMIN E
D'ALCOOL AVEC ALOE VERA & VITAMINE E

ino solutions. **1000 ml (33.8 fl.oz)**

DRUG FACTS
ACTIVE INGREDIENT **PURPOSE**
 ETHYL ALCOHOL 75 % ANTISEPTIC
INACTIVE 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**
 ALCOOL ÉTHYLIQUE 75 % ANTISEPTIQUE
INGRÉDIENT INACTIF: ALOE VERA, VITAMINE E, EAU(AQUA), GLYCÉRINE, EXTRAIT DE CITRON.
MODE D'EMPLOI: NETTOYANT ANTIBACTÉRIEN 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. INFLAMMABLE.** 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 MÉDECIN. GARDER DANS UN ENDROIT SOUS 110° F.

Manufactured for / Fabriqué pour:
DISSAN GROUP / GROUPE DISSAN
ino solutions.
9900 BOULEVARD DU GOLF, ANJOU, QC, CANADA, H1J 2Y7
1.888.1NO.SOLU (466.7658) | www.inosolutions.net

628199502145

- P169-2C P 420 U P166-7C P PROCESS C BLACK
-

med2

LEMON SCENT
ODEUR DE CITRON

HAND SANITIZER
GEL DÉSINFECTANT

75% ALCOHOL WITH ALOE VERA & VITAMIN E
D'ALCOOL AVEC ALOE VERA & VITAMINE E

ino solutions. **500 ml (16.9 fl.oz)**

DRUG FACTS
ACTIVE INGREDIENT **PURPOSE**
 ETHYL ALCOHOL 75 % ANTISEPTIC
INACTIVE 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**
 ALCOOL ÉTHYLIQUE 75 % ANTISEPTIQUE
INGRÉDIENT INACTIF: ALOE VERA, VITAMINE E, EAU(AQUA), GLYCÉRINE, EXTRAIT DE CITRON.
MODE D'EMPLOI: NETTOYANT ANTIBACTÉRIEN 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. INFLAMMABLE.** 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 MÉDECIN. GARDER DANS UN ENDROIT SOUS 110° F.

Manufactured for / Fabriqué pour:
DISSAN GROUP / GROUPE DISSAN
ino solutions.
9900 BOULEVARD DU GOLF, ANJOU, QC, CANADA, H1J 2Y7
1.888.1NO.SOLU (466.7658) | www.inosolutions.net

628199502138

Label size : 140W X 56H(mm)

med2
LEMON SCENT
ODEUR DE CITRON
HAND SANITIZER
GEL DÉSINFECTANT

75% ALCOHOL WITH ALOE VERA & VITAMIN E
D'ALCOOL AVEC ALOE VERA & VITAMINE E

NPN 80099770
100 ml (33.8 fl.oz)

ino solutions.

P169-2C P 420 U P166-7C P PROCESS C BLACK

DRUG FACTS
ACTIVE INGREDIENT
ETHYL ALCOHOL 75 %
INACTIVE INGREDIENT: ALOE VERA, VITAMIN E, WATER (AQUA), GLYCERIN, LEMON EXTRACT.
DIRECTIONS: ANTIBACTERIAL & ANTISEPTIC (SKIN) CLEANSER FOR PERSONAL HAND HYGIENE. DISPENSE 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 DEVELOPS, 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
ALCOOL ÉTHYLIQUE 75 %
INGRÉDIENT INACTIF: ALOE VERA, VITAMIN E, EAU (AQUA), GLYCÉRINE, EXTRAIT DE CITRON.
MODE D'EMPLOI: NETTOYANT ANTIBACTÉRIEN ET ANTISEPTIQUE (PEAU) POUR USAGE PERSONNEL DES MAINS. UTILISER UNE POMPE DU PRODUIT ET FROTTER LES MAINS PENDANT 30 SECONDES. LAISSER SÈCHER. LES ENFANTS EN BAS DE 6 ANS DOIVENT ÊTRE SUPERVISÉS EN UTILISANT CE PRODUIT. **MISE EN GARDE: POUR USAGE EXTERNE SEULEMENT. INFLAMMABLE.** TENIR LOIN DES FLAMMES OU DE SOURCES DE CHALEUR. **GARDER HORS DE LA PORTEE 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 MÉDECIN. GARDER DANS UN ENDROIT SOUS 110° F.

Manufactured for | Fabriqué pour:
DISSAN GROUP / GROUPE DISSAN

ino solutions.
9900 BOULEVARD DU GOLF, ANJOU, QC, CANADA, H1J 2Y7
1.888.IND.S0LU (466.7858) | www.inosolutions.net

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
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
SQUALANE (UNII: GW89575KF9)	
PANTHENOL (UNII: WV9CM0O67Z)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
INULIN (UNII: JOS53KRJ01)	
FRUCTOSE, DL- (UNII: 02T79V874P)	
LIMONENE, (+)- (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