

**HAND SANITIZER SPRITZ- alcohol liquid**  
**New Directions Aromatics 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.*

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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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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

## Package Label - Principal Display Panel

**NON-STERILE SOLUTION**  
**SOLUTION NON STÉRILE**

**TOPICAL SOLUTION**  
**SOLUTION TOPIQUE**

**WAR**  
Keep  
child  
on o  
keep  
cont  
water  
rash  
cond  
swall  
Cont  
Pour  
Infla  
chale  
enfa  
sur le  
prod  
oreill  
yeux  
Arrêt  
cas c  
d'agi  
de pi  
demi  
cent

Use[s]: Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.  
/ Utilisation[s]: Désinfectant pour les mains pour aider à réduire les bactéries pouvant causer des maladies. À utiliser lorsque l'eau et le savon ne sont pas disponibles.

Directions: For occasional and personal domestic use. Place enough product on hands to cover all surfaces. Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product.  
/ Mode d'emploi: Pour un usage occasionnel et personnel (domestique). Verser suffisamment de produit pour couvrir l'ensemble de la surface. Frotter soigneusement dans les mains pendant au moins 30 secondes. Laisser sécher. Surveiller les enfants lorsqu'ils utilisent ce produit.

Other information: Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). / Autres informations: Conserver à une température entre 15 et 30C (59-86F). Éviter la congélation et la chaleur excessive au-delà de 40C (104F).

**N.D.A.**  
THE ESSENCE OF NATURE

**ACTIVE INGREDIENT[S]**  
Alcohol 80% v/v  
(Purpose: Antiseptic)

**INGRÉDIENT[S]**  
**ACTIF[S]:**  
Alcool 80% v/v  
(Fonction: Antiseptique)

**INACTIVE INGREDIENTS / INGRÉDIENTS**  
INACTIFS: Glycerin, Hydrogen Peroxide,  
Purified Water USP

**MADE IN CANADA**  
**FABRIQUÉ AU CANADA**

**Alcohol Antiseptic 80%**  
**Alcool antiseptique 80%**

**Hand Sanitizer Spritz**  
**Désinfectant pour les mains Spritz**

**473 ml / 16 fl.oz.**

**QC**  
**300**  
**CERTIFIE**

New  
Missi  
Canad  
1-800

www

473 mL NDC: 74179-900-01



## HAND SANITIZER SPRITZ

Alcohol Antiseptic 80%

Non-Sterile Topical Solution

200 L ( 53 gal )

LOT #80008

COUNTRY OF ORIGIN: CANADA

NOT FOR INGESTION

NPN: 80098163 NDC:74179-900-02

BATCH NO.

For external use only. Keep away from children. Refer to SDS and disclaimers before using this product. Pour usage externe seulement. Garder hors de la portée des enfants. Vérifiez les documents analytiques et mention légale avant d'utiliser ce produit.

80008  
6781 Columbus Road  
Mississauga, Ontario,  
Canada L5T 2G9  
1.800.246.7817  
newdirectionsaromatics.com



## Hand Sanitizer Spritz /



### Danger

Highly flammable liquid and vapour

Causes serious eye irritation

Precautions:

Keep out of reach of children.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Keep container tightly closed.

If eye irritation persists get medical advice/attention.

Store in a well ventilated place. Keep cool.

Dispose of contents/container to authorized waste disposal facility.

### Danger

Liquide et vapeurs très inflammables

Provoque une sévère irritation des yeux

Conseils:

Tenir hors de portée des enfants.

Tenir à l'écart de la chaleur, des surfaces chaudes, des étincelles, des flammes nues et de toute autre source d'ignition. Ne pas fumer.

Maintenir le récipient fermé de manière étanche.

Si l'irritation des yeux persiste: Demander un avis médical/Consulter un médecin.

Stocker dans un endroit bien ventilé. Tenir au frais.

Éliminer le contenu/récipient dans...

See SDS for more information.

Voir SDS pour plus d'informations.

New Directions Aromatics Inc. 6781 Columbus Road, Mississauga, Ontario, CANADA L5T 2G9



# NEW DIRECTIONS AROMATIC S

www.newdirectionsaromatics.com

## DRUG FACTS - HAND SANITIZER SPRITZ

**Active Ingredient[s]:** Alcohol 80% v/v (Purpose: Antiseptic)

**Use[s]:** 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. Do not use 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:** For occasional and personal domestic use. Place enough product on hands to cover all surfaces. Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product.

**Other Information:** Store between 15-30°C (58-86°F). Avoid freezing and excessive heat above 40°C (104°F)

**Inactive Ingredients:** Glycerin, Hydrogen Peroxide, Purified Water USP

200 L NDC: 74179-900-02

**USE[S] / UTILISATION[S]:**  
Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available. / Désinfectant pour les mains pour aider à réduire les bactéries pouvant causer des maladies. À utiliser lorsque l'eau et le savon ne sont pas disponibles.

**DIRECTIONS / MODE D'EMPLOI:**  
For occasional and personal domestic use. Place enough product on hands to cover all surfaces. Rub thoroughly into hands for at least 30 seconds. Allow to dry. Supervise children when they use this product. / Pour un usage occasionnel et personnel (domestique). Verser suffisamment de produit pour couvrir l'ensemble de la surface. Frotter soigneusement dans les mains pendant au moins 30 secondes. Laisser sécher. Surveiller les enfants lorsqu'ils utilisent ce produit.

**OTHER INFORMATION / AUTRES INFORMATIONS:** Store between 15-30C (59-86F). Avoid freezing and excessive heat above 40C (104F). / Conserver à une température entre 15 et 30C (59-86F). Éviter la congélation et la chaleur excessive au-delà de 40C (104F).

**NON-STERILE SOLUTION**

**SOLUTION NON STÉRILE**



**TOPICAL SOLUTION SOLUTION TOPIQUE**

**WARNINGS / AVERTISSEMENTS:**  
For external use only. Flammable. Keep away from heat or flame. Do not use in children less than 2 months of age. Do not use 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. / Pour un usage externe uniquement. Inflammable. Tenir éloigné d'une source de chaleur ou d'une flamme. Ne pas utiliser sur les enfants âgés de moins de 2 mois. Ne pas utiliser sur les plaies ouvertes. Lors de l'utilisation de ce produit, éviter tout contact avec les yeux, les oreilles et la bouche. En cas de contact avec les yeux, les rincer abondamment à l'eau claire. Arrêter l'utilisation et consulter un médecin en cas d'irritation ou d'éruption cutanée. Il peut d'agir de signes d'une affection grave. Tenir hors de portée des enfants. En cas d'ingestion, demander une aide médicale ou contacter un centre antipoison immédiatement.

**N.D.A**  
THE ESSENCE OF NATURE

**ACTIVE INGREDIENT[S]:**  
Alcohol 80% v/v  
(Purpose: Antiseptic)

**INGRÉDIENT[S] ACTIF[S]:**  
Alcool 80% v/v  
(Fonction: Antiseptique)

**INACTIVE INGREDIENTS / INGRÉDIENTS INACTIFS:**  
Glycerin, Hydrogen Peroxide, Purified Water

**NPN NUMBER: 80098163**  
**NDC NUMBER: XXXXX-XXX-XX**

**Alcohol Antiseptic 80%**  
**Alcool antiseptique 80%**

**Hand Sanitizer Spritz**  
**Désinfectant pour les mains Spritz**

**60 ml / 2 fl. oz.**

**Made in Canada / Fabriqué au Canada**

New Directions Aromatics Inc.  
Mississauga, Ontario  
Canada L5T2G9  
1-800-246-7817

24 M



[www.newdirectionsaromatics.com](http://www.newdirectionsaromatics.com)

60 mL NDC: 74179-900-03

## HAND SANITIZER SPRITZ

alcohol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:74179-900
<b>Route of Administration</b>	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
GLYCERIN (UNII: PDC6A3C0OX)	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:74179-900-01	473 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/31/2020	
2	NDC:74179-900-02	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/31/2020	
3	NDC:74179-900-03	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	04/22/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

**Labeler** - New Directions Aromatics Inc. (200570278)

**Registrant** - New Directions Aromatics Inc. (200570278)

### Establishment

Name	Address	ID/FEI	Business Operations
New Directions Aromatics Inc.		200570278	manufacture(74179-900)

Revised: 4/2020

New Directions Aromatics Inc.