

DURAFAST HAND SANITIZER- alcohol hand sanitizer gel
PRINT JET CORP

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 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

237 ml NDC: 76795-750-04

Drug Facts	
Active ingredient(s)	Alcohol 70%
Purpose:	Antiseptic
Use(s)	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
Warning	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 & excessive heat above 40C (104F)
Inactive ingredients	xanthan gum, glycerin, hydrogen peroxide, DI water, fragrance.

DuraFast®

HAND SANITIZER GEL
GEL DÉSINFECTANT

Antiseptic Alcohol / Alcool Antiseptique
LAVENDER FRAGRANCE / PARFUM DE LAVANDE

70% TOPICAL SOLUTION
SOLUTION TOPIQUE À 70%

NON-STERILE SOLUTION
SOLUTION NON STERILE

Made in USA
FAIRE AUX ÉTATS-UNIS

8 oz (237mL)

DuraFast logo is a registered trademark of Sector Nine Distribution Ltd.

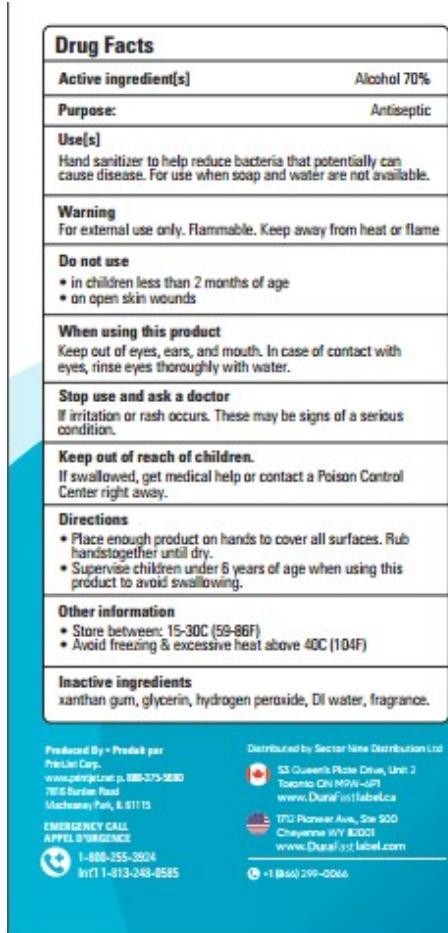
Info-médicaments	
Ingredient(s) actif(s)	Alcool 70%
Utilité:	Antiseptique
Usage(s)	Désinfectant pour les mains pour aider à réduire les bactéries qui peuvent potentiellement causer des maladies. À utiliser lorsque le savon et l'eau ne sont pas disponibles.
Mise en garde	Pour usage externe uniquement. Inflammable. Tenir éloigné de la chaleur ou des flammes
Ne pas utiliser	* chez les enfants de moins de 2 mois * sur des plaies cutanées ouvertes
Lorsque vous utilisez ce produit	Garder hors des yeux, des oreilles et de la bouche. En cas de contact avec les yeux, rincer abondamment les yeux à l'eau.
Arrêtez l'utilisation et demandez à un médecin	En cas d'irritation ou d'éruption cutanée. Ces-ci peuvent être des signes d'une maladie grave.
Garder hors de la portée des enfants	En cas d'ingestion, consulter un médecin ou contacter immédiatement un centre antipoison.
Mode d'emploi	* Place suffisamment de produit sur les mains pour couvrir toutes les surfaces. Frottez-vous les mains jusqu'à ce qu'elles soient sèches. * Supervisez les enfants de moins de 6 ans lors de l'utilisation de ce produit pour éviter l'ingestion.
Autres renseignements	* Conserver entre: 15-30C (59-86F) * Évitez le gel et la chaleur excessive au-dessus de 40C (104F)
Ingrediénts inactifs	gomme de xanthane, glycerine, peroxyde d'hydrogène, eau DI, parfum.

PN: HS102
FDA REGISTERED
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120 ml NDC: 76795-750-02

8550 ml NDC: 76795-750-19



950 ml NDC: 76795-750-05



3785 ml NDC: 76795-750-07



950 ml NDC: 76795-750-06



60 ml NDC: 76795-750-01

Drug Facts	
Active ingredient(s)	Alcohol 70%
Product:	Antiseptic
Usage	Hand sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.
Warning	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 15-30°C (59-86°F) • Avoid freezing & excessive heat above 40°C (104°F)
Inactive ingredients	xanthan gum, glycerin, hydrogen peroxide, DI water, fragrance.

Produced By • Product per
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HAND SANITIZER GEL
GEL DÉSINFECTANT

Antiseptic Alcohol | Alcool Antiseptique
LAVENDER FRAGRANCE • PARFUM DE LAVANDE



70% TOPICAL SOLUTION
SOLUTION TOPIQUE À 70%



NON-Sterile Solution
SOLUTION NON STÉRILE

2 oz (60mL)

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Info-médicaments	
Ingrediént(s) actif(s)	Alcool 70%
Utilité	Antiseptique
Usage(s)	Désinfectant pour les mains pour aider à réduire les bactéries qui peuvent potentiellement causer des maladies. À utiliser lorsque le savon et l'eau ne sont pas disponibles.
Mise en garde	Pour usage externe uniquement. Inflammable. Tenir éloigné de la chaleur ou des flammes.
Ne pas utiliser	• chez les enfants de moins de 2 mois • sur des plaies cutanées ouvertes
Lorsque vous utiliser ce produit	Garder hors de la portée des enfants et de la bouche. En cas de contact avec les yeux, rincer abondamment les yeux à l'eau.
Arrêtez l'utilisation et demandez à un médecin	En cas d'irritation ou d'éruption cutanée. Ceuux-ci peuvent être des signes d'une maladie plus grave.
Garder hors de la portée des enfants	En cas d'ingestion, consultez un médecin ou contactez immédiatement un centre antipoison.
Mode d'emploi	• Placez suffisamment de produit sur les mains pour couvrir toutes les surfaces. Frictionnez les mains jusqu'à ce qu'elles soient sèches. Surveillez les enfants de moins de 6 ans lors de l'utilisation de ce produit pour éviter qu'ils ne l'ingèrent.
Autres renseignements	• Conserver entre 15-30°C (59-86°F) • Evitez le gel et la chaleur excessive au-dessus de 40°C (104°F)
Ingrediénts inactifs	gommage de xanthane, glycerine, peroxyde d'hydrogène, eau DL, parfum.

PN: HS100
FDA REGISTERED
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DURAFAST HAND SANITIZER

alcohol hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76795-750
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.35 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.15 mL in 100 mL
WATER (UNII: 059QF0KOOR)	27.5 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76795-750-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:76795-750-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
3	NDC:76795-750-04	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
4	NDC:76795-750-05	475 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
5	NDC:76795-750-07	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
	NDC:76795-750-050	950 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

6	NDC:76795-750-06	950 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
7	NDC:76795-750-19	8550 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - PRINTJET CORP (158605449)

Registrant - SUE SOTELO (158605449)

Establishment

Name	Address	ID/FEI	Business Operations
PRINTJET CORP		158605449	manufacture(76795-750)

Revised: 8/2020

PRINTJET CORP