

HAND SANITIZER CRISTAL PRIME 100 LITERS- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 25000 LITERS- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 1000 LITERS- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 250ML- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 220 LITERS- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 60ML- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 500ML- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 1 LITER- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 5 LITERS- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 30ML- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 1 GALON- isopropyl alcohol gel
HAND SANITIZER CRISTAL PRIME 100ML- isopropyl alcohol gel
YELLOW USA 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.

CRISTAL PRIME HAND SANITIZER - GEL ALCOHOL 75%

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. 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 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)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP, Isopropanolamine, Carbomer Copolymer Type B

Package Label - Principal Display Panel

DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do no use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Manufactured by:KERALUX IND. E COM. DE COSMÉTICOS
CNPJ: 11.864.739/0001-68 Brazil
Exported by: KG INCORPORATING EMPREENDIMENTOS
CNPJ: 26.227.406/0001-03 Brazil
Technical responsible: Camila Maria de Campos Nunes
CRQ 04.264.172-IV
FDA Listed.

+1 209 690 7799 CUSTOMER SUPPORT USA

Cristal
PRIME

Ethyl Alcohol

**HAND 75%
Sanitizer**

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE
AT KILLING

99,99%

PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

500ml - 16,9 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

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When using this product do no use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

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Cristal
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Ethyl Alcohol

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30ml - 1,01 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do no use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE AT KILLING

99.99%

PERCENT OF ALL BACTERIA

BEFORE USING READ THE INSTRUCTIONS ON THE LABEL

250ml - 8,45 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C). May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do no use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



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PERCENT OF ALL BACTERIA

BEFORE USING READ THE INSTRUCTIONS ON THE LABEL

220 L - 7439 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C). May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

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WARNINGS

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



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AT KILLING

99,99%

PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

1000ml - 33,81 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isopropanolamine, Carbomer Copolymer Type B.

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ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



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AT KILLING

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PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

5 L - 169,07 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isopropanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



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DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

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Stop use and ask a doctor if irritation or rash appears and lasts.

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE
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99,99%

PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

25000 L - 845351 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isopropanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE
AT KILLING

99,99%

PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

60ml - 2,02 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isopropanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do no use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE AT KILLING

99.99%

PERCENT OF ALL BACTERIA

BEFORE USING READ THE INSTRUCTIONS ON THE LABEL

100ml - 3,38 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C). May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



0 79445 12910 2

DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do no use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

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Cristal
PRIME

Ethyl Alcohol

HAND 75% Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE AT KILLING

99.99%

PERCENT OF ALL BACTERIA

BEFORE USING READ THE INSTRUCTIONS ON THE LABEL

1000 L - 33814 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C). May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



0 79445 13791 6

DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Cristal
PRIME

Ethyl Alcohol

HAND 75%
Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE
AT KILLING

99,99%

PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

3,8L - 128,50 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



DRUG FACTS

ACTIVE INGREDIENT.....PURPOSE:
Ethyl Alcohol 75%.....Antimicrobial

USES

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

WARNINGS

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use it in or near the eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash appears and lasts.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Cristal
PRIME

Ethyl Alcohol

HAND 75%
Sanitizer

ANTISEPTIC GEL FOR HANDS

GEL



EFFECTIVE
AT KILLING

99,99%

PERCENT OF
ALL BACTERIA

BEFORE USING READ THE
INSTRUCTIONS ON THE LABEL

100 L - 3381 oz

DRUG FACTS (CONT.)

DIRECTIONS

Put enough product in your palm to cover hands and rub hands together briskly until dry. Children under 6 years of age should be supervised when using this product.

OTHER INFORMATION

Store below 110°F (43°C).
May discolor certain fabrics.

INACTIVE INGREDIENT

Glycerin, Hydrogen Peroxide, Purified Water USP, Isoproanolamine, Carbomer Copolymer Type B.

Flammable product. Keep away from heat, sparks and flames. Do not cut the bottle. Do not pour over the fire.



ATTENTION: Keep out of reach of children and pets.



HAND SANITIZER CRISTAL PRIME 100 LITERS

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-135
Route of Administration	EXTRACORPOREAL, 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: 059QF0KO0R)	28 L in 100 L
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 L in 100 L
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-135-81	100 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

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

HAND SANITIZER CRISTAL PRIME 25000 LITERS

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-138
Route of Administration	EXTRACORPOREAL, 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: 059QF0KO0R)	28 L in 100 L
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 L in 100 L
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-138-95	25000 L in 1 TANK; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

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

HAND SANITIZER CRISTAL PRIME 1000 LITERS

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-137
Route of Administration	EXTRACORPOREAL, 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: 059QF0KO0R)	28 L in 100 L
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 L in 100 L
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 L in 100 L

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:79445-137-91	1000 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	07/01/2020	
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Marketing Information

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

HAND SANITIZER CRISTAL PRIME 250ML

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-130
Route of Administration	TOPICAL, EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-130-25	250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

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

HAND SANITIZER CRISTAL PRIME 220 LITERS

isopropyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-136	
Route of Administration	EXTRACORPOREAL, 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)	28 L in 100 L			
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 L in 100 L			
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 L in 100 L			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-136-82	220 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	07/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

HAND SANITIZER CRISTAL PRIME 60ML			
isopropyl alcohol gel			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-128
Route of Administration	TOPICAL, EXTRACORPOREAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-128-06	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

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

HAND SANITIZER CRISTAL PRIME 500ML

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-131
Route of Administration	TOPICAL, EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
4	NDC:79445-131-	500 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	07/01/2020	

50	Product	07/01/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

HAND SANITIZER CRISTAL PRIME 1 LITER
isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-132
Route of Administration	TOPICAL, EXTRACORPOREAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-132-71	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

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

HAND SANITIZER CRISTAL PRIME 5 LITERS
isopropyl alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG		Item Code (Source)	NDC:79445-134
Route of Administration	EXTRACORPOREAL, TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)				28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)				0.35 mL in 100 mL
ISOPROPANOLAMINE (UNII: UE40BY1BZW)				0.27 mL in 100 mL
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-134-75	5000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	03/30/2020		

HAND SANITIZER CRISTAL PRIME 30ML				
isopropyl alcohol gel				
Product Information				
Product Type	HUMAN OTC DRUG		Item Code (Source)	NDC:79445-127
Route of Administration	TOPICAL, EXTRACORPOREAL			
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPNOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-127-03	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

Marketing Information

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

HAND SANITIZER CRISTAL PRIME 1 GALON

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-133
Route of Administration	EXTRACORPOREAL, TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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: 059QF0KO0R)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPNOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-133-	3800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination	07/01/2020	

73	Product	07/01/2020	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

HAND SANITIZER CRISTAL PRIME 100ML

isopropyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79445-129
Route of Administration	EXTRACORPOREAL, TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 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)	28 mL in 100 mL
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	0.35 mL in 100 mL
ISOPROPANOLAMINE (UNII: UE40BY1BZW)	0.27 mL in 100 mL

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79445-129-10	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2020	

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

Labeler - YELLOW USA CORP (008925051)

Registrant - KG INCORPORATING EMPREENDIMENTOS E SERVICOS EIRELI (945091407)

Establishment

Name	Address	ID/FEI	Business Operations
YELLOW USA CORP		008925051	repack(79445-127, 79445-128, 79445-129, 79445-130, 79445-131, 79445-132, 79445-133, 79445-134, 79445-135, 79445-136, 79445-137, 79445-138)

Establishment

Name	Address	ID/FEI	Business Operations
KERALUX INDUSTRIA E COMERCIO DE COSMETICOS LTDA		900345228	manufacture(79445-127, 79445-128, 79445-129, 79445-130, 79445-131, 79445-132, 79445-133, 79445-134, 79445-135, 79445-136, 79445-137, 79445-138)

Revised: 7/2020

YELLOW USA CORP