ULTRA DEFENSE SANI SMART VANILLA HAND SANITIZER- alcohol denat. gel
Gold Orient International Limited

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.

Ultra Defense Sani Smart Vanilla Hand Sanitizer

Active ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water it not available.

Warnings

For external use only. Flammable, keep away from fire and flames.

When using this product

Do not get into eyes.

If contact occurs, rinse eyes thoroughly with water.

Stop use and ask a doctor if

If irritation and redness develop.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Wet hands thoroughly with product and allow to dry without wiping.

Other information

Store at 68 to 77F (20-25C)

Do not store above 110F (43C)

You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

Inactive ingredients

Water,

Glycerin,

Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Fragrance,
Polysorbate 20,
Sodium Hydroxide,
Red 33,
Yellow 5

Label

SCENT:
VANILLA

HAND SANI GEL=
PANTONE 210 @50%

FIRST SPREAD

LEFT

MANUFACTURED FOR & DIST. BY
K7 DESIGN GROUP INC.
2433 KNAPP ST. BROOKLYN, NY 11235
EXPIRATION : 30/07/2022
LOT CODE : K7-G007020
MADE IN CHINA

8 10398 03658 7

Drug Facts

Active ingredient ***Purpose***

Alcohol Denat. 62%.....Antiseptic

PEEL

LEFT

Drug Facts (continued)

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For external use only

Flammable, keep away from fire and flames

When using this product

- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water

▼

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Stop use and ask a doctor if

- irritation and redness develop

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

Directions

- wet hands thoroughly with product and allow to dry without wiping

▼

SECOND SPREAD

LEFT

Drug Facts (continued)

Other information

- Store at 68° to 77°F (20°-25°C)
- Do not store above 110°F (43°C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

▼

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Yellow 5.

BACK STICKER/ FOLD UP BOOKLET

SCENT:
VANILLA

HAND SANI GEL=
PANTONE 210 @50%

FIRST SPREAD

SECOND SPREAD

MANUFACTURED FOR & DIST. BY
K7 DESIGN GROUP INC.
2433 KNAPP ST. BROOKLYN, NY 11235
EXPIRATION : 30/07/2022
LOT CODE : K7-G007020
MADE IN CHINA

8 10398 03658 7

Drug Facts

Active ingredient	Purpose
Alcohol Denat. 62%	Antiseptic

PEEL

LEFT

Drug Facts (continued)

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For external use only

Flammable, keep away from fire and flames

When using this product
- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Stop use and ask a doctor if
- irritation and redness develop

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

Directions
- wet hands thoroughly with product and allow to dry without wiping

LEFT

Drug Facts (continued)

Other information
- Store at 68° to 77°F (20°~25°C)
- Do not store above 110°F (43°C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Yellow 5.

BACK STICKER/ FOLD UP BOOKLET

SCENT:
VANILLA

HAND SANI GEL=
PANTONE 210 @50%

FIRST SPREAD

LEFT

MANUFACTURED FOR & DIST. BY
K7 DESIGN GROUP INC.
2433 KNAPP ST. BROOKLYN, NY 11235
EXPIRATION : 30/07/2022
LOT CODE : K7-G007020
MADE IN CHINA

8 10398 03658 7

Drug Facts

Active ingredient ***Purpose***

Alcohol Denat. 62%.....Antiseptic

PEEL

RIGHT

GLUE AREA

Drug Facts (continued)

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For external use only

Flammable, keep away from fire and flames

When using this product

- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water

▼

GLUE AREA

SECOND SPREAD

LEFT

Drug Facts (continued)

Other information

- Store at 68° to 77°F (20°~25°C)
- Do not store above 110°F (43°C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

▼

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Yellow 5.

BACK STICKER/ FOLD UP BOOKLET

SCENT:
VANILLA

HAND SANI GEL=
PANTONE 210 @50%

FIRST SPREAD

LEFT

MANUFACTURED FOR & DIST. BY
K7 DESIGN GROUP INC.
2433 KNAPP ST. BROOKLYN, NY 11235
EXPIRATION : 30/07/2022
LOT CODE : K7-G007020
MADE IN CHINA

8 10398 03658 7

Drug Facts

Active ingredient ***Purpose***

Alcohol Denat. 62%.....Antiseptic

PEEL

RIGHT

GLUE AREA

Drug Facts (continued)

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For external use only

Flammable, keep away from fire and flames

When using this product

- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water

▼

GLUE AREA

SECOND SPREAD

LEFT

GLUE AREA

Drug Facts (continued)

Stop use and ask a doctor if

- irritation and redness develop

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

Directions

- wet hands thoroughly with product and allow to dry without wiping

▼

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Other information

- Store at 68° to 77°F (20°~25°C)
- Do not store above 110°F (43°C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

▼

Drug Facts (continued)

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Yellow 5.

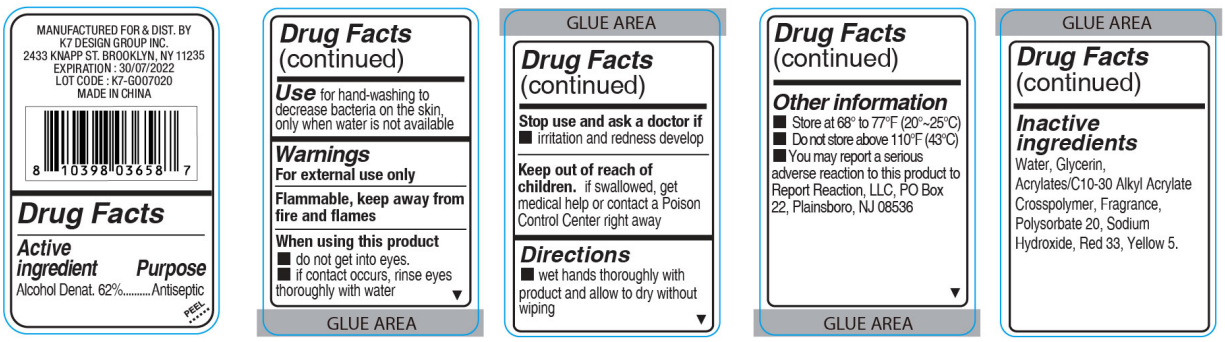
BACK STICKER/ FOLD UP BOOKLET

SCENT:
VANILLA

HAND SANI GEL=
PANTONE 210 @50%

FIRST SPREAD

SECOND SPREAD



BACK STICKER/ FOLD UP BOOKLET

SCENT:
VANILLA

HAND SANI GEL=
PANTONE 210 @50%

FIRST SPREAD

LEFT

MANUFACTURED FOR & DIST. BY
K7 DESIGN GROUP INC.
2433 KNAPP ST. BROOKLYN, NY 11235
EXPIRATION : 30/07/2022
LOT CODE : K7-G007020
MADE IN CHINA

8 10398 03658 7

Drug Facts

Active ingredient	Purpose
Alcohol Denat. 62%	Antiseptic

PEEL

LEFT

Drug Facts (continued)

Use for hand-washing to decrease bacteria on the skin, only when water is not available

Warnings

For external use only

Flammable, keep away from fire and flames

When using this product
- do not get into eyes.
- if contact occurs, rinse eyes thoroughly with water

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Stop use and ask a doctor if
- irritation and redness develop

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

Directions
- wet hands thoroughly with product and allow to dry without wiping

SECOND SPREAD

LEFT

Drug Facts (continued)

Other information
- Store at 68° to 77°F (20°~25°C)
- Do not store above 110°F (43°C)
- You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

GLUE AREA

RIGHT

GLUE AREA

Drug Facts (continued)

Inactive ingredients

Water, Glycerin, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Fragrance, Polysorbate 20, Sodium Hydroxide, Red 33, Yellow 5.

BACK STICKER/ FOLD UP BOOKLET

ULTRA DEFENSE SANI SMART VANILLA HAND SANITIZER

alcohol denat. gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51522-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51522-050-01	1 in 1 CASE	08/05/2020	
1		30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/05/2020	

Labeler - Gold Orient International Limited (679905914)

Establishment

Name	Address	ID/FEI	Business Operations
Gold Orient International Limited		679905914	manufacture(51522-050)

Revised: 8/2020 Gold Orient International Limited