ULTRA DEFENSE SANI SMART 3PK HAND SANITIZER- alcohol K7 Design Group 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.

Ultra Defense Sani Smart 3pk Hand Sanitizer

Drug Facts

Active ingredient

Alcohol 69% v/v

Purpose

Antiseptic

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

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

Inactive ingredients

Strawberry

Water, Glycerin, Propylene Glycol, Carbomer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Red 33.

Raspberry

Water, Glycerin, Propylene Glycol, Carbomer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Blue 1, Red 33.

Kiwi Berry

Water, Glycerin, Propylene Glycol, Carbomer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Blue 1, Yellow 5.

Company Information

MANUFACTURED FOR & DIST. BY K7 DESIGN GROUP LLC. NEW YORK, NY 10016 ORIGIN: CHINA

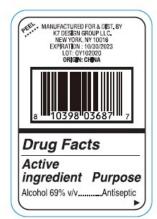
Product Packaging

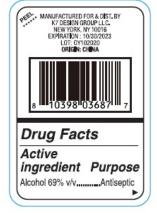












Drug Facts (continued)

Use for hand-washing to decrease bacteria or 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

Use for hand-washing

to decrease bacteria or

the skin, only when

For external use only

from fire and flames

Flammable, keep away

When using this product

do not get into eyes.
if contact occurs.

rinse eyes thoroughly

water is not available

Drug Facts

(continued)

Warnings

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Drug Facts (continued)

Stop use and ask a doctor

irritation and redness

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

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Directions

wet hands thoroughly with product and allow

Drug Facts (continued)

Inactive ingredients

Water, Glycerin, Propylene Glycol, Carbomer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Red 33.

to dry without wiping

Drug Facts (continued)

Stop use and ask a doctor

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

Drug Facts (continued)

Inactive

ingredients Water, Glycerin, Propylene Glycol, Carbomer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Blue 1, Red 33.

Drug Facts

with water

(continued)

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

Warnings

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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

Drug Facts (continued)

Stop use and ask a doctor

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

Drug Facts (continued)

Inactive ingredients

Yellow 5.

Water, Glycerin, Propylene Glycol, Carbomer, Aloe Barbadensis Leaf Extract, Aminomethyl Propanol, Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Blue 1,

ULTRA DEFENSE SANI SMART 3PK HAND SANITIZER

alcohol kit

Product Information

Product Type **HUMAN OTC DRUG** Item Code (Source) NDC:74177-851

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74177-851-01	1 in 1 KIT; Type 0: Not a Combination Product	10/13/2020	

Quan	uantity of Parts		
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BOTTLE, PLASTIC	59 mL	
Part 2	1 BOTTLE, PLASTIC	59 mL	
Part 3	1 BOTTLE, PLASTIC	59 mL	

Part 1 of 3

ULTRA DEFENSE SANI SMART KIWI BERRY HAND SANITIZER

alcohol gel

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	69 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Infor			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/13/2020	

Part 2 of 3

ULTRA DEFENSE SANI SMART STRAWBERRY HAND SANITIZER

alcohol gel

Product Information

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Active ingredient/Active violety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	69 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging					
1	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1		59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Inform	arketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	10/13/2020			

Part 3 of 3

ULTRA DEFENSE SANI SMART RASPBERRY HAND SANITIZER

alcohol gel

Product Information

Route of Administration TOPICAL

Active Ingredient/Active Moiety

ı	Ingredient Name	Basis of Strength	Strength
ı	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	69 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1		59 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	10/13/2020					

Marketing Information							
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not final	part333A	10/13/2020					

Labeler - K7 Design Group Inc. (080357784)

Revised: 10/2020 K7 Design Group Inc.