

TONKA TOUGH CITRUS 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.

Tonka Tough Citrus Hand Sanitizer Kit

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

Other information

- Store at 68F to 77F (20C - 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, Propylene Glycol, Carbomer, Aloe Barbadosensis Leaf Extract, Aminomethyl Propanol,

Fragrance, Tocopheryl Acetate, Denatonium Benzoate, Red 33, Blue 1.

Company Information

MANUFACTURED FOR & DIST. BY K7 DESIGN GROUP LLC

2433 KNAPP ST. BROOKLYN, NY 11235

Product Packaging



TONKA TOUGH CITRUS HAND SANITIZER

alcohol kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74177-963
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74177-963-01	1 in 1 KIT; Type 0: Not a Combination Product	12/11/2020	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PLASTIC	89 mL
Part 2	1 BOTTLE, PLASTIC	89 mL
Part 3	1 TUBE	3.4 g

Part 1 of 3

TOUGH CITRUS SCENT HAND SOAP

other personal cleanliness products soap

Product Information

Route of Administration TOPICAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
INGR	FD&C RED NO. 40 (UNII: WZB9127XOA)	
INGR	METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
INGR	SODIUM COCOYL GLYCINATE (UNII: XLU9KH03XM)	
INGR	EDETATE DISODIUM (UNII: 7FLD91C86K)	
INGR	COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
INGR	SODIUM CHLORIDE (UNII: 451W47IQ8X)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		89 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
Cosmetic			

Part 2 of 3

TOUGH CITRUS SCENT 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)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		89 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	12/11/2020	

Part 3 of 3

TOUGH CITRUS LIP BALM

lipstick lipstick

Product Information

Route of Administration	TOPICAL
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Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	ETHYLHEXYL PALMITATE (UNII: 2865993309)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
INGR	PHENOXYETHANOL (UNII: HIE492ZZ3T)	
INGR	POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
INGR	SQUALANE (UNII: GW89575KF9)	
INGR	CERESIN (UNII: Q1LS2UJO3A)	
INGR	YELLOW WAX (UNII: 2ZA36H0S2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		3.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/11/2020	

Labeler - K7 Design Group Inc. (080357784)

Revised: 12/2020

K7 Design Group Inc.