

OWN BEAUTY - HAND SANITIZER- ethyl alcohol gel

Own Beauty LLC

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.

OWN BEAUTY - HAND SANITIZER GEL (62% ETHYL ALCOHOL), 78265-5014

ACTIVE INGREDIENT

ETHANOL 62%

PURPOSE

ANTISEPTIC

USES

FOR HAND WASHING TO DECREASE BACTERIA ON SKIN.

WARNINGS

FOR EXTERNAL USE ONLY.

FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

DO NOT USE IN EYES. IF CONTACT OCCURS, FLUSH THOROUGHLY WITH WATER. STOP USE AND ASK A DOCTOR IF REDNESS AND IRRITATION DEVELOP AND PERSISTS FOR MORE THAN 72 HOURS.

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 AIR DRY.

OTHER INFORMATION

STORE AT ROOM TEMPERATURE. MAY DISCOLOR CERTAIN FABRICS.

INACTIVE INGREDIENTS

CITRUS + SAGE: PURIFIED WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, TOCOPHERYL ACETATE, COCONUT OIL, CITRUS MEDICA (LEMON) PEEL OIL, ALOE VERA, FRAGRANCE, TRIETHYL CITRATE, CITRUS LIMON (LEMON) PEEL EXTRACT, CITRUS AURANTIFOLIA (LIME) PEEL EXTRACT, CITRUS AURANTIUM DULCIS (ORANGE)

PEEL EXTRACT, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT, VANILLA PLANIFOLIA (VANILLA) FRUIT EXTRACT, CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT

GREEN TEA + CUCUMBER: AQUA/WATER, GLYCERIN, CARBOMER, TRIETHANOLAMINE, TOCOPHERYL ACETATE, COCOS NUCIFERA (COCONUT) OIL, ALOE BARBADENSIS (ALOE) LEAF JUICE, TRIETHYL CITRATE, CITRUS MEDICA (LEMON) PEEL OIL, CAMELIA SINENSIS (GREEN TEA) LEAF EXTRACT, CUCUMIS SATIVUS (CUCUMBER) FRUIT EXTRACT, SANTALUM ALBUM (SANDALWOOD) WOOD EXTRACT, CITRUS AURANTIUM BERGAMIA (BERGAMOT) FRUIT EXTRACT, LAVANDULA ANGUSTIFOLIA (LAVENDER) FLOWER/LEAF/STEM EXTRACT, PYRUS MALUS (APPLE) FRUIT EXTRACT, ELLETERIA CARDAMOMUM (CARDAMOM) SEED EXTRACT, RUBUS IDEAUS (RASPBERRY) FRUIT EXTRACT, ROSA CENTIFOLIA (ROSE) EXTRACT, CUCUMIS MELO (MELON) FRUIT EXTRACT, CAMELIA SINENSIS (BLACK TEA) LEAF EXTRACT, ROSMARINUS OFFICINALIS (ROSEMARY) LEAF EXTRACT, SALVIA OFFICINALIS (SAGE) LEAF EXTRACT

formulation.
Our hand sanitizer gel is 99.9% effective against most common germs. Coconut Oil helps moisturize hands, while Citrus and Lemon essential oils refresh

Active Ingredient	Purpose
Ethanol 62%	Antiseptic

Use ■ for hand washing to decrease bacteria on skin

Warnings For External Use Only
Flammable, keep away from fire or flame.
Do not use in eyes. If contact occurs, flush thoroughly with water. Stop use and ask a doctor if redness and irritation develop and persists for more than 72 hours.
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 air dry.

Other information Store at room temperature. May discolor certain fabrics.

Inactive Ingredients Purified water, Glycerin, Carbomer, Triethanolamine, Tocopherol Acetate, Coconut Oil, Citrus Medica Limonum (Lemon) Peel Oil, Aloe Vera, Fragrance, Triethyl Citrate, Citrus Limon (Lemon) Peel Extract, Citrus Aurantifolia (Lime) Peel Extract, Citrus Aurantium Dulcis (Orange) Peel Extract, Salvia Officinalis (Sage) Leaf Extract, Vanilla Planifolia (Vanilla) Fruit Extract, Cucumis Sativus (Cucumber) Fruit Extract

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MADE FROM 50% POST CONSUMER RECYCLED (PCR) PLASTIC. BEFORE RECYCLING, SEPARATE CAP FROM BOTTLE

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OWN BEAUTY - HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78265-5014
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
SANDALWOOD (UNII: 3641YW25N2)	

BERGAMOT ORANGE (UNII: IET5D90X0D)
CUCUMIS MELO WHOLE (UNII: RDC232W0M5)
ROSEMARY (UNII: IJ67X351P9)
ROSA CENTIFOLIA FLOWER (UNII: CS4TE8FF7O)
WATER (UNII: 059QF0K00R)
GLYCERIN (UNII: PDC6A3C0OX)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
TROLAMINE (UNII: 9O3K93S3TK)
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
COCONUT OIL (UNII: Q9L0O73W7L)
LEMON OIL (UNII: I9GRO824LL)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)
LEMON PEEL (UNII: 72O054U628)
ORANGE PEEL (UNII: TI9T76XD44)
SAGE (UNII: 065C5D077J)
VANILLA (UNII: Q74T35078H)
CUCUMBER (UNII: YY7C30VXJT)
APPLE JUICE (UNII: 9871T0PD5P)
CARDAMOM (UNII: 8BC4CUT4JL)
RASPBERRY (UNII: 4N14V5R27W)
GREEN TEA LEAF (UNII: W2ZU1RY8B0)
LAVANDULA ANGUSTIFOLIA WHOLE (UNII: 51217XIL5L)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78265-5014-5	200 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	
2	NDC:78265-5014-2	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	
3	NDC:78265-5014-1	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/04/2020	

Labeler - Own Beauty LLC (052489743)