

**CLEANWELL NATURAL ORANGE VANILLA HAND SANITIZER- cleanwell natural orange vanilla hand sanitizer spray**

**CleanWell, 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.*

-----

**CleanWell Natural Orange Vanilla Hand Sanitizer**

**Active Ingredient:**

Thymus Vulgaris Oil (Thymol 0.05%)

**Purpose**

Sanitizer

**Use:**

To sanitize hands

**Warning:**

☐ **For external use only**

Instruct children on proper use.

Stop use and ask a doctor if skin becomes irritated.

**Directions:**

Spray until hands are wet and rub thoroughly until dry.

**Inactive Ingredients:**

Aloe Barbadensis (Aloe) Leaf Juice\*, Citric Acid, Citrus Aurantium Dulcis (Orange) Oil, Copper PCA\*, Hydrolyzed Oats\*, Origanum Vulgare (Oregano) Oil, Sodium Citrate, Sodium Coco Sulfate, Sodium Decylglucosides Hydroxypropyl Sulfonate, Vanilla Planifolia (Vanilla) Fruit Extract, Water



## CLEANWELL NATURAL ORANGE VANILLA HAND SANITIZER

cleanwell natural orange vanilla hand sanitizer spray

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:28 107-008
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
THYMOL (UNII: 3J50XA376E) (THYMOL - UNII:3J50XA376E)	THYMOL	0.0005 kg in 1 kg

### Inactive Ingredients

Ingredient Name	Strength
THYME OIL (UNII: 2UK410MY6B)	0.0003 kg in 1 kg
OREGANO LEAF OIL (UNII: 7D0CGR40U1)	0.0001 kg in 1 kg
ORANGE OIL (UNII: AKN3KSD11B)	0.0019 kg in 1 kg
DECANAL (UNII: 31Z90Q7KQJ)	0.00015 kg in 1 kg
VANILLA PLANIFOLIA OIL (UNII: 0A3F415158)	0.002 kg in 1 kg
SODIUM DECYLGLUCOSIDES HYDROXYPROPYLSULFONATE (UNII: 55P9UXJ9C3)	0.0016 kg in 1 kg
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	0.0032 kg in 1 kg
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.00046 kg in 1 kg
SODIUM CITRATE (UNII: 1Q73Q2JULR)	0.0007 kg in 1 kg
COPPER (UNII: 789U1901C5)	0.0008 kg in 1 kg
AMINO ACIDS, OAT (UNII: NU3FAK86IP)	0.001 kg in 1 kg
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.0025 kg in 1 kg

<b>WATER</b> (UNII: 059QF0K00R)	0.98525 kg in 1 kg
---------------------------------	--------------------

--	--

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28107-008-02	0.03 kg in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	11/01/2007	

--	--	--	--	--

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	11/01/2007	

--	--	--	--

**Labeler** - CleanWell, LLC (079787350)

**Registrant** - CleanWell, LLC (079787350)

**Establishment**

Name	Address	ID/FEI	Business Operations
Precise Packaging LLC		079904428	manufacture(28107-008)

Revised: 4/2018

CleanWell, LLC