# CLEANWELL NATURAL ORANGE VANILLA HAND SANITIZING WIPES- cleanwell natural orange vanilla hand sanitizing wipes cloth 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.

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#### CleanWell Natural Orange Vanilla Hand Sanitizing Wipes

#### **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:**

Apply thoroughly to hands and face as desired. Close lid between uses to retain moisture. Do not flush wipes. **To Dispense:** Lift tab at front of lid to open. Pull up corner of center sheet adn thread through dispenser slit in lid. Pull out exposed wipe at 45 angle and snap off. The next wipe is ready for dispensing.

#### **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 Planifolla (Vanilla) Fruit Extract, Water



### CLEANWELL NATURAL ORANGE VANILLA HAND SANITIZING WIPES

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Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:28107-007	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Basis of Strength	Strength		
THYMOL	0.0005 kg in 1 kg		
	3		

Inactive Ingredients		
Ingredient Name	Strength	
THYME OIL (UNII: 2UK410 MY6 B)	0.0003 kg in 1 kg	
OREGANO LEAF OIL (UNII: 7D0 CGR40 U1)	0.0001 kg in 1 kg	
ORANGE OIL (UNII: AKN3KSD11B)	0.001 kg in 1 kg	
VANILLA PLANIFOLIA OIL (UNII: 0 A3F415158)	0.002 kg in 1 kg	
SODIUM DECYLGLUCO SIDES HYDRO XYPRO PYLSULFO NATE (UNII: 55P9 UXJ9 C3)	0.0016 kg in 1 kg	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	0.0032 kg in 1 kg	
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	0.00046 kg in 1 kg	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	0.0007 kg in 1 kg	

<b>COPPER</b> (UNII: 789 U19 0 1C5)	0.00008 kg in 1 kg
AMINO ACIDS, OAT (UNII: NU3FAK86IP)	0.001 kg in 1 kg
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.0025 kg in 1 kg
WATER (UNII: 059QF0KO0R)	0.98656 kg in 1 kg

	Packaging			
# Item Code Pac		Package Description	Marketing Start Date	Marketing End Date
	1 NDC:28107-007-	0.16952 kg in 1 CANISTER; Type 0: Not a Combination Product	06/15/2010	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	06/15/2010	

## Labeler - CleanWell, LLC (079787350)

## Registrant - CleanWell, LLC (079787350)

Establishment			
Name	Address	ID/FEI	Business Operations
Tufco LP		079862872	manufacture(28107-007)

Revised: 4/2018 CleanWell, LLC