

CLEANWELL NATURAL ORIGINAL HAND SANITIZER WIPES- cleanwell natural original hand sanitizer 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.

CleanWell Natural Original Hand Sanitizing Wipes

Active Ingredient:

Thymus Vulgaris Oil (Thymol 0.05%)

Purpose

Sanitizer

Use:

To sanitize hands.

For external use only

Instruct children on proper use.

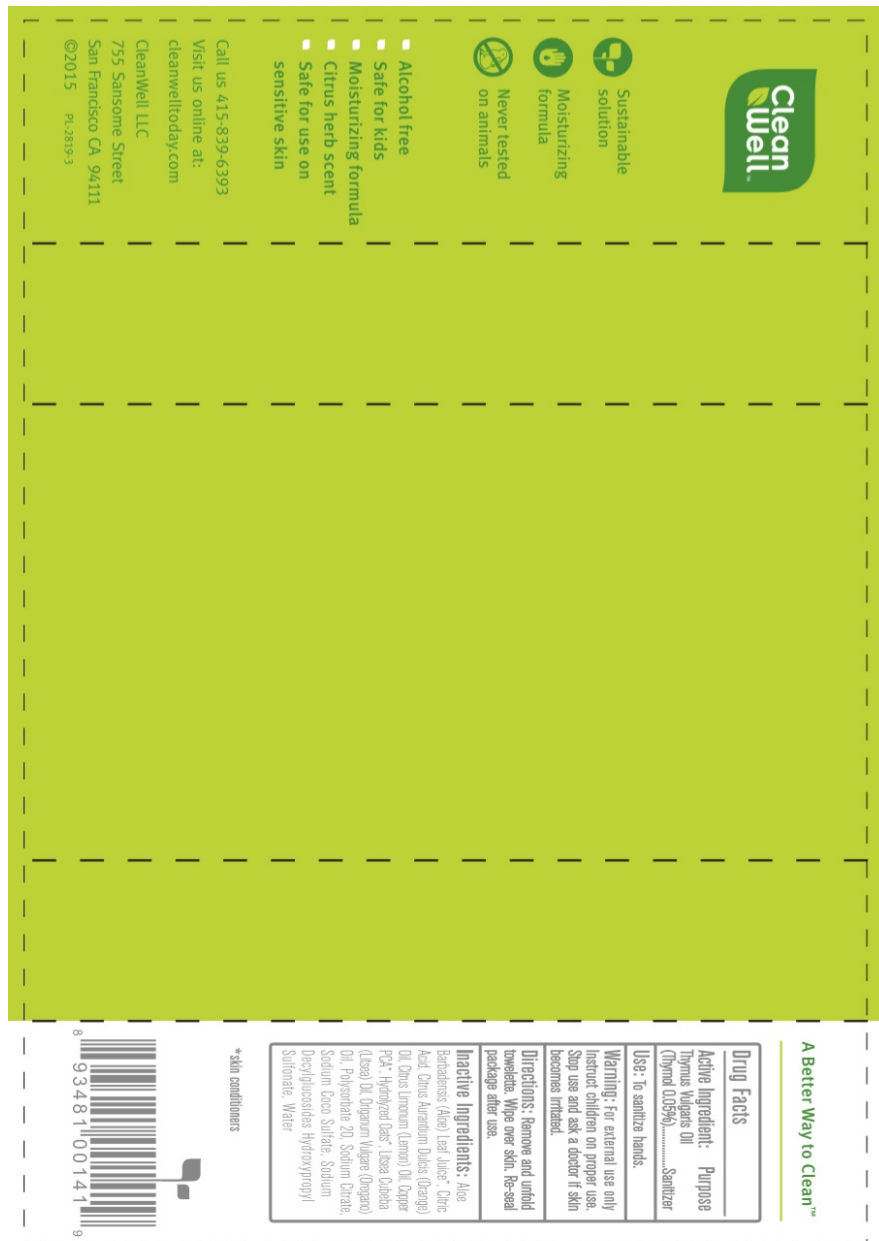
Stop use and ask a doctor if skin becomes irritated

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 and 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 Barbadosis (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 ORIGINAL HAND SANITIZER WIPES

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:28107-002
Route of Administration	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
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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)	0.0005 kg in 1 kg
NERAL (UNII: 8M466BQL1X)	0.0018 kg in 1 kg
LEMON OIL (UNII: I9GRO824LL)	0.00075 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)	0.00008 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
WATER (UNII: 059QF0KO0R)	0.98651 kg in 1 kg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28107-002-09	0.16952 kg in 1 CANISTER; Type 0: Not a Combination Product	06/15/2010	
2	NDC:28107-002-08	0.04328 kg in 1 POUCH; 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(28107-002)