

## **CLEAR DEFENSE HARVEST APPLE- ethyl alcohol gel**

**Melaleuca 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.*

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### **Clear Defense Harvest Apple**

#### **Active ingredient**

Ethyl alcohol 62%

#### **Purpose**

Antimicrobial

#### **Uses**

- for handwashing to reduce bacteria on the skin
- recommended for repeated use

#### **Warnings: For external use only**

**Do not use** in or near eyes. In case of contact, rinse eyes thoroughly with water.

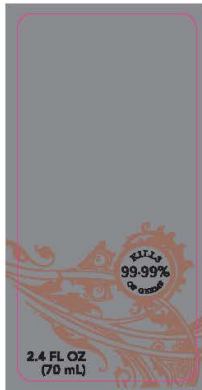
**Stop use and ask a doctor if** irritation or rash appears and lasts

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

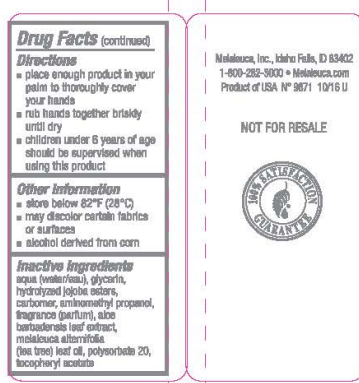
**Directions** ■ place enough product in your palm to thoroughly cover your hands ■ rub hands together briskly until dry ■ children under 6 years of age should be supervised when using this product

**Other information** ■ store below 82°F (28°C) ■ may discolor certain fabrics or surfaces ■ alcohol derived from corn

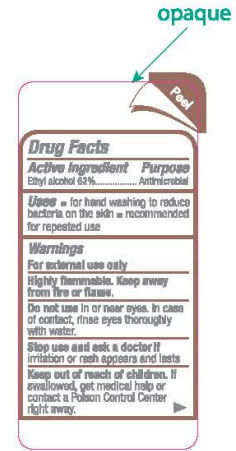
**Inactive ingredients** water, glycerin, xylitol, anhydroxylitol, xylitylglucoside, carbomer, aminomethyl propanol, fragrance, aloe barbadensis leaf extract, melaleuca alternifolia leaf oil, polysorbate 20, tocopheryl acetate, jojoba esters, butyrospermum parkii, theobroma cacao seed butter, mangifera indica seed butter, blue 1 lake, titanium dioxide, yellow 5 lake



Visible through bottle



under peel







back panel

**Melaleuca** The Wellness Company Artwork Information

1. File name and Revision Date:	Clear Def Brandied Apple 20z.ai
2. Part Number:	502039871
3. Color: Process, PMS (up to 8):	Black, 7623 C, 424 C,
4. Label size:	1.09 x 2.23
5. Format:	Adobe Illustrator CC 2015
6. Artwork contact. Name & Phone #:	208.522.0700
7. Last revised date:	16 June 2016

			
Black	7623 C	424 C	dieline

transparent



2.4 oz front label

Melaleuca The Wellness Company Artwork Information

1. File name and Revision Date:	Clear Def Brandied Apple 2oz.ai
2. Part Number:	502029871
3. Color: Process, PMS (up to 8):	Black, 4795 C, 7623 C
4. Label size:	(see dieline)
5. Format:	Adobe Illustrator CC 2015
6. Artwork contact. Name & Phone #:	Kimberly Anderson 208.522.0700
7. Last revised date:	30 June 2016



CLEAR DEFENSE HARVEST APPLE

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-273
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	36.58 g in 59 mL
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### Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
ANHYDROXYLITOL (UNII: 8XWR7NN42F)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
COCOA BUTTER (UNII: 512OYT1CRR)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
MANGIFERA INDICA SEED BUTTER (UNII: 4OXD9M35X2)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
SHEA BUTTER (UNII: K49155WL9Y)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TEA TREE OIL (UNII: VIF565UC2G)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
XYLITYLGLUCOSIDE (UNII: O0IEZ166FB)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-273-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/01/2016	

**Labeler** - Melaleuca Inc (139760102)

**Registrant** - Melaleuca Inc (139760102)

### Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca Inc		079711683	manufacture(54473-273)