

ACNE WASH- salicylic acid liquid
Harmon Stores 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.

FACE VALUES OIL-FREE PINK GRAPEFRUIT FACIAL & BODY ACNE WASH

☐Active Ingredients

Salicylic Acid 2.0%

Purpose

Acne Treatment

Uses

for the treatment of acne.

Warnings

☐For external use only

☐When using this product • skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs only use one topical acne medication at a time. • avoid contact with eyes. If contact occurs, flush thoroughly with water.

☐Keep out of reach of children. ☐If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

- cover the entire affected area with a thin layer and rinse thoroughly one to three times daily
- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day

Other information

- may stain some fabrics

Inactive Ingredients

water, sodium C14-16 olefin sulfonate, cocamidopropyl betaine, sodium chloride, linoleamidopropyl PG-dimonium chloride phosphate, polysorbate 20, anthemis nobilis flower extract, citrus grandis (grapefruit) fruit extract, aloe barbadensis leaf juice, chamomilla recutita (matricaria) flower extract, C12-15 alkyl lactate, cocamidopropyl PG-dimonium chloride phosphate, polyquaternium-7, ascorbyl palmitate, propylene glycol, sodium benzotriazolyl butylphenol sulfonate, PEG-120 methyl glucose dioleate, PEG-80 sorbitan laurate, disodium EDTA, benzalkonium chloride, fragrance, red 40, Ext. Violet 2

FACE VALUES OIL-FREE PINK GRAPEFRUIT FACIAL & BODY ACNE WASH

9.1 FL OZ (269mL)

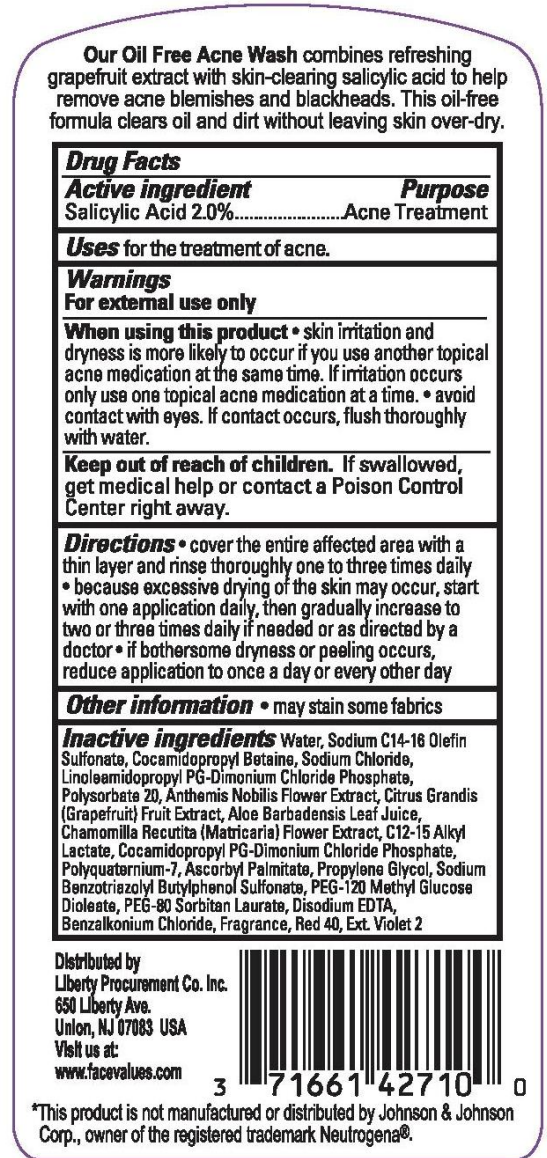
Front Clear Label

 Clear Area

Back White Label



Front
Colors: K / Yellow / White

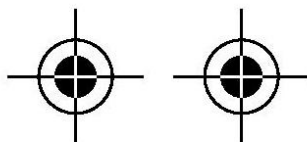


Back
Colors: K

FACE VALUES OIL-FREE PINK GRAPEFRUIT FACIAL & BODY ACNE WASH

2 FL OZ (59mL)

NDC 63940-053-61



ACNE WASH			
salicylic acid liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-053
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	20 mg in 1 mL	
Inactive Ingredients			
Ingredient Name	Strength		
WATER (UNII: 059QF0K00R)			
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)			
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)			
SODIUM CHLORIDE (UNII: 451W47IQ8X)			
LINOLEAMIDO PROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: 5Q87K461JO)			
POLYSORBATE 20 (UNII: 7T1F30V5YH)			
CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG)			
PUMMELO (UNII: ET1TN5W71X)			
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
CHAMOMILE (UNII: FGL3685T2X)			
C12-15 ALKYL LACTATE (UNII: GC844VRD7E)			
COCAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: H2KVQ74JM4)			
POLYQUATERNIUM-7 (70/30 ACRYLAMIDE/DADMAC; 1600 KD) (UNII: 0L414VCS5Y)			

ASCORBYL PALMITATE (UNII: QN83US2B0N)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOTRIAZOLYL BUTYLPHENOL SULFONATE (UNII: 0LA2QC9O3Z)	
PEG-120 METHYL GLUCOSE DIOLATE (UNII: YM0K64F20V)	
PEG-80 SORBITAN LAURATE (UNII: 239B50Y732)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
EXT. D&C VIOLET NO. 2 (UNII: G5UX3K0728)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63940-053-54	269 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/05/2016	
2	NDC:63940-053-61	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part358H	02/05/2016	

Labeler - Harmon Stores Inc. (804085293)

Registrant - Fruit of the Earth, Inc. (079559467)

Establishment

Name	Address	ID/FEI	Business Operations
Fruit of the Earth, Inc.		008193513	manufacture(63940-053)