

I DEW CARE TEA TREE O STARTERKIT- salicylic acid
Memebox Corporation

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.

82904-304 I DEW CARE TEA TREE-O STARTER KIT

Active Ingredient

Salicylic Acid 1.5%

Purpose

Acne Treatment

Use

For the treatment of acne

Warnings

For external use only

Warnings

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.

Warnings

Stop use and ask a doctor if skin irritation occurs or gets worse.

Warnings

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

Directions

- Pump 1~2 times and massage on wet face in circular motions. ■ Rinse thoroughly with clean water.
- Use daily. AM & PM. ■ If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Inactive Ingredients

Water, Dipropylene Glycol, Glycerin, Disodium Cocoamphodiacetate, Methylpropanediol, Lauryl Hydroxysultaine, Sodium Chloride, Sodium Cocoyl Alaninate, Coco-Betaine, Tromethamine, Acrylates Copolymer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Citric Acid, Hexylene Glycol, Laminaria Japonica Extract, Eclipta Prostrata Leaf Extract, 1,2-Hexanediol, Fructooligosaccharides, Butylene Glycol, Beta-Glucan, Hydrogenated Lecithin, Melaleuca Alternifolia (Tea Tree) Extract, Hydrolyzed Hyaluronic Acid, Propanediol, Citrus Unshiu Peel Extract

Label



I DEW CARE TEA TREE O STARTERKIT

salicylic acid kit

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:82904-304

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82904-304-01	1 in 1 KIT; Type 0: Not a Combination Product	09/27/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE, PUMP	50 mL in 100
Part 2	1 BOTTLE	11 mL in 100
Part 3	1 POUCH	24 mL in 100

Part 1 of 3

I DEW CARE CLEAN ZIT AWAY ACNE FOAMING CLEANSER

salicylic acid liquid

Product Information

Item Code (Source)	NDC:82904-303
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
LAMINARIA JAPONICA (UNII: WE98HW412B)	
DISODIUM COCOAMPHODIACETATE (UNII: 18L9G3U51M)	
TROMETHAMINE (UNII: 023C2WHX2V)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
HEXYLENE GLYCOL (UNII: KEH0A3F75J)	
COCO-BETAINE (UNII: 03DH2IZ3FY)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	
METHYLPROPANEDIOL (UNII: N8F53B3R4R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BETA VULGARIS ROOT FRUCTOOLIGOSACCHARIDES (UNII: N2UDM48ZD6)	
LAURYL HYDROXYSULTAINE (UNII: 176KKP31OZ)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

PROPANEDIOL (UNII: 5965N8W85T)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
ECLIPTA PROSTRATA LEAF (UNII: H86R96580E)	
TANGERINE PEEL (UNII: JU3D414057)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82904-303-02	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	09/27/2022	

Part 2 of 3

I DEW CARE ROLL WITH TEA TREE ROLL ON FACE OIL

tea tree oil oil

Product Information

Item Code (Source)	NDC:82904-305
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TEA TREE OIL (UNII: VIF565UC2G) (TEA TREE OIL - UNII: VIF565UC2G)	TEA TREE OIL	4 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
OLIVE OIL (UNII: 6UYK2W1W1E)	
APPLE SEED OIL (UNII: 9ACA4K9013)	
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
CAMELLIA JAPONICA SEED OIL (UNII: U37N0S910T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82904-305-01	11 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/27/2022	

Part 3 of 3

I DEW CARE HERES THE TEA TREE

tee tree oil patch

Product Information

Item Code (Source)	NDC:82904-306
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K) (MELALEUCA ALTERNIFOLIA LEAF - UNII:G43C57162K)	MELALEUCA ALTERNIFOLIA LEAF	0.25 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
COCOA (UNII: D9108TZ9KG)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
MONARDA DIDYMA LEAF (UNII: JY15982UBB)	
APPLE (UNII: B423VGH5S9)	
WINE GRAPE (UNII: 3GOV20705G)	
PAPAYA (UNII: KU94FIY6JB)	
PRUNUS MUME FRUIT (UNII: 639190I8CU)	
TEA TREE OIL (UNII: VIF565UC2G)	
4-TERPINEOL, (+/-)- (UNII: L65MV77ZG6)	
LIMOSILACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP)	
FRAGRANCE 13576 (UNII: 5EM498GW35)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
MENTHA SUAVEOLENS LEAF (UNII: 1341ZC68MK)	
MATRICARIA RECUTITA LEAF (UNII: 6I9LN466F0)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)
BETAINE (UNII: 3SCV180C9W)
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CENTELLA ASIATICA TRITERPENOIDS (UNII: 4YS74Q4G4J)
DIPROPYLENE GLYCOL (UNII: E107L85C40)
WATER (UNII: 059QF0KO0R)
GLYCERIN (UNII: PDC6A3C0OX)
1,2-HEXANEDIOL (UNII: TR046Y3K1G)
TREHALOSE (UNII: B8WCK70T7I)
POLYGLYCERYL-10 LAURATE (UNII: MPJ2Q8W8G)
GLYCERYL CAPRYLATE (UNII: TM2TZD4G4A)
ARGININE (UNII: 94ZLA3W45F)
GLYCERYL ACRYLATE/ACRYLIC ACID COPOLYMER (300000 CP AT 2%) (UNII: MEA9KH24QG)
PAEONIA SUFFRUTICOSA ROOT (UNII: 7M7E9A2C8J)
HYALURONATE SODIUM (UNII: YSE9PPT4TH)
CHAMOMILE (UNII: FGL3685T2X)
COPOVIDONE K25-31 (UNII: D9C330MD8B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82904-306-01	24 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/27/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	09/27/2022	

Labeler - Memebox Corporation (067317179)

Registrant - Memebox Corporation (067317179)

Establishment

Name	Address	ID/FEI	Business Operations
KOLMAR KOREA CO., LTD.		689512611	manufacture(82904-304)

