

AIRE-MASTER ANTIBACTERIAL LIQUID HANDSOAP- triclosan liquid

Aire-Master of America, 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.

Active Ingredient

Active Ingredient

Triclosan .3%

Purpose

Purpose

Antiseptic

Indications

Indications:

Handwash to help reduce bacteria that potentially can cause disease.

Directions

Directions: Wet hands, apply liberal amount of product and rub hands together for 30 seconds. Rinse thoroughly.

Warnings

Warnings:

-FOR EXTERNAL USE ONLY

-Keep away from eyes. In case of eye contact, flush thoroughly with water and then seek medical advice.

-If swallowed, drink large amounts of water and seek medical attention.

-Avoid contact with face and broken skin. If contact occurs, flush with water.

-If irritation develops, discontinue use. If condition persists, consult a doctor.

Keep out of reach of children.

Note: Keep from freezing.

Other Ingredients

Other Ingredients:

Water, Sodium Lauryl Sulfate, Cocamide DEA, Cocamidopropyl Betaine, Glycerin, DMDM Hydantoin, Fragrance, Aloe Barbadensis Leaf Juice, Sodium Chloride, Citric Acid.

Questions or Comments

Questions or Comments? 888-667-6066

Drug Facts	
Active Ingredient	Purpose
Triclosan .3%.....	Antiseptic
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• If swallowed, drink large amounts of water and seek medical attention.	
• Avoid contact with face and broken skin. If contact occurs, flush with water.	
• If irritation develops, discontinue use. If condition persists, consult a physician.	
• Keep out of the reach of children.	
Note: Keep from freezing.	
Other Ingredients: Water, Sodium Lauryl Sulfate, Cocamide DEA, Cocamidopropyl Betaine, Glycerin, DMDM Hydantoin, Fragrance, Aloe Barbadensis Leaf Juice, Sodium Chloride, Citric Acid.	
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Aire-Master of America
PO Box 2310 • Nixa, MO 65714

AIRE-MASTER ANTIBACTERIAL LIQUID HANDSOAP

triclosan liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65133-180
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	0.3 g in 10 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65133-180-14	4 in 1 CASE	01/01/2016	
1	NDC:65133-180-01	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:65133-180-28	708 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2016	
3	NDC:65133-180-15	24 in 1 CASE	01/01/2016	
3	NDC:65133-180-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

4	NDC:65133-180-03	208198 mL in 1 DRUM; Type 0: Not a Combination Product	01/01/2016	
5	NDC:65133-180-16	24 in 1 CASE	01/01/2016	
5	NDC:65133-180-04	251 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:65133-180-17	6 in 1 CASE	01/01/2016	
6	NDC:65133-180-04	251 mL in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:65133-180-18	24 in 1 CASE	01/01/2016	
7	NDC:65133-180-05	251 mL in 1 CONTAINER; Type 0: Not a Combination Product		
8	NDC:65133-180-19	8 in 1 CASE	01/01/2016	
8	NDC:65133-180-06	1000 mL in 1 POUCH; Type 0: Not a Combination Product		
9	NDC:65133-180-20	24 in 1 CASE	01/01/2016	
9	NDC:65133-180-07	59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:65133-180-21	180 in 1 CASE	01/01/2016	
10	NDC:65133-180-07	59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:65133-180-22	4 in 1 CASE	01/01/2016	
11	NDC:65133-180-08	1893 mL in 1 BOTTLE; Type 0: Not a Combination Product		
12	NDC:65133-180-23	48 in 1 CASE	01/01/2016	
12	NDC:65133-180-09	81 mL in 1 BOTTLE; Type 0: Not a Combination Product		
13	NDC:65133-180-10	946353 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2016	
14	NDC:65133-180-24	12 in 1 CASE	01/01/2016	
14	NDC:65133-180-11	63974 mL in 1 BOTTLE; Type 0: Not a Combination Product		
15	NDC:65133-180-25	12 in 1 CASE	01/01/2016	
15	NDC:65133-180-11	63974 mL in 1 BOTTLE; Type 0: Not a Combination Product		
16	NDC:65133-180-26	6 in 1 CASE	01/01/2016	
16	NDC:65133-180-11	63974 mL in 1 BOTTLE; Type 0: Not a Combination Product		
17	NDC:65133-180-27	100 in 1 CASE	01/01/2016	
17	NDC:65133-180-12	37 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
OTC monograph not final	part333E	01/01/2016	

Labeler - Aire-Master of America, Inc. (057897381)

Establishment

Name	Address	ID/FEI	Business Operations
Aire-Master of America, Inc.		057897381	manufacture(65133-180)

Revised: 1/2020

Aire-Master of America, Inc.