

XTRACARE ANTIBACTERIAL HAND CLEANSE ORIGINAL- triclosan soap
Rejoice International, 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.

XtraCare Antibacterial Hand Cleanse

Active Ingredient	Purpose
Triclosan 0.15%.....	Antibacterial

Antibacterial moisturizing Hand Soap

Original

Kills the Germs

Elimiates bacteria on hands

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

☐**Uses**

for hand washing to decrease bacteria on the skin.

☐**Warnings**

for external use only

When using this product☐ avoid contact with eyes. In case of eye contact, flush with water.

☐**Stop use and ask a doctor**☐ if irritation and redness develops.

☐**Directions**

- pump into hands
- lather vigorously for at least 15 seconds
- rinse and dry thoroughly.

☐**Inactive Ingredients**

water, sodium c14-16 olefin sulfonate, sodium laureth sulfate, cocamide DEA, sodium chloride, PEG-150 distearate, fragrance, citric acid, glycerin, disodium EDTA, aloe barbadensis leaf juice, methylchloroisothiazolinone, methylisothiazolinone, fd&c yellow no. 5, d&c red no. 33.

☐**Other information**

- store at room temperature

DISTRIBUTED BY:

REJOICE INTERNATIONAL, INC.

48325 BINGHAMPTON DR., NORTHVILLE, MI 48168, USA

MADE IN CHINA

Drug Facts

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XTRACARE ANTIBACTERIAL HAND CLEANSE ORIGINAL

triclosan soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57337-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRICLOSAN (UNII: 4NM5039Y5X) (TRICLOSAN - UNII:4NM5039Y5X)	TRICLOSAN	6.6 in 443 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CO CO DIETHANOLAMIDE (UNII: 92005F972D)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

METHYLCHLORO ISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57337-022-01	443 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/03/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/03/2013	

Labeler - Rejoice International, Inc. (078741245)

Establishment

Name	Address	ID/FEI	Business Operations
China Ningbo Shangge Cosmetic Technology Corp.		529287434	manufacture(57337-022)

Revised: 9/2019

Rejoice International, Inc.