SAN E 2 HAND WASH 6265- benzalkonium chloride soap
The Roxxon 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.

SAN E 2 Hand Wash 6265 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Benzalkonium Chloride 2.5%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & Usage Section

for hand-washing to decrease bacteria on the skin

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

if swallowed, get medical help or contact a Poison Control Center right away

Drug Facts Box OTC-Dosage & Administration Section

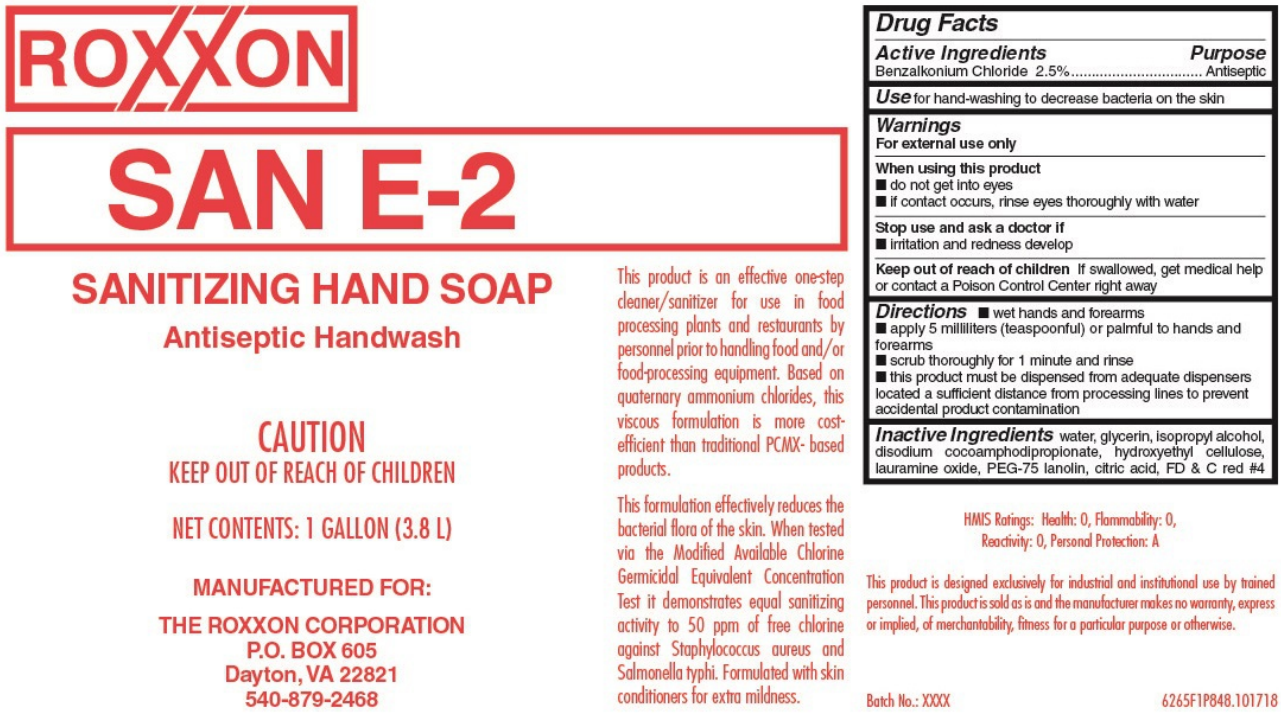
- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

Drug Facts Box OTC-Inactive Ingredient Section

ater, glycerin, isopropyl alcohol, disodium cocoamphodiproprionate, hydroxyethylcellulose, lauramine oxide,

PEG-75 lanolin, citric acid, FD and C red no.4

SAN E 2 Hand Wash 6265 Drug Facts and Label



SAN E 2 Hand Wash 6265 Label

SAN E 2 HAND WASH 6265

benzalkonium chloride soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62467-265
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	25.0 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)	
DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62467-265-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/17/2018	
2	NDC:62467-265-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	10/17/2018	
3	NDC:62467-265-13	800 mL in 1 BAG; Type 0: Not a Combination Product	10/17/2018	
4	NDC:62467-265-08	1 in 1 BOX	10/17/2018	
4		1000 mL in 1 BAG; 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	10/17/2018	

Labeler - The Roxxon Corporation (113133094)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(62467-265)

Revised: 7/2019 The Roxxon Corporation