

GERM A STAT- chloroxylenol soap
Warsaw Chemical Holdings, LLC

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.

Germ A Stat 6544 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 0.3%

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

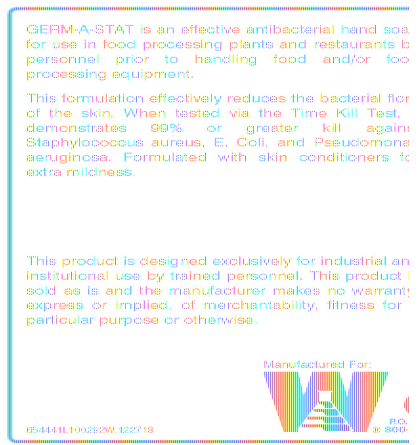
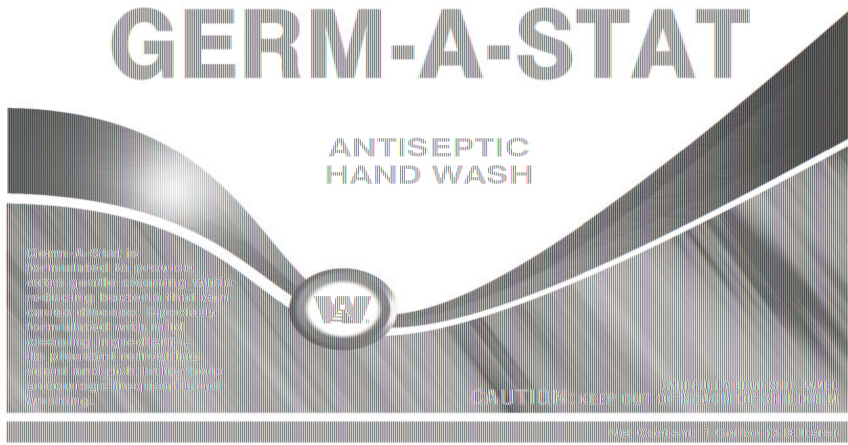
Drug Facts Box OTC-Dosage & Administration Section

- 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

water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, sodium chloride, citric acid, DMDM hydantoin, fragrance, FD and C yellow no.5, food red 10

Germ A Stat 6544 Antiseptic Hand Wash



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GERM A STAT				
chloroxylenol soap				
Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72379-544	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3 mg in 1 mL	
Inactive Ingredients				
	Ingredient Name	Strength		
	WATER (UNII: 059QF0K00R)			
	PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
	SODIUM LAURETH SULFATE (UNII: BPV390UAP0)			
	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
	DECYL GLUCOSIDE (UNII: Z17H97EA6Y)			
	SODIUM CHLORIDE (UNII: 451W47IQ8X)			
	DMDM HYDANTOIN (UNII: BYR0546TOW)			
	COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)			
	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72379-544-14	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	06/21/2018	
2	NDC:72379-544-10	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	06/21/2018	

3	NDC:72379-544-12	1000 mL in 1 BAG; Type 0: Not a Combination Product	06/21/2018	
4	NDC:72379-544-13	800 mL in 1 BAG; Type 0: Not a Combination Product	06/21/2018	
5	NDC:72379-544-27	800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	06/21/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/21/2018	

Labeler - Warsaw Chemical Holdings, LLC (081244708)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(72379-544)

Revised: 12/2018

Warsaw Chemical Holdings, LLC