

FRESH START- chloroxylenol soap
Pro Chem, 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.

Fresh Start 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

Fresh Start 800 mL box



CAUTION: KEEP OUT OF REACH OF CHILDREN
 Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
 (If you do not understand this label, find someone to explain it to you in detail.)

This product is an effective antibacterial hand soap for use in food processing plants and restaurants by personnel prior to handling food and/or food processing equipment.

This formulation effectively reduces the bacterial flora of the skin. When tested via the Time Kill Test, it demonstrates 99% or greater kill against Staphylococcus aureus, E. Coli, and Pseudomonas aeruginosa. Formulated with skin conditioners for extra mildness.

This product is designed exclusively for industrial and institutional use by trained personnel. This product is sold as is and the manufacturer makes no warranty, express or implied, of merchantability, fitness for a particular purpose or otherwise.

Drug Facts	
Active Ingredient	Purpose
Chloroxylenol 0.3%	Antiseptic
Uses for hand-washing to decrease bacteria on the skin	
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> ■ do not get into eyes ■ if contact occurs, rinse eyes thoroughly with water 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> ■ irritation and redness develop 	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions ■ wet hands and forearms	
<ul style="list-style-type: none"> ■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms ■ scrub thoroughly for 1 minute and rinse 	
Inactive Ingredients water, decyl glucoside, sodium laureth sulfate, cocoamide MIPA, propylene glycol, DMDM hydantoin, sodium chloride, citric acid, fragrance, FD&C yellow no. 5, food red 10	

SOLD BY: PRO CHEM, INC.

1475 BLUEGRASS LAKES PARKWAY, ALPHARETTA, GA 30004

NET CONTENTS: 800 ML 27 FL OZ

6544M4P984.122718

Fresh Start 800 mL box

FRESH START

chloroxylenol soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63830-950
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: 059QF0KO0R)	
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)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63830-950-06	1 in 1 BOX	04/20/2022	
1		800 mL in 1 BAG; Type 0: Not a Combination Product		



Fresh Start

Antibacterial Hand Soap
Antiseptic Hand Soap



CAUTION: KEEP OUT OF REACH OF CHILDREN

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand this label, find someone to explain it to you in detail.)

This product is an effective antibacterial hand soap for use in food processing plants and restaurants by personnel prior to handling food and/or food processing equipment.

This formulation effectively reduces the bacterial flora of the skin. When tested via the Time Kill Test, it demonstrates 99% or greater kill against *Staphylococcus aureus*, *E. Coli*, and *Pseudomonas aeruginosa*. Formulated with skin conditioners for extra mildness.

This product is designed exclusively for industrial and institutional use by trained personnel. This product is sold as is and the manufacturer makes no warranty, express or implied, of merchantability, fitness for a particular purpose or otherwise.

Drug Facts

Active Ingredient

Chloroxylenol 0.3%

Purpose

Antiseptic

Uses for hand-washing to decrease bacteria on the skin

Warnings

For external use only

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation and redness develop

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

Directions ■ wet hands and forearms

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

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

SOLD BY: PRO CHEM, INC.

1475 BLUEGRASS LAKES PARKWAY, ALPHARETTA, GA 30004

NET CONTENTS: 800 ML 27 FL OZ

6544M4P984.122718

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2022	

Labeler - Pro Chem, Inc. (061396065)

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

Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(63830-950)

Revised: 4/2022

Pro Chem, Inc.