

**LX0380 LYNX GLACIER FRESH ANTISEPTIC HAND AND BODY WASH 6380-chloroxylenol soap
ABC Compounding Co., 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.

LX0380 Lynx glacier fresh Antiseptic Hand & Body Wash 6380 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, DMDM hydantoin, fragrance, methylchloroisothiazolinone, methylisothiazolinone, aloe barbadensis, acid red 1

LX0380 Lynx glacier fresh Antiseptic Hand & Body Wash 6380

LX0380 *Lynx*
glacier fresh
antiseptic hand & body wash

NET CONTENTS: 1000 ML 33.8 FL OZ

Aloe Vera!

An effective antibacterial hand soap for use in food service facilities, hotels, athletic facilities, correctional facilities, business/office buildings, dressing rooms, factories, institutional facilities, locker rooms, nurseries, shower and bath areas, public facilities, public restrooms, schools, daycare centers, and campgrounds. Formulated with skin conditioners for extra mildness.

| Drug Facts | |
|--|----------------|
| Active Ingredient | Purpose |
| Chloroxylenol 0.3%..... | Antiseptic |
| Use 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, cocamide MIPA, propylene glycol, DMDM hydantoin, fragrance, methylchloroisothiazolinone, methylisothiazolinone, aloe barbadensis, acid red 1, acid blue 25 | |

Mfd by: ABC Compounding Co., Inc.
P.O. Box 16247, Atlanta, GA 30321
6380P6LL-LX0380.113022

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NET CONTENTS: 1000 ML 33.8 FL OZ

LX0380 *Lynx* glacier fresh antiseptic hand & body wash



An effective antibacterial hand soap for use in food service facilities, hotels, athletic facilities, correctional facilities, business/office buildings, dressing rooms, factories, institutional facilities, locker rooms, nurseries, shower and bath areas, public facilities, public restrooms, schools, daycare centers, and campgrounds. Formulated with skin conditioners for extra mildness.

Drug Facts

| Active Ingredient | Purpose |
|-------------------------|------------|
| Chloroxylenol 0.3%..... | Antiseptic |

Use 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, cocamide MIPA, propylene glycol, DMDM hydantoin, fragrance, methylchlorisothiazolinone, methylisothiazolinone, aloe barbadensis, acid red 1, acid blue 25

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LX0380 LYNX GLACIER FRESH ANTISEPTIC HAND AND BODY WASH 6380

chloroxylenol soap

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62257-380 |
| 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 |
|---|----------|
| ACID BLUE 25 (UNII: S2E15W6FSN) | |
| METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN) | |
| METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ACID RED 1 (UNII: 3365R6427R) | |
| WATER (UNII: 059QF0K00R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| DECYL GLUCOSIDE (UNII: Z17H97EA6Y) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62257-380-12 | 1000 mL in 1 BAG; Type 0: Not a Combination Product | 12/12/2022 | |
| 2 | NDC:62257-380-17 | 532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 06/07/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 12/12/2022 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| ABC Compounding Co., Inc. | | 003284353 | manufacture(62257-380) |

Revised: 6/2023

ABC Compounding Co., Inc.