



Nobac® L

Anti-Bacterial
Hand Lotion

Overview

Nobac® L Anti-Bacterial Hand Lotion is based on the active ingredient **Nobac Benzalkonium Chloride** in a unique non-greasy, moisturizing and conditioning formulation. Featuring **Macat BD** (behenamidopropyl dimethylamine) for viscosity building with cetearyl alcohol with extra-conditioning, **Masurf LL** (lauryl laurate) for non-greasy smooth skin feel, and **Enhansys M-110** for moisturization and preservative-free formulating.

Benzalkonium Chloride, which is listed in the Antiseptic monograph as Category III for safety and efficacy. This category allows Benzalkonium chloride based products to be marketed in use patterns that fall within the monograph as long as the formulations conform to the percentage ranges in the monograph, which is 0.1-0.13% for Benzalkonium chloride. As in the case of Ethanol based Instant Hand Sanitizers, Benzalkonium chloride based products qualify for monograph "grandfathering" with a demonstrated use pattern established for a material time and extent prior to December, 1975.

Typical Properties

Physical form.....	White, opaque lotion
Viscosity @20°C, Brookfield LV2	8-10,000cps
Benzalkonium chloride, active %.....	0.13
pH	4.5-5.5
Specific Gravity @20°C	0.91±0.02
Flash point (PMCC)	>200°F(>93°C)

Handling Information

Note - Manufacturing, Packaging and Marketing of this product may be subject to regulation by the Food and Drug Administration and may be subject to Enforcement Action. Contact Mason Chemical Company for details.

Refer to and follow the guidelines in the Material Safety Data Sheet (MSDS) available from Mason Chemical Company for information on the safe use, handling and disposal of this product.

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Anti-Bacterial Hand Lotion

Nobac® L Anti-Bacterial Hand Lotion is a formulation that features Mason Personal Care ingredients for unique non-greasy, conditioning and moisturizing properties that leave the skin with a soft, refreshing and silky afterfeel.

Formula and Mixing Instructions from Nobac® L

Ingredient:	Wt. %
Water	to 100.0
Nobac Benzalkonium Chloride, 50%	0.26
Macat BD	3.00
Cetearyl Alcohol	6.00
Petrolatum	4.00
Masurf LL	3.00
Glycerin	2.50
Enhansys M-110	1.50
Dimethicone	0.10
Lactic Acid, 88%	0.60
Viscosity @20°C, Brookfield LV2-8-10,000cps; pH 4.5-5.5	

Procedure:

Charge ingredients Water-Dimethicone. Heat to 80-85°C, mixing until homogeneous. Add Lactic Acid, Cool to ambient temperature, QC and package.

INCI Names:

Macat BD: Behenamidopropyl Dimethylamine

Masurf LL: Lauryl Laurate

Enhansys M-110: Glycereth-2 Cocoate and Benzoic Acid and C4-18 Perfluoroalkylethyl Thiohydroxypropyltrimonium Chloride

Labeling guidance for Nobac® L

Drug Facts	
Active ingredient	Purpose
Benzalkonium Chloride 0.13%	Antimicrobial
Uses _ For hand sanitizing to decrease bacteria on the skin Recommended for repeated use	
Warnings	
For external use only	
When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.	
Stop use and ask a doctor if irritation or redness develops, or if condition persists for more than 72 hours.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions _ Dispense a small amount of lotion into palm of hand _ Rub thoroughly over all surfaces of both hands	
Inactive ingredients Water, Cetearyl Alcohol, Petrolatum, Behenamidopropyl Dimethylamine Lactate, Lauryl Laurate, Glycerin, Glycereth-2 Cocoate, Dimethicone, Benzoic Acid, C4-18 Perfluoroalkylethyl Thiohydroxypropyl-trimonium Chloride.	

When marketing Nobac L as an OTC Antiseptic, FDA Drug Facts Labeling and OTC Drug Manufacturing guidelines must be followed. The Drug Facts label illustrated here for Nobac L, is an example of appropriate labeling for this use pattern.

Refer to FDA "Draft Guidance for Industry Labeling OTC Human Drug Products" at <http://www.fda.gov/cder/guidance/5008dft.htm> for detailed information on Drug Facts labeling. Refer to (59 FR 31402) 21 CFR Parts 333 and 369 Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule, FDA-[Docket No. 75N-183H], RIN 0905-AA06 for specific use pattern guidelines and requirements.

In general, any claim that suggests that a product affects the structure or function of the body is a drug claim. Depending on the claim it may fall within an OTC monograph or may require an NDA. NDA claims, which are outside the scope of Nobac include: antiviral, antifungal, residual antimicrobial protection, or helps heal skin or helps heal irritation.

Contact Mason Chemical Company for more details on labeling, manufacturing and regulatory information.