



Nobac® E

Instant Foam Hand Sanitizer

Featuring Masurf® AF patent pending alcohol foamer

Overview

Nobac® E Instant Foam Hand Sanitizer is a 62% Ethyl Alcohol based hand sanitizer formulation that delivers a thick, stable foam.

Nobac® E Instant Foam Hand Sanitizer is a formulation that features Masurf AF-115DE, a Patent-Pending ingredient optimized for foaming aqueous polar organic solvents. Nobac® E illustrates the unique properties that can be achieved with Masurf AF-series ingredients. In this example, Nobac E represents an easy to process product that is non-greasy, conditioning and moisturizing, that leaves the skin with a soft refreshing afterfeel, delivered in a pleasing foam.

Typical Properties

Physical form..... Clear, light amber solution
pH 6.5-8.5
Specific Gravity @20°C 0.89±0.02

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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Formula and Mixing Instructions from Nobac® E

Ingredient:	Wt. %
Water	to 100.0
Ethyl Alcohol.....	62.0
Masurf AF-115DE	5.00
Masurf G-2C	0.10
Dye, Fragrance.....	q.s.

Procedure:

Charge ingredients, mix until homogeneous. QC and package.

INCI Names:

Masurf AF-115DE: DEA-C8-18

Perfluoroalkylethyl Phosphate

Masurf G-2C: Glycereth-2 Cocoate

Labeling guidance for Nobac® E

Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol 62%	Antimicrobial
Uses _ For hand sanitizing to decrease bacteria on the skin that could cause disease. _ Recommended for repeated use	
Warnings	
Flammable. Keep away from fire or flame.	
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 _ Place enough product in your palm to thoroughly cover your hands _ Rub hands together briskly until dry _ Children under 6 years of age should be supervised when using this product	
Other information _ Store below 110°F (43°C) _ May discolor certain fabrics or surfaces	
Inactive ingredients Water, DEA-C8-18 Perfluoroalkylethyl Phosphate, Glycereth-2 Cocoate	

When marketing Nobac E 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.