



SURELEASE[®]
AQUEOUS ETHYLCELLULOSE DISPERSION

Product Information

Formula No: E-7-19040

Surelease[®] is a complete, optimally plasticized aqueous dispersion designed specifically for modified release and taste masking applications. Using ethylcellulose as the rate controlling polymer, Surelease brings technological advances with dependable, reproducible extended release profiles that are consistent from laboratory to pilot and production scale processes.

Key Characteristics

- Aqueous dispersion
- Complete, optimally formulated system
- Easy to use and environmentally friendly
- Consistent and reproducible drug release profiles
- Regulatory acceptance in the United States, Europe and a number of other regions. Currently there is no precedence of use in Japan.

Applications

- **Bead & Particle Coating:**
Surelease is used primarily as a barrier membrane for developing extended release dosage forms. Drug release can be effectively controlled by applying Surelease coating onto bead and particulate substrates. Fluid-bed coating is the most commonly used technique for coating of small particles.
- **Matrix Granulation:**
Surelease can be used as a binder in wet granulation applications for production of free flowing granules, which can subsequently be compressed into tablets to achieve an extended drug release profile.
- **Taste Mask Coating:**
Ethylcellulose, the rate controlling polymer in Surelease is water insoluble and provides highly effective taste masking properties for unpalatable actives.

General Manufacturing Process Description

Ethylcellulose is blended with Oleic Acid and Medium Chain Triglycerides, then extruded and melted. The molten plasticized ethylcellulose is then directly emulsified in ammoniated water in a high shear mixing device under pressure. Ammonium Oleate is formed in situ to stabilize and form the dispersion of plasticized ethylcellulose particles. Additional Purified Water is then added to achieve the final solids content. (Reference: U.S Patents 4,123,403 and 4,502,888).

Stability

Surelease provides dependable modified release dissolution performance throughout its shelf life period.

Some degradation of the Medium Chain Triglycerides and Oleic Acid occurs during the manufacturing process. This degradation results in the formation of low levels of glycerin, various fatty acids and their corresponding fatty acid amides. The levels of these degradants increase throughout the shelf life period.

Independent toxicology experts have qualified the degradants and concluded that they “do not pose any toxicological hazard and are unlikely to cause adverse health consequences.”

Packaging

Surelease is supplied as 25% w/w dispersion in tightly sealed polyethylene containers. Surelease is available in multiples of 18.0kg weights.

Shelf Life

Surelease has a shelf life of 18 months from date of manufacture when properly stored.

Recommended Storage Conditions

Store in tightly sealed containers. Avoid exposure to high humidity and temperatures above 30°C (86°F).

Keep from Freezing

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<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Nishiyama, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
<i>Europe</i>			Goa, India	91-832-288-3434	91-832-288-3440
Dartford, Kent, England	44-1322-293000	44-1322-627200	Seoul, Korea	82-2-2057-2713	82-2-2057-2179
Bougival, France	33-1-3082-1582	33-1-3082-7879	<i>Latin America</i>		
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Buenos Aires, Argentina	54-911-4552-1565	54-911-4552-3997
Gallarate, Italy	39-0331-776932	39-0331-776831	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Budapest, Hungary	36-1-200-8000	36-1-200-8010	Bogota, Colombia	571-418-1202	571-418-1257
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792	Santa Fe, Mexico	525-5-3000-5700	525-5-3000-5701
Istanbul, Turkey	90-216-465-0360	90-216-465-0361	Caracas, Venezuela	58-212-442-4819	58-212-442-8724

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