



SURELEASE[®]
AQUEOUS ETHYLCELLULOSE DISPERSION

Product Information

Formula No: E-7-19020

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 certain other regions.

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 Dibutyl Sebacate, 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 Dibutyl Sebacate and Oleic Acid occurs during the manufacturing process. The extent of this degradation and identification/qualification of the specific degradants is currently under investigation.

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

World Headquarters

Colorcon

415 Moyer Blvd., P.O. Box 24, West Point, PA 19486-0024

Tel: 215-699-7733 Fax: 215-661-2605 Website: www.colorcon.com e-mail: info@colorcon.com

Locations*United States*

Locations	Telephone	Facsimile
Santa Ana, California	714-549-0631	714-549-4921
Indianapolis Indiana	317-545-6211	317-545-6218
Humacao, Puerto Rico	787-852-3815	787-852-0030

Europe

Dartford, Kent, England	44-1322-293000	44-1322-627200
Bougival, France	33-1-3082-1582	33-1-3082-7879
Idstein, Germany	49-6126-9961-0	49-6126-9961-11
Gallarate, Italy	39-0331-776932	39-0331-776831
Budapest, Hungary	36-1-200-8000	36-1-200-8010
Istanbul, Turkey	90-216-465-0360	90-216-465-0361
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792

Locations*Asia/Pacific*

Singapore	65-6438-0318	65-6438-0178
Fuji-gun, Shizuoka, Japan	81-5-4465-2711	81-5-4465-2730
Shanghai, China	86-21-5442-2222	86-21-5442-2229
Goa, India	91-832-288-3434	91-832-288-3440
Seoul, Korea	82-2-2057-2713	82-2-2057-2179

Latin America

Buenos Aires, Argentina	54-11-4552-1565	54-11-45523997
Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Bogota, Colombia	571-418-1202	571-418-1257
Caracas, Venezuela	58-212-442-4819	58-212-442-8724
Santa Fe, Mexico	52-55-3000-5700	52-55-3000-5701/02

The information contained herein, to the best of our knowledge is true and accurate. Any recommendations or suggestions are made without warranty or guarantee, since the conditions of use are beyond our control. Any information contained herein is intended as a recommendation for use of our products so as not to infringe on any patent.

© Colorcon, 2006. The information contained in this document is proprietary to Colorcon and may not be used or disseminated inappropriately.

Surelease® is a registered trademark of BPSI Holdings Inc.

mr/surelease/prod_info_19020/05.2006-Rev 4

First Published: 12.2000. Revised 05.2006