

## Easy cleaning of hot melt extrusion? Why not!

A purge compound for hot melt extrusion terminates difficulties to clean the extruder after processing.

## Product Information

### HME Cleaner Plus (GMP)

More than half of New Chemical Entities (NCEs), which were developed recently, tend to show high crystallinity and poor solubility in water. Solid dispersion is a technique to improve the solubility and bioavailability of these NCEs. Hot-melt extrusion (HME) is one of the main methods to prepare solid dispersions.

Enteric Polymers (e.g. ACOAT®, EUDRAGIT®, Kollicoat® etc.), which are widely used as an enteric coating agent, are useful carriers for solid dispersions and applicable for HME. However, these polymers are insoluble in water and users often have difficulties cleaning their extruder after processing.

**HME Cleaner Plus (GMP)** is an almost water-soluble purge compound with a micro-cleansing effect which solves this cleaning difficulty for the HME process. **HME Cleaner Plus (GMP)** provides effective clean-up because of its high detergency and low residual properties.

Shin-Etsu developed the HME Cleaner in 2012 as technical material. Based on Shin-Etsu's formulation, **BIOGRUND** now offers this cleaner, produced in accordance with IPEC GMP guidelines and meeting all requirements of USP/ NF, Ph.Eur. and JP. All ingredients have been used as pharmaceutical excipients including water-soluble cellulose ethers.

### How to use HME Cleaner Plus (GMP)

After your actual extrusion of solid dispersion, set your extruder (mixing zones) at more than 160°C (depending on scale size). **HME Cleaner Plus (GMP)** may adhere to the barrels when it is below 160°C. In cases of extrusion at higher temperature (200°C), keep the temperature for the first extrusion with HME Cleaner Plus (GMP) until substitution is completed. Then adjust the temperature (170°C) for additional cleaning extrusion. **HME Cleaner Plus (GMP)** starts to decompose over 200°C.

Before cleaning process:



After cleaning process:



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## General Information on BIOGRUND

Since 1999, **BIOGRUND** has been developing and producing special powder preparations for film coating, sugar-coating, colouring and tableting, which are used in pharmaceutical products, food and nutritional supplements and cosmetics all over the world. These one-step products minimize and simplify working times for all applications. **BIOGRUND** is EXCiPACT™ certified and international standards for quality and environmental management (ISO 9001 & 14001) are implemented as well as a HACCP.

### Contact us

**BIOGRUND** GmbH  
Neukirchner Str. 5  
65510 Huenstetten  
Germany

T +49 (0) 6126-952 63-0  
F +49 (0) 6126-952 63-33

**BIOGRUND** US, Inc.  
23465 Rock Haven Way  
Unit 125  
Sterling, VA 20166  
USA

T +1 (703) 665-2147  
F +1 (703) 665-2148

**BIOGRUND** International AG  
Beim Bahnhof 5  
6312 Steinhausen  
Switzerland

T +41 (0) 41-747 14-50  
F +41 (0) 41-747 14-55

www.biogrund.com  
info@biogrund.com