

# Bormed™ solutions for healthcare applications

Bormed™ SB815MO ampoules made by BREVETTI ANGELA



Keep Discovering

 **BOREALIS**

بروج  
**Borouge**



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# The Bormed™ Concept

With over 35 years of experience in the healthcare industry, Borealis Bormed™ is founded on the principles of service, commitment and conformance – Because we care.

## Service

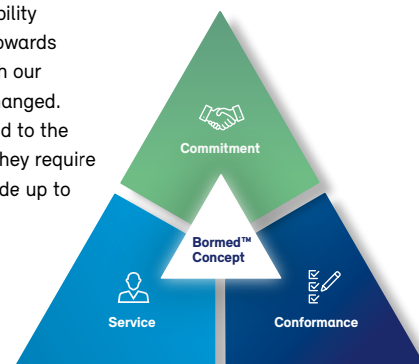
Get specialised project support from start to finish, including one-to-one expert consultation and unrivalled access to data that goes beyond product data sheet. By providing global support and thorough market understanding, we help you answer any challenge.

## Commitment

Address your sustainability challenges and work towards long term success, with our grades remaining unchanged. While we are committed to the grades as they are, if they require changing, we will provide up to five years' availability.

## Conformance

Conform and adapt to current and future regulatory requirements around the world with Bormed. This safeguards your investment and enables significant cost savings over a project's lifetime, offering you independent pharmacopeia and ISO10993 analysis reports, and extractable testing data.



## The Bormed Concept delivers

- Consistency of product recipe via rigorous change control procedure
- Bormed Directive: Operating instructions for the development, production, storage and delivery to the end customer of Bormed
- Continuity of supply to mitigate the risk of a change during your product life cycle: In case of change, product made available up to 5 years (2 years pre-notification and a last call volume combined with 3-year shelf life)
- Pharmacopeia compliance: Regular external testing of Ph. Eur., USP and ISO 10993 – analysis reports can be shared upon request; US DMF listing; following VDI 2017 guideline on “Medical Grade Plastics”
- Externally tested extractable profiles that can be shared upon request (under NDA) and can support your E&L testing programme
- Specific technical support given during the project development phase
- Moldflow data and other rheological characteristics
- Globally active dedicated team of experienced technical and regulatory specialists
- Bormed InCompounds: For tailor-made, customised solutions by partnering with trusted and recognised healthcare compounders (at present Avient, MELITEK, MOCOM and Wittenburg Group)

# The Bornewables™ line of Bormed™ & Borcycle™ C

## Embrace circularity

Meet your sustainability targets with ISCC Plus-certified polyolefins produced from renewable or chemically recycled feedstocks. The Bornewables™ and Borcycle™ C offer the same material performance and regulatory compliance as virgin Bormed™ medical grades.



### The Bornewables

The Bornewables offer circular Bormed polyolefins with a reduced carbon footprint and are produced with renewable feedstock derived entirely from waste and residue streams.



### Borcycle C

Borcycle C is the chemically recycled line of Bormed and renews plastic back to plastic, giving polyolefin-based, post-consumer waste another life.

# High Density Polyethylene

Bormed™ Grade	MFR 190°C/2.16 kg [g/10 min] ISO 1133	Density [kg/m³] ISO 1183	Flexural Modulus [MPa] ISO 178	Melting Point [°C] DSC	Special Features	BFS/EBM	IBM/ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
HE2581-PH	0.3	958	1,400	131		●	●	●		✓	✓	027656	✓
HE7541-PH	4	954	1,250	129				●		✓	✓	027654	✓
HE9621-PH	12	964	1,300	133				●		✓	✓	029149	✓

# Low Density Polyethylene

Bormed™ Grade	MFR 190°C/2.16 kg [g/10 min] ISO 1133	Density [kg/m³] ISO 1183	Flexural Modulus [MPa] ISO 178	Melting Point [°C] DSC	Special Features	BFS/EBM	IBM/ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
LE6607-PH	0.3	927	270	115	No additives	●			●	✓	✓	008124 027108	*
LE6609-PH	0.3	930	300	117	No additives	●	●		●	✓	✓	017927 028752	*
LE6600-PH	1.5	919	170	110	No additives	●	●		●	✓	✓	027587	*

## Key:

EBM: Extrusion blow moulding

BFS: Blow-fill-seal

IBM: Injection blow moulding

ISBM: Injection stretch blow moulding

IM: Injection moulding

EP: European pharmacopeia

USP: United States pharmacopeia

- Main application
- Secondary application
- ✓ Grade has been tested. For detailed information please refer to medical compliance statement on [www.borealisgroup.com](http://www.borealisgroup.com)
- \* For more information, please refer to the respective medical statement at [www.borealisgroup.com](http://www.borealisgroup.com)

All figures are typical values - data should not be used for specification work

# Plastomers

Bormed™ Grade	MFR 190°C/ 2.16 kg [g/10 min] ISO 1133	Density [kg/m3] ISO 1183	Flexural Modulus [MPa] ISO 178	Melting Point [°C] DSC	Special Features	BFS/ EBM	IBM/ ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
PL8830-PH	1.1	883	23	73					●	*	✓	033070	✓

**Key:**

EP: European pharmacopeia

USP: United States pharmacopeia

- Main application
- Secondary application
- ✓ Grade has been tested. For detailed information please refer to medical compliance statement on [www.borealisgroup.com](http://www.borealisgroup.com)
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# Polypropylene Homopolymer

Bormed™ Grade	MFR 230°C/2.16 kg [g/10 min] ISO 1133	Flexural Modulus [MPa] ISO 178	Charpy Notched impact 23°C [kJ/m²] ISO 179/1eA	Melting Point [°C] DSC	Special Features	BFS/ EBM	IBM/ ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
DM55pharm	2.8	1,400	3.5	164				●	●	✓	✓	009146	*
HD800CF	8	1,600	3.0	164				●	●	✓	✓	020240	✓
HD850MO	8	1,850	3.0	162				●	●	✓	✓	017929	✓
HD810MO	10	1,250	4.5	164	Nu, Rad			●		*	✓	009040	✓
HF840MO	19	1,250	3.0	160	Slip			●		*	✓	009040	✓
HG820MO	28	1,800	2.0	162	Nu			●		*	✓	027799	✓

# Polypropylene Heterophasic Copolymer

Bormed™ Grade	MFR 230°C/2.16 kg [g/10 min] ISO 1133	Flexural Modulus [MPa] ISO 178	Charpy Notched impact 23°C [kJ/m²] ISO 179/1eA	Melting Point [°C] DSC	Special Features	BFS/ EBM	IBM/ ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
BJ868MO	70	1,500	5.5	165				●		*	✓	033438	✓

## Key:

Nu: Nucleation

Rad: Radiation package

Slip: Slip agent

IM: Injection moulding

EP: European pharmacopeia

USP: United States pharmacopeia

- Main application
- Secondary application
- ✓ Grade has been tested. For detailed information please refer to medical compliance statement on [www.borealisgroup.com](http://www.borealisgroup.com)
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# Polypropylene Random Copolymers

Bormed™ Grade	MFR 230°C/2.16 kg [g/10 min] ISO 1133	Flexural Modulus [MPa] ISO 178	Charpy Notched impact 23°C [kJ/ m²] ISO 179/1eA	Melting Point [°C] DSC	Special Features	BFS/ EBM	IBM/ ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
RB801CF	1.9	750	7.9	140		●	●		●	✓	✓	028484	*
RD804CF	8	1,000	4.0	150			●	●	●	✓	✓	028486	*
RD808CF	8	700	6.0	140			●	●	●	✓	✓	028487	*
RD834CF	8	1,000	4.0	150	AB, Slip				●	✓	✓	031866	*
RE816CF	11	800	5.0	145	AB				●	✓	✓	028485	*
RF825MO	20	1,100	6.0	150	Nu			●		*	✓	031607	✓
RF830MO	20	1,100	5.0	150	Nu, Rad			●		*	✓	031609	✓
RG835MO	30	1,200	5.0	150	Nu, Slip			●		*	✓	031608	✓
RJ880MO	45	950	5.5	150	Nu, AS			●		*	✓	027840	✓

## Key:

AB: Anti-block

AS: Anti-static

Nu: Nucleation

Rad: Radiation package

Slip: Slip agent

EBM: Extrusion blow moulding

BFS: Blow-fill-seal

IBM: Injection blow moulding

ISBM: Injection stretch blow moulding

IM: Injection moulding

EP: European pharmacopeia

USP: United States pharmacopeia

● Main application

● Secondary application

✓ Grade has been tested. For detailed information please refer to medical compliance statement on [www.borealisgroup.com](http://www.borealisgroup.com)

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# Polypropylene Random Heterophasic Copolymers (Soft PP)

Bormed™ Grade	MFR 230°C/2.16 kg [g/10 min] ISO 1133	Flexural Modulus [MPa] ISO 178	Charpy Notched impact 23°C [kJ/m²] ISO 179 /1eA	Melting Point [°C] DSC	Special Features	BFS/ EBM	IBM/ ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
SC820CF	3.9	550	12	141				●	●	✓	✓	020243	*
SC876CF	3.8	330	77	148					●	✓	✓	027916	*

# Polypropylene Terpolymer

Bormed™ Grade	MFR 230°C/2.16 kg [g/10 min] ISO 1133	Flexural Modulus [MPa] ISO 178	Charpy Notched impact 23°C [kJ/m²] ISO 179 /1eA	Melting Point [°C] DSC	Special Features	BFS/ EBM	IBM/ ISBM	IM	Film	EP*	USP*	DMF nr.	ISO 10993*
TD109CF	6	700	4.0	131				●	●	✓	✓	024931	*

## Key:

EBM: Extrusion blow moulding

BFS: Blow-fill-seal

IBM: Injection blow moulding

ISBM: Injection stretch blow moulding

IM: Injection moulding

EP: European pharmacopeia

USP: United States pharmacopeia

- Main application
- Secondary application
- ✓ Grade has been tested. For detailed information please refer to medical compliance statement on [www.borealisgroup.com](http://www.borealisgroup.com)
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# Sterilisation

The process of sterilisation can be carried out by several different approaches with heat (steam), chemical (Ethylene oxide or EtO) and irradiation being the most common.

## Steam sterilisation

Sterilisation with water vapour (steam) is one of the most commonly used heat sterilisation techniques for pharmaceutical packaging. Products made out of PP and HDPE materials are typically sterilised at the standard conditions of a constant temperature of 121°C (250°F). At this temperature, there is a holding time of at least 15 minutes needed to achieve sterility. These materials can also withstand the higher 'fast' autoclaving temperatures of 134°C (273°F). However, LDPE products need to be sterilised at a lower temperature due to the lower melting point of LDPE materials as do temperature sensitive materials that are packed in PP or HDPE – for example dextrose (D-Glucose). In this case, 'equivalence' methods can be applied to calculate the holding time that is needed at lower temperatures in order to achieve the same sterility assurance level. One of the most widely referenced equivalence methods is the F0 method that is referred to in Ph. Eur and US Pharmacopeia.

Depending on the contents, final product design and manufacturing process of the application, the optimum Bormed™ product needs to be determined. The dimensional stability (deformation) of the moulded item always needs to be checked – internal and/or external tensions can deform the product during sterilisation, e.g. relaxation of moulded-in stress.

## EtO sterilisation

Ethylene oxide is widely accepted as a standard technique, especially for disposable medical devices. Treatments are generally carried for at least 3 hours with differing temperatures (30°C - 60°C typically) and gas concentrations. EtO is highly effective at killing viruses and bacteria, including spores. Final products made out of all Bormed materials can be sterilised with EtO.

## Radiation sterilisation

Gamma ray irradiation sterilisation is used in an increasing number of applications. Gamma rays have high energy and penetration and as such are frequently used for disposable equipment/items that are bulk packaged. Extensive safety measures are required for both operators and additionally the radioactive isotopes from where the gamma rays originate.

Some polymers, especially PP, are sensitive to degradation (formation of radicals) due to the high energy used. As a result of the radiation the final product can become brittle and/or yellow either directly after radiation or after a certain undefined time (see Figure 1). Certain additives typically used in polyolefin resins and masterbatches are very sensitive to irradiation and as such should be avoided. Additionally, it is important to consider the 'delivered' dosage of irradiation, rather than the 'emitted' level as bulk irradiation will mean full dosage is not delivered to every part.

In order to mitigate the effects of the irradiation, PP resins can be specially additivated. Bormed HD810MO, a homopolymer, and Bormed RF830MO, a random copolymer, have been specially developed in order to be used with gamma irradiation.

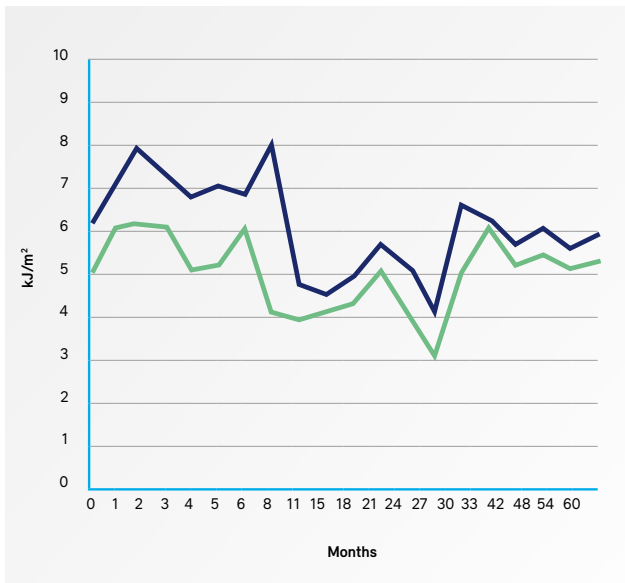


Figure 1: Charpy notched impact 23°C - Bormed™ HD810MO.

## Further information



### Polypropylene MFR

230°C/2.16 kg [g/10 min] = ISO 1133

### Polyethylene MFR

190°C/2.16 kg [g/10 min] = ISO 1133

For product technical statements, product safety information sheets and all compliance and medical statements, visit us at [www.borealisgroup.com](http://www.borealisgroup.com) or contact your Borealis or Borouge representative.

### Contact:



[www.borealisgroup.com/contact](http://www.borealisgroup.com/contact)

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**About Borealis** Borealis is one of the world's leading providers of advanced and circular polyolefin solutions and a European market leader in base chemicals, fertilizers and the mechanical recycling of plastics. We leverage our polymers expertise and decades of experience to offer value adding, innovative and circular material solutions for key industries. In re-inventing for more sustainable living, we build on our commitment to safety, our people and excellence as we accelerate the transformation to a circular economy and expand our geographical footprint.

With head offices in Vienna, Austria, Borealis employs 6,900 employees and operates in over 120 countries. In 2021, Borealis generated total sales and other income of EUR 10,153 million and a net profit of EUR 1,396 million. OMV, the Austria-based international oil and gas company, owns 75% of Borealis, while the remaining 25% is owned by a holding company of the Abu-Dhabi based Mubadala. We supply services and products to customers around the globe through Borealis and two important joint ventures: Borouge (with the Abu Dhabi National Oil Company, or ADNOC, based in UAE); and Baystar™ (with TotalEnergies, based in the US).

[www.borealisgroup.com](http://www.borealisgroup.com)

[www.borealiseverminds.com](http://www.borealiseverminds.com)

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