

# Bormed™ solutions for healthcare moulding and film applications



Bormed™ SB815MO ampoules made by BREVETTI ANGELA

 BOREALIS

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Borouge



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# The Bormed™ Concept

We understand that in the healthcare market, safety and efficiency of the product matters most and thus you need the right partner to do business with in a reliable and meaningful way. We achieve this through our dedicated, constantly developing range of polyethylene and polypropylene grades, our global team and, critically, the Bormed™ Concept. This is more than simply documentation and technical service, rather it is all encompassing – from product conception to production, procurement, support and distribution. It is based on the three core principles of service, commitment and conformance which cover the different aspects of active information management, change control and security of supply. Additionally, through our technical expertise and an ongoing, clear dialogue with our business partners, we remain at the forefront of healthcare trends and challenges allowing us to evolve our Bormed™ offering to the industry, providing tailored healthcare solutions for you. Because we care.

## Commitment

Our commitment to and understanding of the healthcare market is tangible in everything we do. We provide security of supply, for the short and long term, with higher stock levels and planning prioritisation. We seek out cooperation with our business partners, the OEMs, converters and machinery suppliers. We believe in consistency – combined with step change innovation which we drive at our state of the art facility in Linz, Austria. Experience, technical expertise and a forward looking attitude make us the right partner for the healthcare market.

## Service

It is important to have the right material and the right information at the right time in the right place. To achieve this, we steer information and notifications proactively, aiming to provide you with what you need to know, when you need it, in a concise and structured format. We lead open discussions with our business partners which enables us to remain at the forefront of industry trends and challenges. Through our dedicated global team of specialists, from R&D to technical support to sales and extensive dedicated distribution networks, we are able to provide fast and reliable delivery.

## Conformance

Borealis' expertise results in a maintained consistency of the variables used to make polyolefins for the healthcare market – safeguarding continued regulatory compliance, be it the European or US Pharmacopeia, or ISO standards. Going beyond this, we have dedicated procedures in place to avoid uncontrolled changes and variations in quality. Our change control procedure ensures the highest quality standards. This goes hand in hand with enhanced operating instructions, which ensure that anyone involved in Bormed™, knows Bormed™ – from product development to production, supply chain and support functions.

## The Bormed™ Concept delivers:

- Consistency of formulation
- Continuity of supply for at least two years
  - Shelf life letters of up to three years
- Change control procedure
  - Bormed™ Directive: operating instructions for the development, production and delivery to the end customer of Bormed™ products
- Pharmacopeia compliance
  - External testing of Ph. Eur., USP, ISO 10993, DMF listing
  - Extractable profiles
  - Microbiology



# High Density Polyethylene

Boreled™ Grade	MFR 190°C/2.16kg [g/10min] ISO 1133	Density [kg/m <sup>3</sup> ] 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*
<b>HD-PE</b>													
HE2581-PH	0.3	958	1,250	131		●	●	●		✓	✓	027656	✓
HE7541-PH	4	954	1,250	129				●		✓	✓	027654	✓
HE9621-PH	12	962	1,300	133				●		✓	✓	029149	✓

# Low Density Polyethylene

Boreled™ Grade	MFR 190°C/2.16kg [g/10min] ISO 1133	Density [kg/m <sup>3</sup> ] 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*
<b>LD-PE</b>													
LE6607-PH	0.3	927	290	114	No additives	●			●	✓	✓	008124/027108	*
LE6609-PH	0.3	930	330	117	No additives	●	●		●	✓	✓	017927	*
LE6600-PH	1.5	919	250	110	No additives	●	●		●	✓	✓	027587	*

## Key:

EBM: Extrusion blow moulding

IBM/ISBM: Injection stretch blow 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/en/search/](http://www.borealisgroup.com/en/search/)

\* For more information, please refer to the respective medical statement at [borealisgroup.com](http://borealisgroup.com)

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

# Polypropylene Homopolymer

Bormed™ Grade	MFR 230°C/2.16kg [g/10min] 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*
<b>PP Homopolymers</b>													
DM55pharm	2.8	1,350	4.0	164				●	●	✓	✓	009146	*
HD800CF	8	1,400	4.3	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	1,900	2.0	162	Nu			●		*	✓	027799	✓

# Polypropylene Heterophasic Copolymer

Bormed™ Grade	MFR 230°C/2.16kg [g/10min] 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*
<b>PP Heterophasic Copolymer</b>													
BJ868MO	70	1,500	5.5	166				●		*	✓	**	✓

## Key:

Nu: Nucleation

Rad: Radiation package

Slip: Slip agent

EBM: Extrusion blow moulding

IBM/ISBM: Injection stretch blow 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/en/search/](http://www.borealisgroup.com/en/search/)

\* For more information, please refer to the respective medical statement at [borealisgroup.com](http://borealisgroup.com)

\*\* in preparation

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

# Polypropylene Random Copolymers

Boremed™ Grade	MFR 230°C/2.16kg [g/10min] 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*
<b>PP Random copolymer</b>													
RB801CF	1.9	750	11.0	140		●	●		●	✓	✓	028484	*
RD804CF	8	1,000	4.8	151			●	●	●	✓	✓	028486	*
RD808CF	8	700	9.0	140			●	●	●	✓	✓	028487	*
RD834CF	8	1,000	3.7	150	AB, Slip				●	✓	✓	**	*
RE816CF	11	800	5.5	145	AB				●	✓	✓	028485	*
RE870MO	13	1,050	6.0	150			●	●		✓	✓	031606	✓
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

IBM/ISBM: Injection stretch blow 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/en/search/](http://www.borealisgroup.com/en/search/)

\* For more information, please refer to the respective medical statement at [borealisgroup.com](http://borealisgroup.com)

\*\* in preparation

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# Polypropylene Random Heterophasic Copolymers (Soft PP)

Borned™ Grade	MFR 230°C/2.16kg [g/10min] 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*
<b>PP Random Heterophasic Copolymers</b>													
SB815MO	1.5	425	80	145		●	●	●	●	✓	✓	027540	✓
SC820CF	3.9	550	26	141				●	●	✓	✓	020243	*
SC876CF	3.8	330	77	149					●	✓	✓	027916	*

# PP Terpolymer

Borned™ Grade	MFR 230°C/2.16kg [g/10min] 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*
<b>PP Terpolymer</b>													
TD109CF	6	900	700	131				●	●	✓	✓	024931	*

## Key:

EBM: Extrusion blow moulding

IBM/ISBM: Injection stretch blow 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/en/search/](http://www.borealisgroup.com/en/search/)

\* For more information, please refer to the respective medical statement at [borealisgroup.com](http://borealisgroup.com)

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

# Plastomer

Borned™ Grade	MFR 190°C/2.16kg [g/10min] 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					●	*	✓	**	✓

# PO Specialties

Grade	MFR 230°C/2.16kg [g/10min] 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*
<b>PO Specialties</b>													
WD170CF#	6.5	910	800	151					●	✓	✓	020242	*
WE150CF#	12.5	925	1,000	151	Slip, AB				●	*	✓		*

## Key:

AB: Anti-block

Slip: Slip agent

EBM: Extrusion blow moulding

IBM/ISBM: Injection stretch blow 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/en/search/](http://www.borealisgroup.com/en/search/)

- # WD170CF and WE150CF are not Borned™ branded
- \* For more information, please refer to the respective medical statement at [borealisgroup.com](http://borealisgroup.com)
- \*\* in preparation

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

# 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 and medical devices. 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  $F_0$  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.

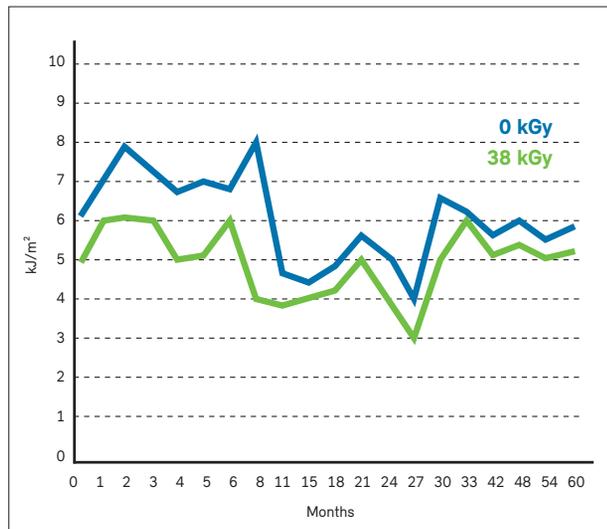


Figure 1: Charpy notched impact 23°C - Bormed™ HD810MO.

# Facts

Polypropylene MFR  
[230°C/2.16 kg] g/10 min = ISO 1133

Polyethylene MFR  
[190°C/2.16 kg] g/10 min = ISO 1133

EBM= Extrusion blow moulding  
BFS = Blow-fill-seal  
IBM= Injection blow moulding  
ISBM= Injection stretch blow moulding  
IM= Injection moulding

Food contact regulations and certificate on pharmaceutical use  
If required, contact your Borealis or Borouge representative for a certificate.

For Technical Data Sheets, Safety Data Sheets and Product Liability Statements please visit us at [www.borealisgroup.com](http://www.borealisgroup.com) and [www.borouge.com](http://www.borouge.com) or contact your Borealis or Borouge representative.

All Bormed™ grades are produced and sold under dedicated Healthcare directives including enhanced change control, increased security of supply, proactive notifications. A healthcare policy and risk assessment process applies.

For any information related to Healthcare, please contact us [www.borealisgroup.com](http://www.borealisgroup.com), [www.borouge.com](http://www.borouge.com), [www.borealisbecausewecare.com](http://www.borealisbecausewecare.com)

# Notes

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Bormed™ - Because we care | Date of issue: September 2021

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 2020, Borealis generated EUR 6.8 billion in sales revenue and a net profit of EUR 589 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).

For more information visit: [www.borealisgroup.com](http://www.borealisgroup.com) | [www.borealiseverminds.com](http://www.borealiseverminds.com)

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**For more information :**

visit [www.borealisgroup.com](http://www.borealisgroup.com) and [www.borouge.com](http://www.borouge.com)  
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