



Bormed™

Conformidade, Serviço e
Comprometimento com
grau médico para soluções
parenterais

Paulo Cavacas

Business Development Manager Healthcare

Borealis AG

 **BOREALIS**

Agenda

01



Who we are

02



Setting the scene

03



The Bormed™
Concept

04



Bormed™
for BFS

05



Bormed™
for pouch
systems

06

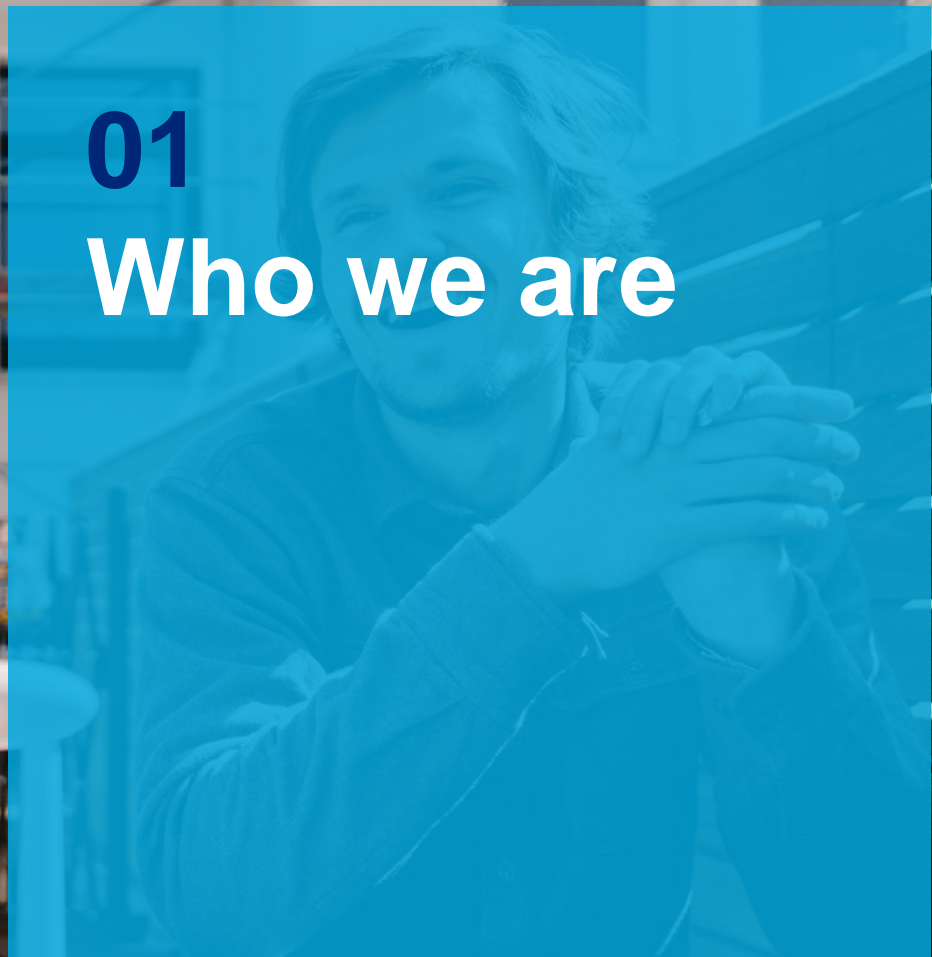


Bormed™
Contributing to
a healthier
planet



01

Who we are



Who we are

What makes us us

120

Countries. Head Office
in Vienna, Austria

6,000

employees
worldwide



Production and distribution
of advanced and circular
polyolefins solutions and base
chemicals

Ownership structure:

75%

OMV, Austria

25%

ADNOC, United
Arab Emirates



Our JV's: Bayport Polymers
(**Baystar**™) – brings Borstar®
technology to American polyethylene
markets



Our JV's: Borouge – one of
the world's largest integrated
polyolefin complexes (Ruwais,
UAE)

#2

Among polyolefin
producers in Europe

EUR 2,111 million

net profit

128

Priority patents filed
in 2022

3

Polyolefin recycling
operations in Europe



02

Setting the Scene

The healthcare dimension in polymers

Often, the materials used in Healthcare applications **are relatively standard**.

Only a few have **specific Healthcare related properties** i.e. for gamma irradiation.

What **makes the difference** for polymer producers supplying the Healthcare grade is their **level of understanding** of the industry they supply, **added services and support**.



The 'missing' Healthcare dimension in PO food approved grades

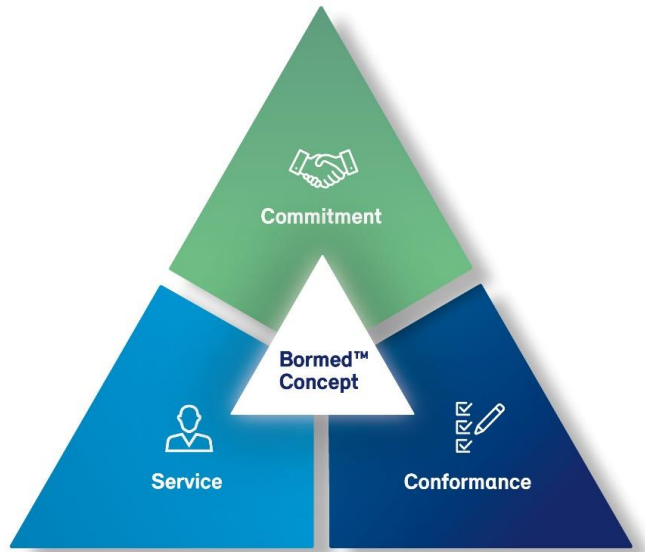
Typical changes associated with production of standard, food contact polymer grades...

- Additive composition
- Production recipe (catalyst, process aid)
- Production technology
- Production location

...are **NOT** typically notified

Ultimately this means, that any Healthcare specific testing (compendial, stability, E&L....) of food contact polymers has **NO** relevance if the material is changed without notification **AFTER** the testing has been done.

Patient safety can be compromised.



03

The Bormed™ Concept

What the market told us... A wish list

Medical Grade
Plastics

Compliance statements &
relevant documentation

Proven track record

Sustainable solutions

Regulatory support

Expert
advice

Security of supply

Robust change
management

Modelling and
simulation support

Extensive list of raw material
mechanical performance

Bormed™ Concept: Dedicated service for the Healthcare Industry

Commitment

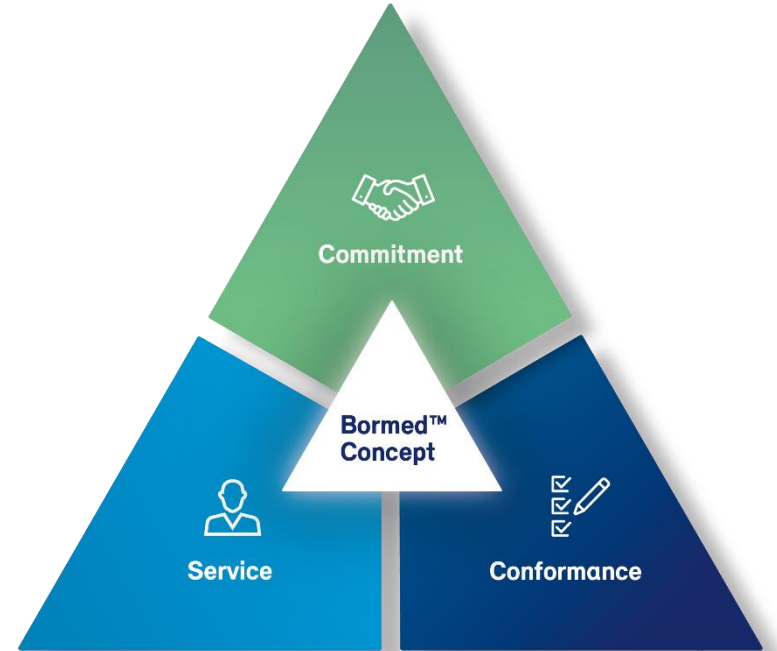
- Dedicated portfolio of branded PE & PP
- Continuity of supply regulated by Technical Delivery Specification
- Product made available up to 5 years (2 years pre-notification and a last call volume combined with 3 year shelf life)
- Consistency of the product recipe via rigorous change control procedure
- The Bormed™ Directive (PO4047): operating instructions for the development, production, storage and delivery to the end customer of Bormed™ products

Conformance

- Pharmacopeia compliance
 - External Ph. Eur., USP (incl. 661.1) and ISO 10993 testing: analysis reports can be shared on request; DMF listing; following VDI guidelines on MGP

Service

- Extractable profiles that can be shared on request
- Globally available dedicated team of experienced technical and regulatory specialists
- Innovation in products and services relevant for Healthcare industry





04

**Bormed™
for BFS**

Bormed™ for BFS Material Solutions

Regardless of what material you need, Borealis aims to be the supplier of choice through our complete portfolio offering



Bormed LDPE	Bormed HDPE	Bormed Semi-soft PP
LE6600-PH	HE2581-PH	RB801CF
LE6607-PH		
LE6609-PH		

	LDPE	HDPE	RB801CF
Processability	+	+	+
Ph.Eur compliance	+	+	+
Transparency	+	-	++
Sterilisation at 121°C	-	+	+
Low Stiffness (Flex) => Collapsibility	+	--	-

SBM Study 1000ml BFS containers

Joint contribution SBM – Rommelag - Borealis

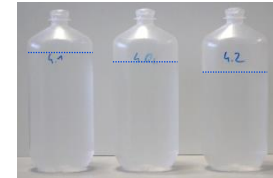
Borealis – different standard resins

Standard Resin	Production site	PE / PP	Melting Point
LE6607-PH	1130021150 Schwechat	PE	114°C
LE6607-PH	186948 Porvoo	PE	114°C
LE6609-PH	1130019750 Schwechat	PE	117°C



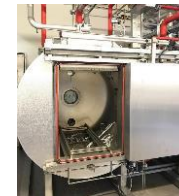
Rommelag – bottles with different fill grades

- ▶ 900 ml
- ▶ 1000 ml
- ▶ 1100 ml



SBM – sterilization test runs @ test lab AUSTRIA

- ▶ Different **temperatures** as **close** as possible to **melting point**
- ▶ Different **loading pattern**
- ▶ Different **positions** in 3 layers to evaluate influences
- ▶ Cycle control via **reference sensors / BFS Bottle**



Source: Syntegon project team

SBM Study 1000ml BFS containers

Results for PE LE6607-PH (SW) with 109/110,5/112 and 113,5°C

Sterilization @ 109°C (MP 114°C, target F0=8)

- ▶ No significant difference in layer, no difference direct vs. single box

Sterilization @ 110,5°C (MP 114°C, target F0=8)

- ▶ No significant difference in layer, **better shape/standing in single box**
All bottles show **slight distortion**

Sterilization @ 112°C (MP 114°C, target F0=8)

- ▶ All sizes more **blown up on bottom**, first **dents in shoulder area**
- ▶ No significant difference in layer, **much better shape in single box**

With optimized cycle parameters and single boxes difficult but feasible!

Sterilization @ 113,5°C (MP 114°C, target F0=8)

- ▶ All bottles show **strong deformations** and dents
- ▶ No significant difference in layer, better shape in single box, outside box **bottles partly stuck/melted** together



109°C



112°C.

SBM Study 1000ml BFS containers

Results for PE LE6607-PH (PO) – 109 / 110,5 / 112 and 113,5°C

Sterilization @ 109°C (MP 114°C, target F0=8)

- ▶ No significant difference in layer, 900ml shape improved in single box

Sterilization @ 110,5°C (MP 114°C, target F0=8)

- ▶ No significant difference in layer, improvement in shape and standing in single box, 900ml again worst shape.

Sterilization @ 112°C (MP 114°C, target F0=8)

- ▶ All sizes show **more dents** and **900ml first deformations**
- ▶ No significant difference in layer, **much better shape in single box**

More sensitive than SW production but with optimized cycle parameters and single boxes feasible!

Sterilization @ 113,5°C (MP 114°C, target F0=8)

- ▶ All bottles show **strong deformations and dents**, partly stuck/melted together – **not recommended**



109°C



112°C.

SBM Study 1000ml BFS containers

Results for PE LE6609-PH (SW) with 112 and 113,5°C

Sterilization @ 112°C (MP 117°C, target F0=8)

- ▶ Bottle **shape very nice**, tends to blow up (less in 900ml)
- ▶ No significant difference in layer and single box

Sterilization @ 113,5°C (MP 117°C, target F0=8)

- ▶ All with **very nice shape**, few **small dents** on the shoulders more with 900ml
- ▶ No significant difference in layer, shape better in single box
- ▶ With **optimized cycle parameters** and **single boxes** difficult but **feasible!**

115°C dismissed, strong deformations and dents not recommendable



112°C



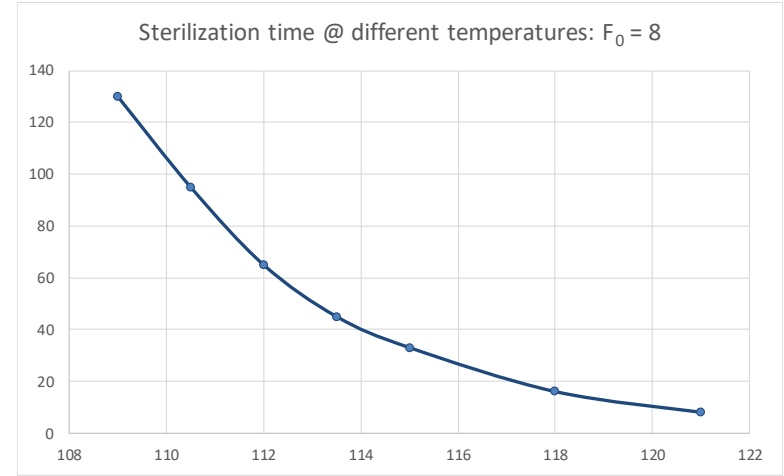
113,5°C.

SBM Study 1000ml BFS containers

Summary: Capacity Example

Sterilization temperature		109 °C	112 °C	121 °C
Loading / Unloading	[min]	15	15	15
Heating / Cooling	[min]	55	55	65
Sterilization	[min]	130	65	20
TOTAL Cycle time		200	135	100
Bottles per batch	[pcs]	8 500	8 500	8 500
Cycles per day ^{*)}		6	9	12
Cycles per year ^{**)}		2 040	3 060	4 080
TOTAL OUTPUT p.a.	[pcs]	17.300.000	26.000.000	34.700.000

50% 100%



Higher sterilization temperature






- ⇒ shorter cycle time
- ⇒ higher output or
- ⇒ smaller autoclaves



05

Bormed™ for Pouch Systems

Bormed™ used for Film Applications

Primary Packaging			Secondary Packaging	Primary Packaging Blisters & Sachets
Soft pouches	Tubing	Nutrition		
				
<p>Infusion therapies</p> <ul style="list-style-type: none"> – Intravenously administered drugs – Peritoneal dialysis with drainage bag 	<ul style="list-style-type: none"> – Soft PP tubing (combined with PP based moulded ports & connectors) 	<ul style="list-style-type: none"> – Clinical nutrition for critical & chronically ill patients – Hospital use and home administration 	<ul style="list-style-type: none"> – Overwrap for CAPD and IV bags 	<ul style="list-style-type: none"> – PP thermoformed sheet & lidding film for mono-blisters – 4-side sealed single portion packs (e.g. aspirin sachets)
<ul style="list-style-type: none"> – Transparency – Sterilisability – Collapsibility 	<ul style="list-style-type: none"> – Kink resistance – Transparency – Sterilisability 	<ul style="list-style-type: none"> – Barrier – Sterilisability – Printability 	<ul style="list-style-type: none"> – Easy open feature – Excellent barrier properties – Sterilisability 	<ul style="list-style-type: none"> – Mono-material solution – Convenient medicine packaging

Key performance criteria for Film Applications



Outside layer

Transparent heat resistant layer

- High Tm
- Sterilisation resistance
- Transparency
- Toughness

Core layer

Very soft, very tough and transparent layer

- High Toughness at low temperatures
- Sterilisation resistance and post sterilisation transparency
- Softness for easy collapsibility of the bag

Sealing layer

Transparent and sealable layer

- Low S.I.T / Seal ability
- Sterilisation resistance (seal toughness, no sticking) and post sterilisation transparency
- Peelable layer

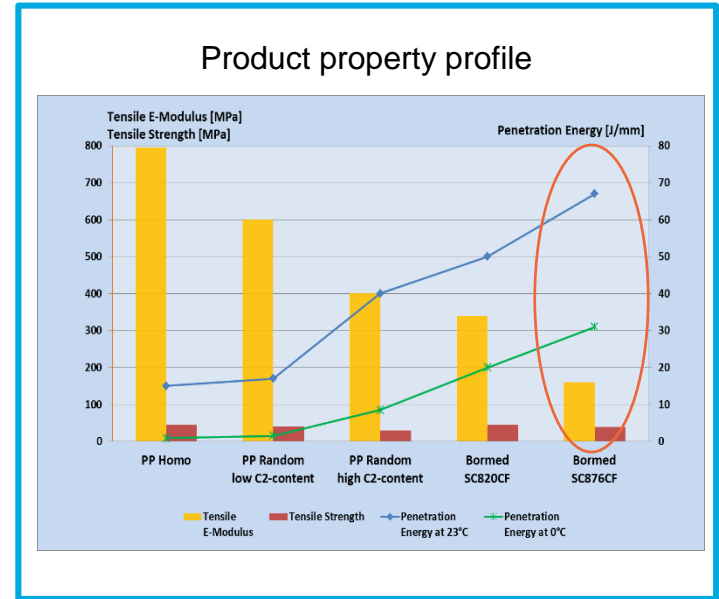
Bormed™ Product Portfolio for Film Applications

	Functionality	Film layer	Product name	ISO 1133 MFR 230/2.16 (g/10min)	ISO 178 Flexural modulus (MPa)
PP Homopolymers	Heat resistance for sealing / Sterilisation resistance / Transparency	Outside layer	Bormed DM55pharm	2.8	1350
			Bormed HD800CF	8	1400
PP Random Copolymers	Sterilisation resistance / Transparency / Toughness / Sealing	Outside layer / Core layer / Sealing layer	Bormed RB801CF	1.9	750
			Bormed RD804CF	8	1000
			Bormed RD834CF	8	1000
			Bormed RD808CF	8	700
			Bormed RE816CF	11	800
PP Terpolymer	Sealing	Sealing layer	Bormed TD109CF	6	700
PP Soft (PP Random heterophasic Copolymers)	Softness / Toughness	Core layer	Bormed SC820CF	3.9	550
			Bormed SC876CF	3.8	330
PO Specialties	Peelable	Sealing layer	WD170CF	6.5	800
			WE150CF	12.5	1000
	Softness / Toughness	Outside layer / Core layer / Sealing layer	Bormed PL8830PH		

Bormed™ SC876CF offers a true step-change innovation

The novel polymer design results in a material with

- Excellent balance between high toughness and high transparency at low temperature after steam sterilisation
- Very good thermal stability
- Significant reduction of impact modifiers in film formulation
- Full Pharmacopeia compliance (EP, USP, DMF listing)

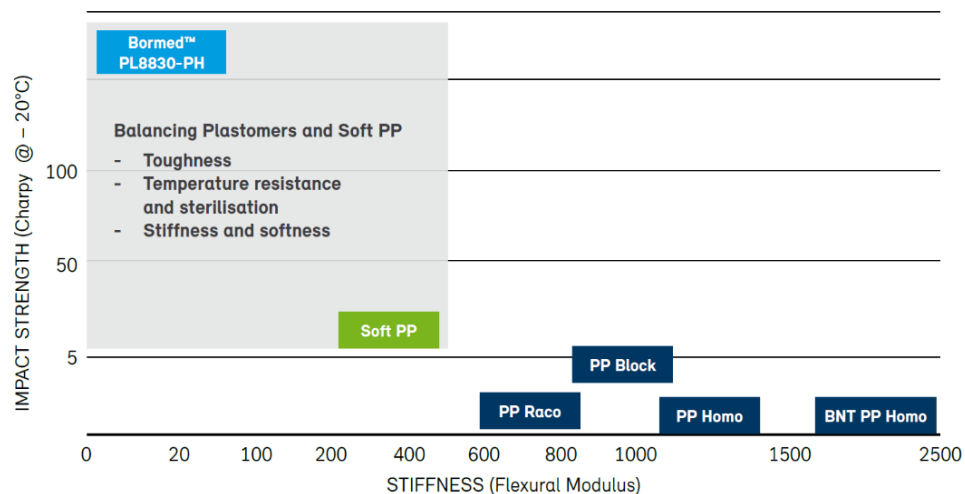


Properties measured on a 50µm thick monolayer cast film produced acc. to Borealis internal standard

Bormed™ PL8830-PH & Bormed™ Soft PP: Enlarging the PO performance envelope in Pharma packaging

IV Pouches

Bormed PL8830-PH & Bormed Soft PP



Key benefits:

- Allow significant reduction of impact modifiers in film formulation
- Excellent balance between high toughness at low temperature and good transparency after steam sterilisation
- Secured processing window for steam sterilisation at 121°C; offers opportunities as blending / compounding component

06

Bormed™

**Contributing to a
healthier planet**



Acceleration of circular production

We will increase circular product capacity to 1.8 mt by 2030



Six-fold increase in share of circular products and solutions from today's 100 kt to 600 kt by 2025 and further to 1.8 million tons by 2030



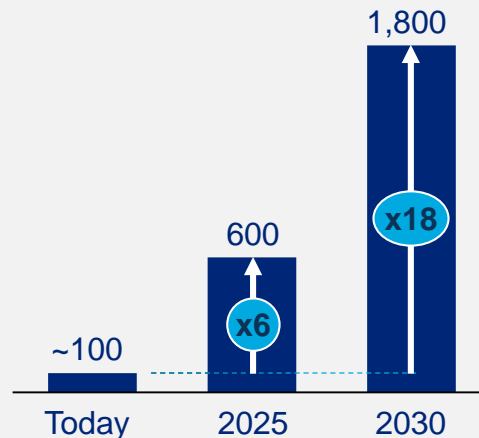
Moving from a linear towards a circular economy will also significantly reduce Scope 3** emissions



Invest in compounding and adjacencies to accelerate value creation through innovation

Circular products and solutions

in kt*



*Includes recycled and renewable polymers and chemicals as well as renewable hydrocarbons

** Scope 3 are indirect GHG emissions that are a consequence of company activities but occur from sources outside or not controlled by the company.

Borealis is fully committed to closing the loop

Accelerating the transition to a circular economy by addressing DfR, plastic waste and climate change

Design for Recycling



Design for Recycling

- Eco-efficient design so that healthcare applications can be collected, sorted and recycled (e.g. “mono” material)
- Example: substitution of PVC/Al blister materials with 100% PP solution

Borcycle™ C



Chemical recycling

- Plastic Neutrality
- Value: fight plastic waste; meet recycling targets
- Virgin equivalent, food approved and medical grade (Bormed)
- ISCC+ certified mass balance

The Bornewables™



Renewable-based (2nd gen.) POs

- Carbon Neutrality
- Value: reduce carbon footprint by at least 120%; fossil depletion by ~70%*
- Virgin equivalent, food approved and medical grade (Bormed)
- ISCC+ certified mass balance

Commercially available solutions for Healthcare

*vs. fossil-based in terms of GWP and abiotic resource depletion / LCA based on ISO14040, ISO14044, ISO14067 critically reviewed by third party panel

Summary

Bormed™ solutions for parenteral solutions

- **Bormed medical grade approach:** dedicated service to the healthcare industry, based: **Commitment, Compliance, Service**
- **Wide PE and PP** offer for pharma packaging and medical devices/diagnostics
- **Parenteral solutions** validated through value chain cooperation
- **Environmentally sustainable** Bormed alternatives **available now** with reduced carbon footprint by at least 120% vs. fossil with **No change** in quality, purity, processing, specifications



Thank you!

Let's re-invent!

Paulo Cavacas

Business Development Manager Healthcare

paulo.cavacas@borealisgroup.com

The ideas documented in this presentation are property of Borealis AG unless otherwise stated. The content and layout of this presentation is protected by copyright laws. Unauthorized use or reproduction, as well transmission to third parties, in whole or in part, is not permitted unless explicitly authorized.