



# Experts in excipients.

The whole world of lactose.



# How we got where we are today.

The world of lactose is the world of MEGGLE. What began in 1887 as a dairy operation in the town of Wasserburg, near Munich, is now one of the world's leading manufacturers of pharmaceutical lactose. We have been providing the pharmaceutical market segment for more than 60 years with a broad-based lactose product portfolio found nowhere else in the industry. Over 30 years of experience in direct compaction tableting also speak for themselves – and for us.

With committed, highly qualified employees in all disciplines, our clients can benefit from the experience and innovative drive of a pioneer in industrial milk and whey processing. We are constantly working to develop high-tech, functional products for implementation in customer applications, where they can deliver maximum performance. Even with our advances in innovation, we remain what we always have been: a family business with strict values and high standards. Performance and partnership with our customers are at the core of our success. You can count on that; we do, too.

## Our vision

Short-term goals are important. Everyone should have them. But long-term goals are what define a company's vision and chart its overall course. We are guided by our vision each and every day.

- Development and implementation of innovative, functional products for application in new dosage forms.
- Pioneering in pharmaceutical excipient development.
- Leading with our independent, global network in the fields of research, development, technical support, engineering, sales, and distribution.
- Exceeding customer expectations in resolving challenges with new and existing formulations.



# MEGGLE stands for added value.

MEGGLE means more; above all, more service. We are not simply a producer and supplier. We are your partner, your advisor, your development team. Whatever you need, you can call on our team of experts to help with all aspects of development, production, application, and processing of pharmaceutical excipients. You can rely on our worldwide network of application engineers to assist you quickly. Whether you work with us as part of a coordinated contract production activity or innovative contract development project, our FormulaB development center aligns specifically to your needs and requirements. We share our experience and expertise with our customers and partners. Innovation is what drives us, and we are in constant contact with global scientific and educational institutions to our benefit and yours.

## MEGGLE in brief:

- Modern, innovative product range
- Quality systems that meet the highest international standards
- Fully implemented GMP/GDP system
- Global sales and distribution network
- Customers in over 100 countries
- Local, individual service
- Extensive expertise
- Team of experienced application advisors around the world
- Global research network
- Contract manufacturing to the highest possible quality standards
- Contract development at our FormulaB technical competence center

*formula*<sup>TM</sup>**B**  
THE ALTERNATIVE  
FORMULATION COMPANY

## FormulaB services:

- Solid dosage formulation development
- Formulation optimization meeting specific production conditions
- Investigation for the most effective technical and economic process selection
- Pilot batch production in D-class facility

Our quality standards are simple:  
Do everything better.

Whatever you are looking for with regard to pharmaceutical lactose, we have it. Our broad portfolio comprises eight product groups with more than 20 products, covering all areas from solid dosage forms (including tablets, capsules, and sachets) to powder formulations and dry powder inhalation, including products unique to MEGGLE.

To guarantee optimum quality and batch-to-batch consistency, we are diligent in our product develop and manufacture to exacting standards in Europe and the United States under strict supervision of our production and quality control systems. In everything we do, we make sure all international quality standards are met or exceeded. This is just one of the many reasons why leading global pharmaceutical and supplement manufacturers have chosen us as a supplier.

### **MEGGLE stands for expertise.**

Making processes faster and better has helped make us a global market leader in direct compression and co-processed tableting excipients. Efficiency is our maxim. Investment in research and development, internally and in close cooperation with well-known scientific and educational institutions all over the world has helped us expand our leading position. Innovation is the driving force behind our success. We prove it anew each and every day. MEGGLE's highly motivated and expert employees are critical to our success – and yours.



international excipients  
certification

**DIN EN ISO 9001:2008**  
QUALITY MANAGEMENT SYSTEM

**DIN EN ISO 50001:2012**  
ENERGY MANAGEMENT SYSTEM

**DIN EN ISO 14001:2004**  
ENVIRONMENTAL MANAGEMENT SYSTEM

# Wherever you are – we're there for you.

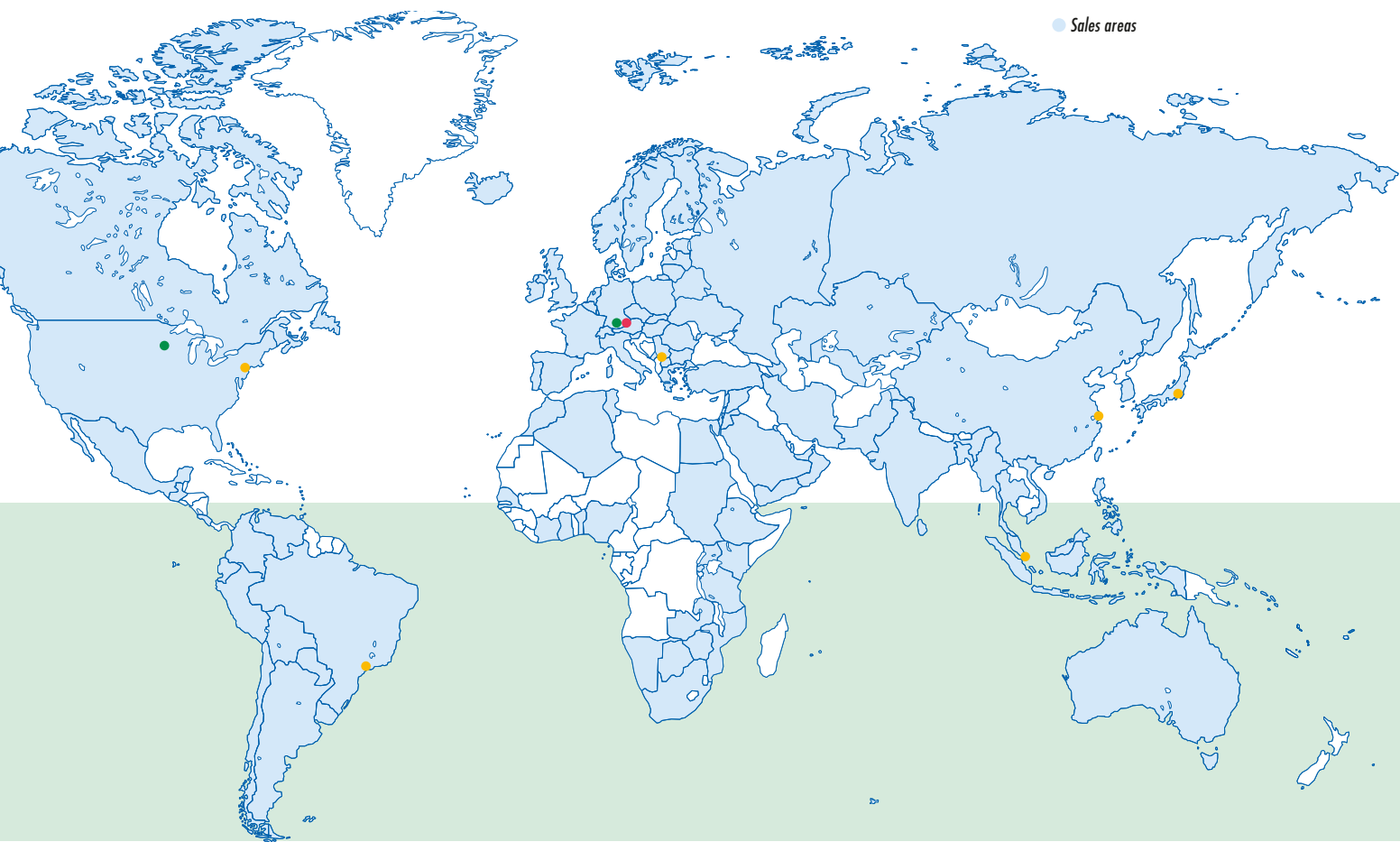
MEGGLE maintains a leading position in more than 100 countries. With production facilities in Wasserburg am Inn, Germany and Le Sueur, Minnesota, where we serve the individual requirements of the North American market, MEGGLE is prepared to meet customer expectations. With our global network of expert representatives, regional offices, and subsidiaries, we are always nearby, wherever you happen to be and with a first-class reputation. When it comes to distribution, advising, and service, you can always count on MEGGLE to deliver the quality and performance you would expect. You can depend on it.

● **Headquarters**  
Wasserburg

● **Production sites**  
Wasserburg  
Le Sueur/Minnesota

● **Regional offices**  
New York  
São Paulo  
Pristina  
Shanghai  
Singapore  
Tokyo

● **Sales areas**

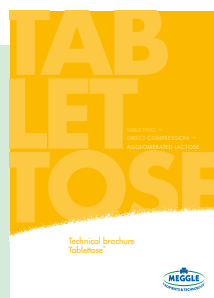


MEGGLE has it:  
The right lactose product for any needs.

Tableting					Powder preparations
Granulation	Direct compression				
milled	agglomerated	spray-dried	anhydrous	co-processed	
GranuLac® 70	Tablettose® 70	FlowLac® 90	DuraLac® H	Cellactose® 80	
GranuLac® 140	Tablettose® 80	FlowLac® 100		MicrocelLac® 100	
GranuLac® 200	Tablettose® 100			StarLac®	
GranuLac® 230				CombiLac®	
SorboLac® 400				sustained release	
				RetaLac®	



Milled/sieved



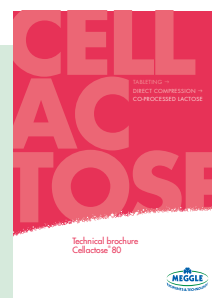
Tablettose®



FlowLac®



DuraLac®



Cellactose®



MicroceLac®

## Dry powder inhalation

sieved

milled

InhaLac® 70

InhaLac® 400

InhaLac® 120

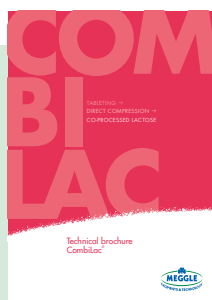
InhaLac® 230

InhaLac® 251

The world of lactose is our whole world. With this in mind, our products are aligned specifically to your needs and applications. For further information on any product shown here, please see the detailed, individual product brochure available for downloading at [www.meggle-pharma.com](http://www.meggle-pharma.com).



StarLac®



CombiLac®



RetaLac®



InhaLac®

All product brochures and specifications can be downloaded as PDFs from [www.meggle-pharma.com](http://www.meggle-pharma.com).

# Maximum effort to meet the very highest standards.

## Milled lactose – for optimum granulation

Granulac® and SorboLac®, milled lactose, have good compaction properties due to its small particle size. It is best granulated, wet or dry, before tablet production. It is the most frequently used excipient for granulation.

### Application

- Wet granulation
- Dry granulation
- Premixes
- Triturations
- Fermentation
- Flavor enhancement

### Products:

- Granulac® 70
- Granulac® 140
- Granulac® 200
- Granulac® 230
- SorboLac® 400

### Product features

- Good compactibility
- Good blending properties
- Narrow particle size distribution
- High storage stability
- High batch-to-batch consistency

## Sieved lactose – with superior blending properties.

Lactose is sieve-fractionated into various grades with a narrow particle size distribution and exhibits good flow. Sieved lactose consists of mono-crystals and agglomerates. Our product variety allows your application to be easily optimized. Due to good blending properties and excellent flowability, our products are especially suitable for powder blends, and capsule and sachet filling.

### Application

- Capsule filling
- Sachet filling
- Powder blends
- Triturations

### Products:

- PrismaLac® 40
- Capsulac® 60
- Sachelac® 80
- Spherolac® 100

### Product features

- Excellent flowability
- Narrow particle size distribution
- Good blending properties
- High storage stability
- High batch-to-batch consistency

## Direct compression (DC) – maximum profitability.

Direct compression is the least complex and most cost-effective alternative to traditional granulation. Because they are convenient and easy to administer, tablets are the most popular pharmaceutical dosage form. They can be produced inexpensively in large volumes. Moreover, dosing accuracy is consistent. Given the efficiencies, direct compression is becoming the preferred process for tablet manufacture by pharmaceutical companies globally. Decreased energy, labor, and capital costs as well as the increase in overall product stability are a few of the many benefits.

Few traditional excipients provide the functional characteristics, specifically powder flow and compactibility, required for robust direct compression tablet manufacture. As a result, modifying traditional excipients may be necessary. This may be accomplished through spray-drying, agglomeration, roller-drying, or co-processing lactose to enhance the functional characteristics desired for directly compressed pharmaceutical dosage forms.

### Products:

DC excipients:

- **Tablettose® 70**
- **Tablettose® 80**
- **Tablettose® 100**
- **FlowLac® 90**
- **FlowLac® 100**
- **DuraLac® H**

Co-processed excipients:

- **Cellactose® 80**
- **MicroceLac® 100**
- **StarLac®**
- **CombiLac®**
- **RetaLac®**

## Lactose for inhalation applications – versatile, in line with your needs.

Inhalac® is tightly controlled sieved or milled lactose specifically designed and especially suited for dry powder inhalation drug delivery. Inhalac® products are available in standard forms or as customized solutions to suit your exacting needs. Inhalac® fulfills the need for excellent flowability, defined particle surface, and chemical and physical stability in dry powder inhalation drug delivery.

Inhalac® is perfect for these applications due to the extremely narrow particle size distribution. This specialized excipient is practically free of unstable, amorphous lactose.

### Products:

- **Inhalac® 70**
- **Inhalac® 120**
- **Inhalac® 230**
- **Inhalac® 251**
- **Inhalac® 400**

# Decisions made easy – all features at a glance.

Our product portfolio encompasses a broad array of options with solutions for any requirement. This table outlines the product properties, dosage form applications, shelf life, and standard package sizes, helping you decide on the perfect solution for your formulation needs – from MEGGLE, of course.



Product decision matrix

MEGGLE product	Type of lactose						Tableting			Powder preparations			
	Sieved	Milled	Agglomerated	Spray-dried	Anhydrous	Co-processed	Wet granulation	Dry granulation	Direct compression	Dry powder inhalation	Capsules	Sachets	Spheres
GranuLac® 70*		■					■	■			■		
GranuLac® 140*		■					■	■					■
GranuLac® 200*		■					■	■					■
GranuLac® 230		■					■	■					■
SorboLac® 400		■					■	■					■
Tablettose® 70			■						■		■	■	
Tablettose® 80			■						■		■	■	
Tablettose® 100			■						■		■	■	
FlowLac® 90				■					■		■	■	
FlowLac® 100				■					■		■	■	
DuraLac® H**					■			■	■		■		■
Cellactose® 80				■		■			■		■	■	
MicroceLac® 100				■		■		■	■		■	■	
StarLac®				■		■		■	■		■	■	
CombiLac®				■		■		■	■		■	■	
RetaLac®			■			■			■				
PrismaLac® 40	■										■	■	
CapsuLac® 60	■										■	■	
SacheLac® 80	■										■	■	
SpheroLac® 100	■										■	■	
InhaLac® 70	■									■			
InhaLac® 120	■									■			
InhaLac® 230	■									■			
InhaLac® 251	■									■			
InhaLac® 400		■								■			

\* Dual manufacturing sites in Germany and the United States

\*\* Manufacturing located in the United States

\*\*\* In preparation

Regulatory				Functionality		Shelf life	Packaging	Special features
Specified acc. to Ph. Eur.	Specified acc. to USP-NF	MEGGLE monograph	Drug master file	Flowability	Compatibility		Packaging (standard PEEVOH-PE inliner)	
■	■**			●●●●●	●●●●●	36 Months	25 kg paper bag	
■	■**			●●●●●	●●●●●	36 Months	25 kg paper bag	
■	■**			●●●●●	●●●●●	36 Months	25 kg paper bag	
■				●●●●●	●●●●●	36 Months	25 kg paper bag	
■				●●●●●	●●●●●	36 Months	20 kg paper bag with alu inliner	
■				●●●●●	●●●●●	36 Months	20 kg paper bag	Reduced fines
■				●●●●●	●●●●●	36 Months	25 kg paper bag	
■				●●●●●	●●●●●	24 Months	20 kg paper bag	Finer initial particle size
■				●●●●●	●●●●●	36 Months	25 kg carton box with alu inliner	Reduced fines
■				●●●●●	●●●●●	18 or 24 Months	25 kg paper bag or carton box with alu inliner	
	■			●●●●●	●●●●●	36 Months	25 kg carton box with alu inliner	
		■	■	●●●●●	●●●●●	36 Months	20 kg paper bag or carton box	Diluent/binder combination
		■	■	●●●●●	●●●●●	18 Months	20 kg paper bag	Diluent/binder combination
		■	■	●●●●●	●●●●●	36 Months	25 kg paper bag	Diluent/disintegrant combination
		■	***	●●●●●	●●●●●	24 Months	20 kg carton box	Diluent/binder/disintegrant combination
		■	■	●●●●●	●●●●●	24 Months	12 kg carton box	Controlled release matrix system
■				●●●●●	●●●●●	36 Months	20 kg paper bag	
■				●●●●●	●●●●●	36 Months	25 kg paper bag	
■				●●●●●	●●●●●	36 Months	25 kg paper bag	
■				●●●●●	●●●●●	36 Months	25 kg paper bag	
	■		***	n/a	n/a	24 Months	25 kg carton box	
	■		■	n/a	n/a	24 Months	25 kg carton box	
	■		***	n/a	n/a	24 Months	25 kg carton box	
	■		***	n/a	n/a	24 Months	25 kg carton box	
	■		■	n/a	n/a	24 Months	15 kg carton box with alu inliner	

●●●●● Excellent  
 ●●●●● Very good  
 ●●●●● Good  
 ●●●●● Satisfactory  
 ●●●●● Sufficient  
 ●●●●● Insufficient/not advised



## Curious? Want to know more?

### Need technical support? Our experts are available to you worldwide.

- Customer meetings
- Technical presentations
- In-house seminars on lactose, direct compression, and all topics having to do with solid dosage forms as well as powder inhalers
- Customer-specific seminars upon request

#### Please contact:

Technical department: Tel. +49 8071 73 394

R & D department: Tel. +49 8071 73 272

#### Inhalation product portfolio:

For more information on our entire Inhalac® portfolio please contact [inhalation@meggle.de](mailto:inhalation@meggle.de)

### Would you like to receive samples?

#### Please contact:

Customer service: Tel. +49 8071 73 476

[service.pharma@meggle.de](mailto:service.pharma@meggle.de)

[www.meggle-pharma.com](http://www.meggle-pharma.com)

#### MEGGLE Group Wasserburg BG Excipients & Technology

Megglestrasse 6–12

83512 Wasserburg

Germany

Phone +49 8071 73 476

Fax +49 8071 73 320

[service.pharma@meggle.de](mailto:service.pharma@meggle.de)

[www.meggle-pharma.com](http://www.meggle-pharma.com)

### Need support for sales-related questions? Our field sales reps and representatives worldwide:

#### Regional Office Eastern Europe/Middle East:

Phone +386 496 244 459 or [arsim.zhubi@meggle.de](mailto:arsim.zhubi@meggle.de)

#### Regional Office Asia:

Phone +68 625 933 06 or [siangmeng.chua@meggle.sg](mailto:siangmeng.chua@meggle.sg)

#### Representativ Office China:

Phone +86 21 3393 2457 308 or [yi.kang@meggle-china.com](mailto:yi.kang@meggle-china.com)

#### Regional Office Japan:

Phone +81 3 3561 3491 or [yokomizo@meggle.co.jp](mailto:yokomizo@meggle.co.jp)

#### Europe/Africa:

Phone +49 8071 73 118 or [service.pharma@meggle.de](mailto:service.pharma@meggle.de)

#### USA/Canada:

Phone +1 844 4MEGGLE (+1 844 463 4453) or

[customer.service@meggle.com](mailto:customer.service@meggle.com)

#### Regional Office Latin America:

Phone +55 11 2893 4831 or [ruth.leinenbach@meggle.com](mailto:ruth.leinenbach@meggle.com)

For additional local representatives, please visit

[www.meggle-pharma.com](http://www.meggle-pharma.com).

MEGGLE representative

*MEGGLE warrants that its products conform to MEGGLE's written specification and makes no other expressed or implied warranties or representations. For any specific usage, the determination of suitability of use or application of MEGGLE products is the sole responsibility of the user. The determination of the use, application, and compliance of this product with regard to any national, regional, or local laws and/or regulations is the sole responsibility of the user, and MEGGLE makes no representation with regards to same. Nothing herein shall be construed as a recommendation or license to use the product or any information that conflicts with any patent or intellectual property of MEGGLE or others and any such determination of use is the sole responsibility of the user.*

© MEGGLE

US 09-21-2016 Sai