## Experts in excipients.

The whole world of lactose.



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## How we became who we are today.

The world of lactose is MEGGLE's world. What began in 1887 as a dairy operation in the town of Wasserburg, near Munich, is now one of the leading manufacturers of pharmaceutical lactose worldwide. For over 70 years, we have been providing the pharmaceutical market with a broad-based lactose product portfolio unmatched in the industry. Over forty years of experience in direct compression also speaks for itself – and for us.

With committed, highly qualified employees in all areas of expertise, our customers benefit from the experience and innovative drive of a true pioneer in industrial milk and whey processing. We constantly work to develop high-tech products that deliver maximum performance in our customers' applications. And yet, in all our advancements and strides toward innovation, we remain what we always have been: a family business with firm values and high standards. Our success is founded upon strong performance and partnerships with customers. You can count on that. We do.

#### Our vision.

Short-term goals are important and good. However, long-term goals are what give a company its perspective and chart its course. It is what guides us each and every day.

- In the development of innovative, effective products and the implementation of trends in the application of new dosage forms.
- In our leadership in the development and innovation in pharmaceutical excipients.
- In our independent, global network in the fields of research, development, technical support, engineering, sales, and distribution.
- Supporting customers in resolving challenges with new and existing formulations.





## MEGGLE stands for more value.

MEGGLE means more. Especially when it comes to service. We are not only a manufacturer and supplier. We are your partner, your advisor, your development team. Whatever your requirements may be, our team of experts is available to you for any questions regarding development, production, application, and processing of pharmaceutical excipients. You can rely on our worldwide network of application engineers to assist you quickly. We welcome specialized contract manufacturing projects where we have the opportunity to share our experience and expertise with customers and partners. We are driven by innovation, which is why we stay close to scientific and educational institutions around the globe. And this benefits you as well.

#### In short, MEGGLE means:

- Modern, innovative product range
- Quality control that meet the highest international standards
- Fully implemented GMP/GDP system
- Global sales and distribution network
- Customers in over 100 countries
- Local, individualized service
- Comprehensive expertise
- Team of experienced application advisors around the world
- Global research network
- Contract manufacturing at the highest level: www.meggle-lohnfertigung.de

#### **Product configuration:**

- The right lactose product for you is only a click away
- Comparing the facts and figures of your preferred products
- All the technical performance parameters for each product, at a glance
- Sample and documentation requests in under a minute

#### DirectCost optimization for your lactose formulations:

- The easiest way to compare wet granulation with direct compression
- Fast evaluations of the cost- and time-saving potential for your formulation
- Total flexibility in batch sizes and procedures
- Immediate graphic visualisations and reports
- Off-line capabilities on all your devices
- Local or cloud-based storage for your calculations

#### We make it easy for you.

What properties, dosages, applications, shelf-life, and standard packaging is available for which MEGGLE lactose product?

Our services will help you find out quickly and easily: **www.meggle-pharma.com** 



# When it comes to quality, our goals are simple: do everything better.

Whatever your needs in pharmaceutical lactose, we have it. Our comprehensive, lactose-based pharmaceutical excipient portfolio is no other in the industry and covers solid dosage forms from tablets, capsules, and sachets to powder formulations and dry powder inhalation. Some of these product are exclusive to MEGGLE.

In order to guarantee optimum quality and batch-to-batch consistency, we develop all our own products and manufacture most of them in-house. A few of our products are made under strict oversight and to our exacting quality standards by contract manufacturers in Europe. We make sure all international quality standards are met or exceeded. This is 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 – and therefore more efficient – has been our motto. It has helped make us a global market leader in direct compression and co-processed tableting excipients. We invest heavily in research and development and work closely with noted scientific and educational institutions all over the world. This is how we have have achieved and maintained our leadership position. Innovation is the driving force behind our success. We prove this every day. MEGGLE's employees are highly motivated, competent, and welcome change.





DIN EN ISO 5000 ENERGY MANAGEMENT SYSTEM

### IN EN ISO 14001 IRONMENTAL MANAGEMENT SYSTEM

## Wherever you are - we are there for you.

MEGGLE is present. We are in over 100 countries. We have production facilities in Wasserburg-am-Inn in Bavaria as well as in Le Sueur/Minnesota in the US from which we service the North American market. Our global network for expert representatives, regional offices, and subsidiaries ensure that we are always nearby, bringing our first-class reputation. Whereever you are, when it comes to distribution, consultation, and service, you can count on the same quality you have come to expect of our products.

 Production sites Wasserburg Le Sueur/Minnesota
Regional offices New York São Paulo Priština Shanghai

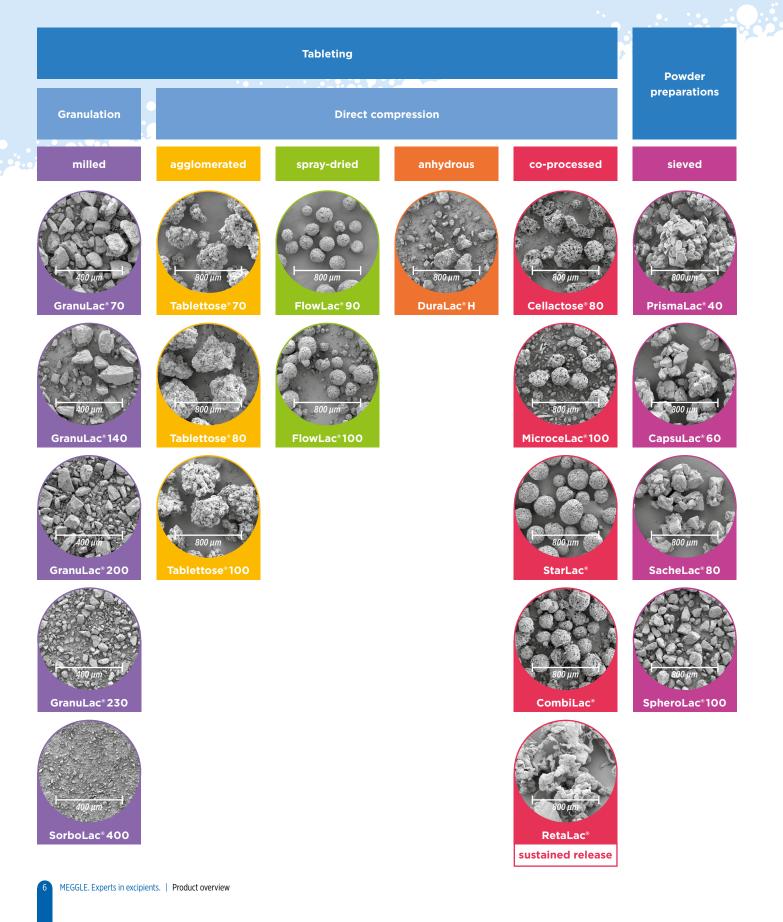
> Singapore Tokyo

Sales areas

Headquarters

Wasserburg

## MEGGLE has got it: The right lactose product to meet any demand.



#### Dry powder inhalation

sieved

milled

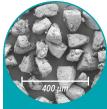
InhaLac<sup>®</sup> 500 micronized



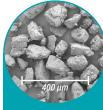
InhaLac\*70 InhaLac\*400



InhaLac®120



InhaLac®160



InhaLac®230



The world of lactose is our world. We are able to meet the specifics needs of any and all of your applications. For further information on any product shown here, please refer to the specific product brochure available for downloading at www.meggle-pharma.com.





















All product brochures and specifications can be downloaded as PDFs from **www.meggle-pharma.com.** 

## The highest dedication to the highest standards.

#### Milled lactose – for optimum granulation.

Milled Lactose shows a limited flowability and should therefore be granulated before tabletting. GranuLac® and SorboLac® have a small particle size. Because of its good compression and blending properties, lactose is the most frequently used excipient for granulation.

#### **Applications:**

- Wet granulation
- Dry compression
- Premixes
- Triturations
- Fermentation
- Flavor off-set

#### Products:

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

#### Advantages:

- 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 narrow particle size distributions and exhibits good flow. Sieved lactose consists of mono-crystals and agglomerates. The variety of products allows you to optimize your selection for your particular application. Good blending properties and excellent flowability make these products especially well-suited to powder blends, and capsule and sachet filling.

#### **Applications:**

- Capsule filling
- Sachet filling
- Powder blend
- Triturations

#### Products:

- PrismaLac® 40
- CapsuLac<sup>®</sup> 60
- SacheLac<sup>®</sup> 80
- SpheroLac<sup>®</sup>100

#### Advantages:

- 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 alternative to traditional granulation. Because they are convenient and safe to administer, tablets are the most popular pharmaceutical dosage form. They can be produced inexpensively in large volumes. Moreover, the prescribed active ingredient dosage can be prepared with a higher degree of accuracy. In the pharmaceutical industry, Direct Compression has already become the preferred method for manufacturing tablets. This is because of its economical production due to cost-effectiveness in manufacturing sites, labor, validation, as well as the increase in overall stability of the active ingredient within the tablet.

The selection of pharmaceutical excipients for direct compression is more critical than that for granulation in general, or wet granulation in particular. Few traditional excipients combine the functional characteristics, specifically powder flow and compactibility, required for robust direct compression. This makes modifying traditional excipients a necessity.

Co-processed excipients:

- Cellactose® 80

- StarLac\*

- RetaLac®

- CombiLac®

- MicroceLac® 100

#### Products:

- Tablettose® 70
- Tablettose® 80
- Tablettose® 100
- FlowLac® 90
- FlowLac<sup>®</sup> 100
- DuraLac® H

flexible, according to your requirements.

Lactose for inhalation applications -

InhaLac<sup>®</sup> is sieved, milled or micronized pharmaceutical lactose that is especially suited to applications in dry powder inhalation drug delivery. The InhaLac<sup>®</sup> product line is available in standard formulation or as a customized solutions to suit your requirements. Sieved InhaLac<sup>®</sup> has excellent flowability, defined particle surface, and chemical and physical stability that are the characteristics needed in dry powder inhalation excipients. The sieved product qualities are practically free of amorphous lactose.

The finely milled lactose InhaLac® 400 as well as the micronized lactose InhaLac® 500 are both excellently suited as tertiary components in dry powder inhalation drug delivery. As such, they are able to elevate the efficiency of the formulation. In addition they may serve as the basis for soft pellet formulations.

InhaLac®'s special suitabilities are due to its narrow particle size distribution.

#### Products:

- InhaLac® 70
- InhaLac® 120
- InhaLac® 160
- InhaLac® 230
- InhaLac® 251
- InhaLac® 400
- InhaLac® 500



# 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, re-test and standard package sizes, helping you decide on the perfect solution for your formulation needs – from MEGGLE, of course.

Product decision matrix														
	Product category					Ta	bletir	ng	Powder preparations					
											_			
										Ę	ation			
				-				5	E	Direct compression	Dry powder inhalation			
			-	Agglomerated	þ	s	Co-processed	Wet granulation	Dry granulation	bre	er in			
	_		Micronized	mer	drie	Anhydrous	oces	rant	anu	con	pwo	les	ts	es
	Sieved	Milled	cro	olgi	ray.	hyd	ud-	et g	y gr	rect	y pc	Capsules	Sachets	Spheres
MEGGLE product	Si	Σ	Σ	Ą	Sp	Ar	ដ	≥	ā	Ō	ā	ů	Sa	Sp
GranuLac® 70*		-						-						
GranuLac® 140*														
GranuLac® 200*														
GranuLac® 230														
SorboLac® 400														
Tablettose® 70														
Tablettose® 80														
Tablettose® 100														
FlowLac® 90														
FlowLac® 100														
FlowLac® 100														
DuraLac® H**														
Cellactose® 80														
MicroceLac® 100														
StarLac <sup>®</sup>														
CombiLac®														
RetaLac®														
PrismaLac® 40														
CapsuLac® 60														
SacheLac <sup>®</sup> 80														
SpheroLac® 100														
InhaLac® 70														
InhaLac® 120														
InhaLac® 160														
InhaLac® 230														
InhaLac® 251														
InhaLac® 400														
InhaLac® 500														
* Dual production site	s in Ge	rmany	and the	e US										

\*\* US production site

\*\*\* In process

MEGGLE

MEGGLE App:

Droduct docisio

MEGGLE

Regulatory Functionality		onality	Retest/Shelf-life	Packaging			Special features			
Ph. Eur./USP-NF/JP compliant	MEGGLE Specification	Drug master file	Flowability	Compactibility		Packaging unit	PE-EVOH-PE inliner	Aluminum inliner		
■*					36 Months	25 kg paper bag				
<b>*</b>					36 Months	25 kg paper bag				
■*				•••••	36 Months	25 kg paper bag				
					36 Months	25 kg paper bag				
					36 Months	20 kg paper bag				
					36 Months	20 kg paper bag			Reduced fines, improved flowability	
					36 Months	25 kg paper bag				
					24 Months	20 kg paper bag			Improved compactibility performance	
					36 Months	25 kg carton box			Virtually dust-free	
					18 Months	25 kg paper bag				
					24 Months	25 kg carton box				
<b>*</b> *					36 Months	25 kg carton box				
					36 Months	20 kg paper bag			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 plastic drum			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	25 kg carton box				
			n/a	n/a	24 Months	15 kg carton box				
			n/a	n/a	18 Months	10 kg carton box				
			•••• Ехс	cellent						

- •••• Very good
- Good
- Satisfactory
- ••••• Sufficient
- Insufficient/not advised



## Are you curious? Would you like to know more?

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

- Meetings with customers
- 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-requested seminars

#### Please contact:

Technical department: Phone: +49 8071 73 623 Research and Development: Phone: +49 8071 73 138

#### Inhalation products portfolio:

For more information on our entire InhaLac® portfolio, please contact inhalation@meggle.de

#### Would you like to receive samples?

#### Please contact our customer service:

Phone: +49 8071 73 476 service.pharma@meggle.de www.meggle-pharma.com

#### Do you have sales related questions? Our field sales representatives are available worldwide:

Africa and Middle East: Phone: +20 100 1486 826 or hani.calache@meggle.de Asian Regions: Phone: +68 625 933 06 or siangmeng.chua@meggle.sg China: Phone: +86 21 3393 2457 308 or yi.kang@meggle-china.com Japan: Phone: +81 3 3561 3491 or yokomizo@meggle.co.jp Europe: Phone: +49 8071 73 118 or service.pharma@meggle.de USA and Canada: Phone: +1 844 4MEGGLE (+1 844 463 4453) or customer.service@meggle.com Central and South American Regions: Phone: +55 11 2893 4831 or fabio.ikuno@meggle.com

For additional regional representatives, please visit us at www.meggle-pharma.com.

Submitted by		

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