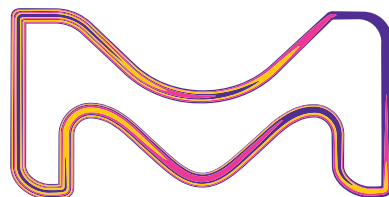


MERCK



Granulated Materials

Easy handling for improved
process efficiency



The life science business
of Merck operates as
MilliporeSigma in the
U.S. and Canada.

SAFC[®]

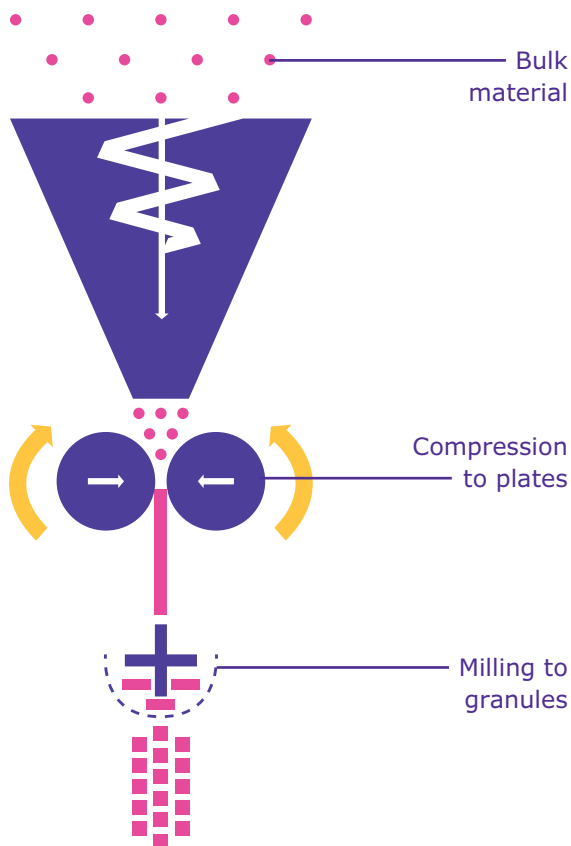
Pharma & Biopharma Raw
Material Solutions

Accelerating Manufacturing Processes

Caking and clumping of chemicals, dust formation and laborious weighing have a negative impact on manufacturing efficiency and may even lead to process interruptions, quality deviations and operator safety risks.

Buffer preparation, to name one example, is a core operation in pharmaceutical manufacturing and is closely linked to plant schedule and capacity. Just-in-time, flexible handling of chemical raw materials is key – delays are not an option.

Granulated raw materials are free-flowing and easy to handle. Their greatly reduced caking behavior facilitates processability, speeds up manufacturing processes and increases operator safety.



Discover our new innovative granulated raw materials:

Glycine Granulated
Urea Granulated
Potassium Chloride Granulated

- Greatly reduced caking
- Better handling and processability
- Increased operator safety
- Multi-compendial
- Emprove® Expert products with low endotoxin levels for high risk applications

Dry Granulation by Roller Compaction

- Compression force only
- No water or other additives used
- Ideal for highly sensitive materials

The raw materials are compacted by dry granulation. This water and additive-free process uses compression force to condense the materials. Compared to other compaction methods, dry granulation is very gentle and particularly appropriate for heat and moisture sensitive materials. By using this process, we ensure that characteristics of the raw materials are preserved and the highest quality standards are met.

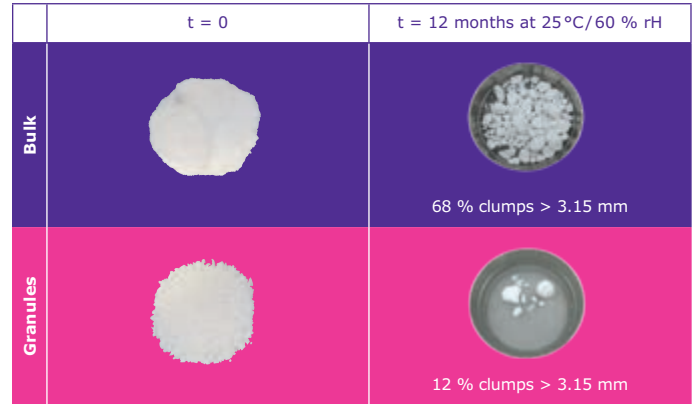
The quality, consistency and compliance of our raw materials is fully documented and supported by a secure and robust supply chain.

Material Properties

Caking is a chemical product property of various compounds, such as glycine and urea, and can lead to complete solidification.

Our granulated materials show significantly reduced caking even under long-term storage conditions. Occasionally emerging small clumps can be easily broken. In contrast, bulk material shows intense caking up to monoblock formation.

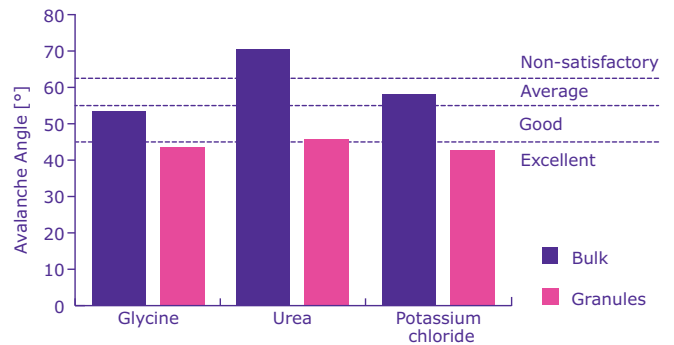
The picture on the right shows granulated urea in comparison to standard bulk material as an example.



Flowability

Our granulated materials provide excellent flowability, whereas respective bulk material only shows average or even non-satisfactory results. Free-flowing characteristics of granular material strongly improve handling and processability.

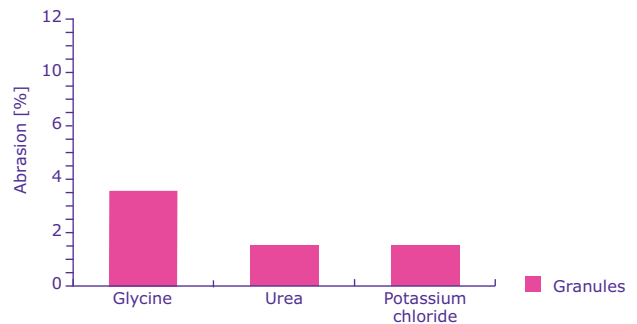
Flowability was determined by powder analyzer, a method measuring the avalanche angle necessary to induce material flow. Lower avalanche angles equal better flowability.



Abrasion

Sustained integrity of granules during transport and storage is key to preserve their positive characteristics. Granulated materials exhibit excellent integrity with very low abrasion rates.

Material integrity was tested using an abrasion drum with ceramic balls. The drum was rotated at 20 rpm for 10 min and the percentage of fine particles mass <500 µm was determined.



Dissolution

Dissolution behavior of granulated material is comparable to bulk material. Studies showed slightly faster dissolution of bulk material due to larger surface area.

Dissolution studies were performed by dissolving 80 g of the respective material in 800 mL of purified water. Samples were stirred at 250 rpm at room temperature and particles were determined by focused beam reflectance measurement (FBRM).

Raw Material	Dissolution Time [min]	
	Bulk	Granulated
Glycine	6.0	8.0
Urea	5.0	8.5
Potassium chloride	6.0	6.5

The Emprove® Program

Your fast track through regulatory challenges.

Ensuring the compliance of your pharma and biopharma products involves the compilation of a vast amount of data, which can be time and resource intensive. Our Emprove® Program helps you meet the latest regulatory requirements for risk assessment and offers assistance in developing more robust processes.

To help you optimize your process, our Emprove® Program provides comprehensive and thorough documentation for approximately 400 raw and starting materials as well as a selection of filters, single-use

devices and components. It not only covers the latest regulatory requirements, but also anticipates industry expectations not yet covered by regulation. The Emprove® Program is organized into three different types of dossiers. Every dossier supports you throughout different stages of your operations: qualification, risk assessment, and optimization – so you can speed your way through the regulatory maze.

Find out more at:
www.merckmillipore.com/emprove

Ordering Information

Glycine Granulated EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP

Cat. No.	Pack Size	Packaging
1.03669.1000	1 kg	Plastic bottle in corrugated box
1.03669.5000	5 kg	Plastic bottle in corrugated box
1.03669.9012	12 kg	PE bag in PE bucket
1.03669.9025	25 kg	PE bag in corrugated box
1.03669.9500	500 kg	Big Bag

Potassium Chloride Granulated EMPROVE® EXPERT Ph Eur, BP, JP, USP

Cat. No.	Pack Size	Packaging
1.04165.1000	1 kg	Plastic bottle in corrugated box
1.04165.9026	25 kg	PE bag in PE bucket
1.04165.9500	500 kg	Big Bag

To facilitate qualification processes, the 1 kg package is available for 3 different batches.

For further information, please visit MerckMillipore.com or contact your local sales representative.

Urea Granulated EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS

Cat. No.	Pack Size	Packaging
1.04166.1000	1 kg	Plastic bottle in corrugated box
1.04166.9026	25 kg	PE bag in PE bucket
1.04166.9150	150 kg	PE bag in PE drum
1.04166.9800	800 kg	Big Bag

Discover our comprehensive portfolio of buffers, salts, and other specialty chemicals suitable for biopharmaceutical manufacturing and formulation, as well as related information on risk mitigation.

Formulation Product Finder App:
MerckMillipore.com/formulationapp

Risk Mitigation Tool:
MerckMillipore.com/emprove-risk-mitigation

The typical technical data above serve to generally characterize the product. These values are not meant as specifications and they do not have binding character. The product specification is available separately at: MerckMillipore.com

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To place an order or receive technical assistance, please visit MerckMillipore.com/contactPS

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