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.

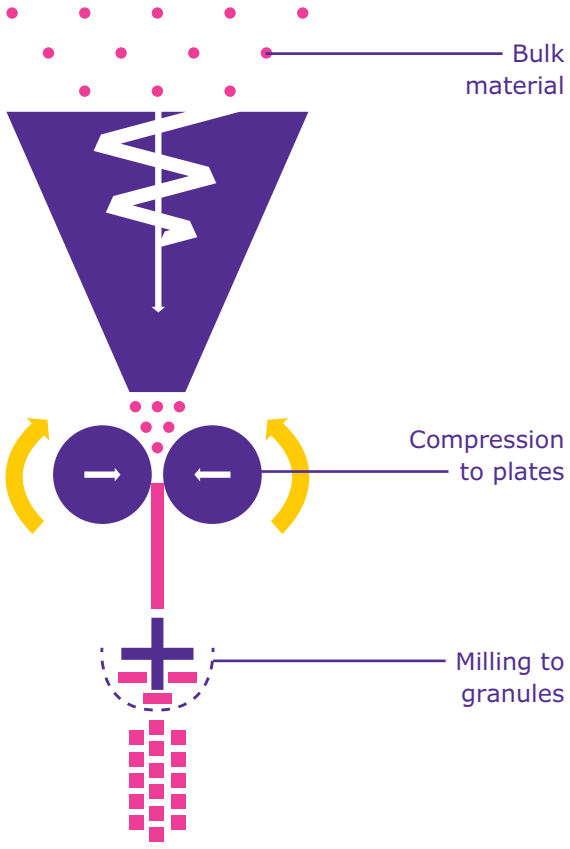
Buffer preparation, to name one example, is a core operation in pharmaceutical manufacturing and is closely linked to plant schedule and capacity. Just-in-time, flexible handling of chemical raw materials is key – delays are not an option.

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 innovative granulated raw materials:

Ammonium Sulfate,
Glycine,
Potassium Chloride,
Sodium Chloride,
Sodium Dihydrogen Phosphate,
Di-Sodium Hydrogen Phosphate,
Urea

- 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.

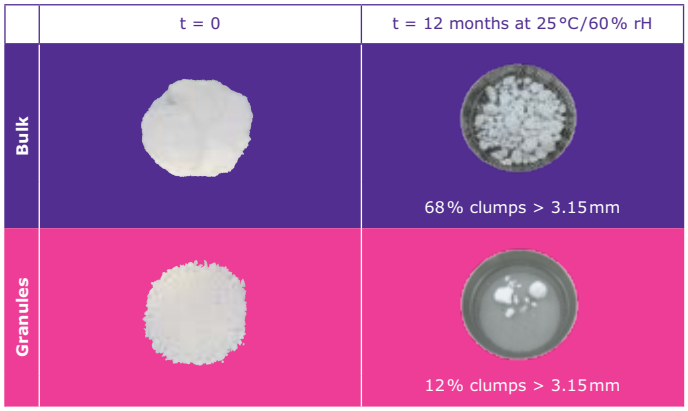
The quality, consistency and compliance of our raw materials is fully documented and supported by a secure and robust supply chain.

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.

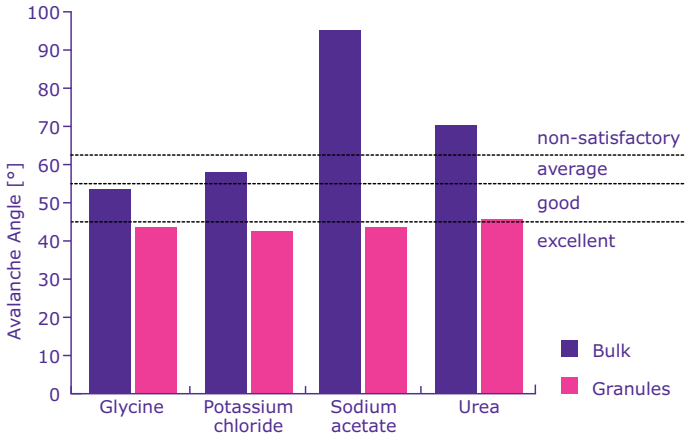
The picture on the right shows granulated urea in comparison to standard bulk material as an example.



Flowability

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

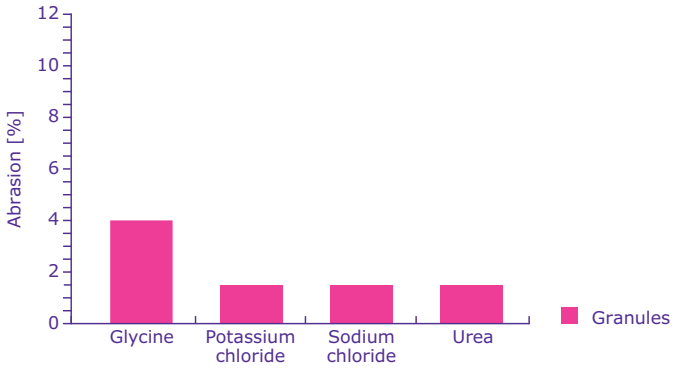
Flowability was determined by powder analyzer, a method measuring the avalanche angle necessary to induce material flow. Lower avalanche angles equal better flowability.*



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).*

	Dissolution Time [min]	
Raw Material	Bulk	Granulated
Glycine	6.0	8.0
Potassium chloride	6.0	6.5
Sodium chloride	4.0	5.5
Urea	5.0	8.5

*Data for representative products shown, further data available on request.

Emprove® Program – Two Decades of Easing Risk Management

Twenty Years of Speeding up Your Journey. And Still Accelerating.

Maintaining compliance with Good Manufacturing Practices (GMP) requirements at any given time in your drug manufacturing process can be complex and challenging – especially in a global, dynamic environment. As a drug manufacturer, you need to compile a vast amount of information from your suppliers to ensure that the raw materials and components you purchase meet the technical, regulatory and supply needs for their designated application, use and function. This can be resource- and time-intensive, as well as expensive.

20 years ago, we launched the Emprove® Program to accelerate your risk assessments and help you maintain compliance. As your processes evolved, so did the Emprove® Program, anticipating challenges and keeping you ahead of the curve. With a comprehensive digital platform, the Emprove® Program speeds your drug development journey by offering convenient access to reliable information for a broad portfolio of high-quality products. This way, the Emprove® Program enables you to:

- make more agile, risk-based decisions
- maintain compliance and
- demonstrate control – saving you time and money

Ordering Information

Product Name	Cat. No.	Pack Size	Packaging
Ammonium Sulfate Granulated EMPROVE® EXPERT ACS, ChP, NF	**1.04161.1000**	1 kg	PE bottle
	1.04161.9026	25 kg	PE bag (in PE pail)
Glycine Granulated EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP	**1.03669.1000**	1 kg	PE bottle
	1.03669.5000	5 kg	PE bottle
	1.03669.9012	12 kg	PE bag (in PE pail)
	1.03669.9025	25 kg	PE bag (in corrugated cardboard box)
	1.03669.9500	500 kg	Big bag
Potassium Chloride Granulated EMPROVE® EXPERT Ph Eur, BP, JP, USP	**1.04165.1000**	1 kg	PE bottle
	1.04165.9026	25 kg	PE bag (in PE pail)
	1.04165.9500	500 kg	Big bag
Sodium Acetate Trihydrate Granulated EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP	**1.04162.1000**	1 kg	PE bottle (in corrugated cardboard box)
	1.04162.9026	25 kg	PE bag (in PE pail)
	1.04162.9500	500 kg	Big bag
Sodium Chloride Granulated EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP	**1.04163.1000**	1 kg	PE bottle
	1.04163.9010	10 kg	PE bag (in PE pail)
	1.04163.9026	25 kg	PE bag (in PE pail)
	1.04163.9500	500 kg	Big bag
Sodium dihydrogen phosphate dihydrate granulated EMPROVE® EXPERT Ph Eur, BP, ChP, JPE, USP	**1.47345.1000**	1 kg	PE bottle
	1.47345.9026	25 kg	PE bag (in PE pail)
	1.47345.9500	500 kg	Big bag
di-Sodium hydrogen phosphate heptahydrate granulated EMPROVE® EXPERT DAC, USP	**1.47574.1000**	1 kg	PE bottle
	1.47574.9026	25 kg	PE bag (in PE pail)
	1.47574.9500	500 kg	Big bag
Urea Granulated EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS	**1.04166.1000**	1 kg	PE bottle
	1.04166.9026	25 kg	PE bag (in PE pail)
	1.04166.9150	150 kg	PE bag (in PE drum)
	1.04166.9800	800 kg	Big bag

To facilitate qualification processes, the 1 kg package is available in 3 different batches.
For further information, please visit **SigmaAldrich.com** or contact your local sales representative.

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: **SigmaAldrich.com**

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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.

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