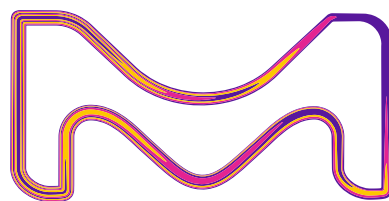


MERCK



# Granulated Materials

Easy handling for improved  
process efficiency

The Life Science business of Merck  
operates as MilliporeSigma in the  
U.S. and Canada.

# 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.

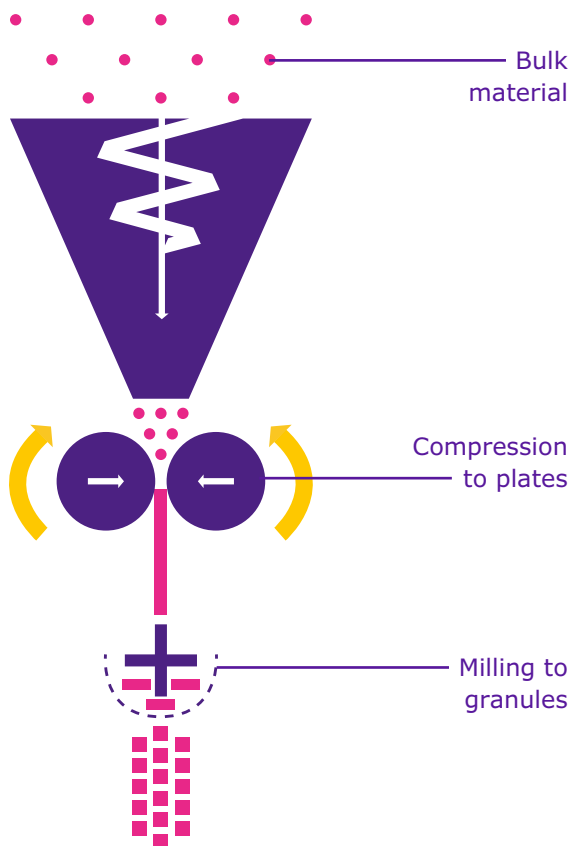
Buffer preparation, to name one example, is a core operation in pharmaceutical manufacturing and is closely linked to plant schedule and capacity. Just-in-time, flexible handling of chemical raw materials is key – delays are not an option.

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 Granulated  
Glycine Granulated  
Potassium Chloride Granulated  
Sodium Acetate Trihydrate Granulated  
Sodium Chloride Granulated  
Urea 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.

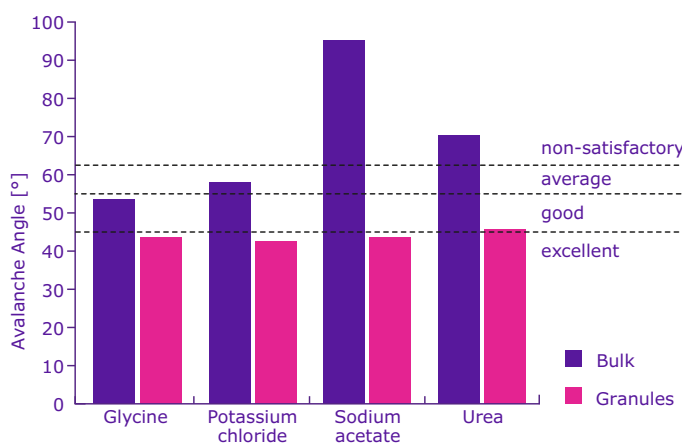
The picture on the right shows granulated urea in comparison to standard bulk material as an example.



## Flowability

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

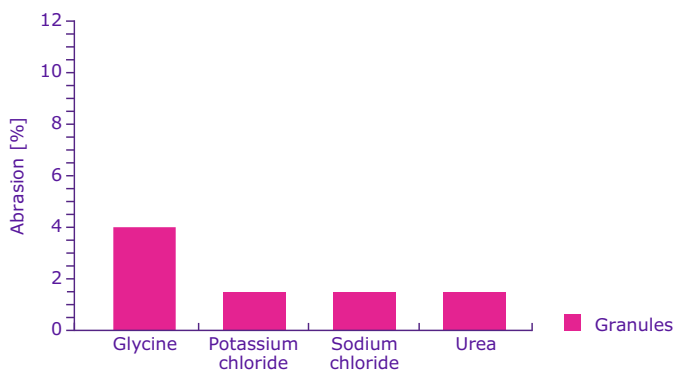
Flowability was determined by powder analyzer, a method measuring the avalanche angle necessary to induce material flow. Lower avalanche angles equal better flowability.



## 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).

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

# The Emprove® Program

## The Smart Way to Master Compliance and Control

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. In order to facilitate and accelerate this process, we developed our Emprove® Program. Beside a selection of filtration and single-use components, it contains more than 500 pharma raw and starting materials addressing different levels of risk. Each product in the portfolio is complemented with different types

of dossiers supporting you with reliable technical, regulatory, and supply information: API Information Package, Elemental Impurities Information, Material Qualification Dossier, Quality Management Dossier, and Operational Excellence Dossier.

For more information, please visit:  
**[SigmaAldrich.com/emprove-chemicals](https://SigmaAldrich.com/emprove-chemicals)**

## Ordering Information

| Product Name                                                                                   | Cat. No.            | Pack Size | Packaging                            |
|------------------------------------------------------------------------------------------------|---------------------|-----------|--------------------------------------|
| <b>Ammonium Sulfate Granulated</b><br><b>EMPROVE® EXPERT ACS, ChP, NF</b>                      | <b>1.04161.1000</b> | 1 kg      | PE bottle                            |
|                                                                                                | <b>1.04161.9026</b> | 25 kg     | PE bag (in PE pail)                  |
| <b>Glycine Granulated</b><br><b>EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP</b>                   | <b>1.03669.1000</b> | 1 kg      | PE bottle                            |
|                                                                                                | <b>1.03669.5000</b> | 5 kg      | PE bottle                            |
|                                                                                                | <b>1.03669.9012</b> | 12 kg     | PE bag (in PE pail)                  |
|                                                                                                | <b>1.03669.9025</b> | 25 kg     | PE bag (in corrugated cardboard box) |
|                                                                                                | <b>1.03669.9500</b> | 500 kg    | Big bag                              |
| <b>Potassium Chloride Granulated</b><br><b>EMPROVE® EXPERT Ph Eur, BP, JP, USP</b>             | <b>1.04165.1000</b> | 1 kg      | PE bottle                            |
|                                                                                                | <b>1.04165.9026</b> | 25 kg     | PE bag (in PE pail)                  |
|                                                                                                | <b>1.04165.9500</b> | 500 kg    | Big bag                              |
| <b>Sodium Acetate Trihydrate Granulated</b><br><b>EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP</b> | <b>1.04162.1000</b> | 1 kg      | PE bottle (in corrugated box)        |
|                                                                                                | <b>1.04162.9026</b> | 25 kg     | PE bag (in PE pail)                  |
|                                                                                                | <b>1.04162.9500</b> | 500 kg    | Big bag                              |
| <b>Sodium Chloride Granulated</b><br><b>EMPROVE® EXPERT Ph Eur, BP, ChP, JP, USP</b>           | <b>1.04163.1000</b> | 1 kg      | PE bottle                            |
|                                                                                                | <b>1.04163.9026</b> | 25 kg     | PE bag (in PE pail)                  |
|                                                                                                | <b>1.04163.9500</b> | 500 kg    | Big bag                              |
| <b>Urea Granulated</b><br><b>EMPROVE® EXPERT Ph Eur, BP, JP, USP, ACS</b>                      | <b>1.04166.1000</b> | 1 kg      | PE bottle                            |
|                                                                                                | <b>1.04166.9026</b> | 25 kg     | PE bag (in PE pail)                  |
|                                                                                                | <b>1.04166.9150</b> | 150 kg    | PE bag (in PE drum)                  |
|                                                                                                | <b>1.04166.9800</b> | 800 kg    | Big bag                              |

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

For further information, please visit **[SigmaAldrich.com](https://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](https://SigmaAldrich.com)**

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To place an order or receive technical assistance, please visit **[SigmaAldrich.com/contactAF](https://SigmaAldrich.com/contactAF)**

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