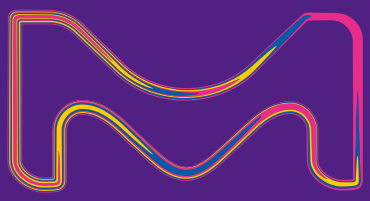
MERCK



smart and flexible formulation

Benefit from the versatility of PEGs – for every application

SAFC®

Pharma & Biopharma Raw Material Solutions

A true All-rounder

Low solubility of active pharmaceutical ingredients (APIs) is a frequent hurdle encountered during pharmaceutical development, one which impairs drug bioavailability and thus the efficacy and success of the final drug product. Many solvents provide good solubilization but may also be irritant, volatile or simply incompatible with your desired dosage form. And when formulating the final dosage form, additional excipients are needed to ensure the right consistency in liquid and semi-solid formulations, or to act as lubricants or binders in solid dosage forms.

Wouldn't it be good if there were a single class of excipients that could do all this?

There is. Polyethylene glycols (PEGs) have a variety of possible applications, including as solubilizers, lubricants, binders and consistency enhancers. Due to their high polarity, PEGs are extremely hydrophilic and can thus increase the solubility of a broad range of APIs. They are also highly soluble in a broad range of organic and inorganic solvents and thus can be easily combined with the same. All these properties make PEGs an excellent choice for pharmaceutical formulations, whatever their type and intended administration route.

Highly Versatile

- Manifold formulation options (liquid, solid and semi-solid)
- Broad spectrum of polymer lengths to fit any purpose
- Blendings and combinations possible

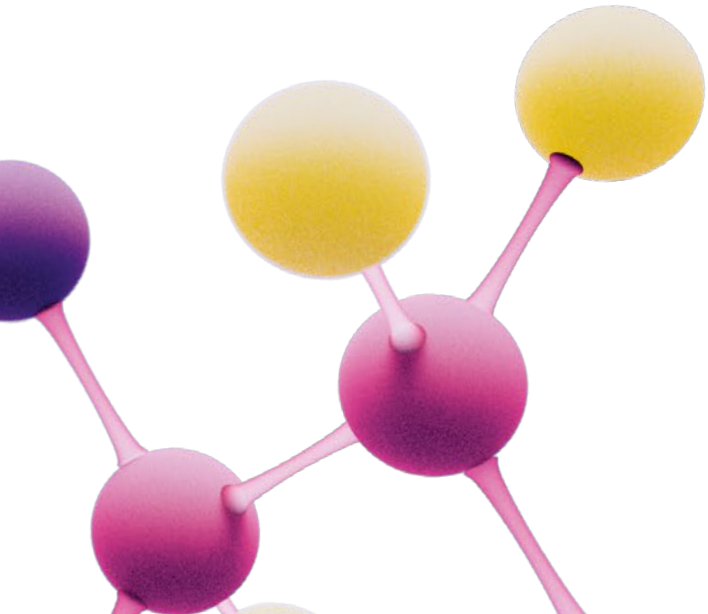
What are PEGs?

PEGs are polyethers synthesized by anionic polymerization of ethylene oxide with hydroxyl initiators. Their mean molecular weight, defined by the respective polymer length, is indicated by a number in the substance name (for instance, PEG 200 has a mean molecular weight of 200 g/mol).

The molecular weight of PEGs not only directly influences their physical form, but also their typical characteristics and application areas. As your supplier of choice, we offer a portfolio of high-quality PEGs ranging from PEG 200 to PEG 20000 perfectly suited to your applications and needs.

Typical Applications of PEGs

- Solubility enhancement
- Consistency adjustment
- Lubricant and binder for tabletting



Benefits

- **Highly soluble in water and many solvents**
- **Non-volatile**
- **Outstanding safety profile**
- **Very broad range of applications**

The right PEG for every purpose

Low molecular weight PEGs

PEG 200 to PEG 400 are liquids and miscible in water at nearly any ratio. As liquid PEGs are non-volatile, they provide significant benefits compared to solvents such as alcohols. They are easier and safer to handle and do not tend to vaporize during storage. Liquid PEGs are widely used as solubilizers and suspending agents in a variety of liquid dosage forms such as drops or liquid capsule fillings, but also act as lubricants in eye drops or as emulsion stabilizers in cremes and ointments.

High molecular weight PEGs

PEG 1000 and above are soft solids or solids. Higher molecular weight PEGs can be dry-mixed with other ingredients for tableting or granulation purposes. During tabletting, they can also function as lubricants and binders. As solid PEGs have relatively low melting points, they are ideal excipients for hot melt extrusion applications and can be used either as a carrier polymer or as a plasticizer, also in coatings.

Blended preparations

Additionally, PEGs are widely used in creams and ointments, and can also serve as a suppository base. The consistency of these preparations can be easily defined and adjusted by mixing liquid PEGs with solid or paste PEGs of a higher molecular weight. Blending PEGs in this way is supported as solid PEGs are not soluble in liquid PEGs; nevertheless, such preparations have excellent solubility and good dissolution behavior in water.

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. To help facilitate and accelerate your risk assessment continuum, we have developed the Emprove® Program, offering convenient access to reliable information for a broad portfolio of products.

Each product in the portfolio is complemented with different types of dossiers: API Information Package, Elemental Impurities Information, Material Qualification Dossier, Quality Management Dossier, and Operational Excellence Dossier. They provide information on the manufacturing process, stability data, elemental impurity information, product quality reports, analytical procedures, and much more. The Emprove® Program includes more than 500 pharma raw and starting materials addressing different levels of risk. To simplify and streamline the selection process, the Emprove® Chemicals portfolio is divided into four categories: Emprove® API, Emprove® Expert, Emprove® Essential, and Emprove® Evolve.

The dossiers can be accessed online in our new Emprove® Suite, our information-as-a-service digital platform. A subscription can help you stay current: In addition to viewing and downloading dossiers, you can also receive notification updates to changes to documents, as well as generate metrics and reports.

For more information, please visit:
SigmaAldrich.com/emprove-chemicals

Be on the safe side – with PEGs

Using PEGs is a safe decision:

PEGs are cited in the FDA's Database for Inactive Ingredients, and numerous safety reports and clinical studies have shown them to be safe for use via various routes of administration. PEGs can be found in marketed products intended for oral, topical, ophthalmic, parenteral, and many other applications. A list of adequate dosing thresholds for different PEG grades and routes is published by the FDA. Due to their excellent safety profile and good physiological tolerability, PEGs are preferable to many other polymer excipients.

Type	Route*							Dosage Form*					
	Nasl	Ophthalmic	Oral	Otic	Parenteral	Rectal	Topical	Capsule	Drops	Injection	Ointment	Suppository	Tablet
PEG 200			●	●			●	●	●		●		●
PEG 300		●	●	●	●		●		●	●	●		●
PEG 400	●	●	●		●	●	●	●		●	●	●	●
PEG 1500			●			●	●	●			●	●	●
PEG 3000			●										●
PEG 3350	●		●		●	●	●	●		●	●	●	●
PEG 4000			●		●	●	●	●		●	●	●	●
PEG 6000			●			●	●	●			●	●	●
PEG 20000			●					●					●

*Examples of PEG grades and their respective route of administration and dosage form in FDA-approved drug products. Information according to FDA Inactive Ingredients Database.

ordering information

Product Name	Physical Form	Cat. No.	Pack Size	Packaging
Polyethylene glycol 200 **EMPROVE® ESSENTIAL DAB 8, NF**	Liquid	817001.5000 817001.9025 817001.9221	5 L 25 L 220 L	PE jerrycan PE jerrycan PE drum
Polyethylene glycol 300 **EMPROVE® EXPERT Ph Eur, NF**	Liquid	817002.5000 817002.9025	5 L 25 L	PE jerrycan PE jerrycan
Polyethylene glycol 400 **EMPROVE® EXPERT Ph Eur, JP, NF**	Liquid	817003.5000 817003.9025 817003.9220	5 L 25 L 220 L	PE jerrycan PE jerrycan PE drum
Polyethylene glycol 1500 **EMPROVE® ESSENTIAL Ph Eur, NF**	Scales	817005.5000 817005.9050	5 kg 50 kg	PE bottle PE bag**
Polyethylene glycol 3000 **EMPROVE® ESSENTIAL Ph Eur, NF**	Scales	817019.5000	5 kg	PE bottle
Polyethylene glycol 3350 **EMPROVE® EXPERT Ph Eur, JP**	Scales	817045.5000 817045.9025	5 kg 25 kg	PE bottle PE bag**
Polyethylene glycol 4000 **EMPROVE® EXPERT Ph Eur, NF**	Powder	817006.5000 817006.9050	5 kg 50 kg	PE bottle PE bag**
Polyethylene glycol 6000 **EMPROVE® ESSENTIAL Ph Eur, NF**	Scales	817007.5000 817007.9050	5 kg 50 kg	PE bottle PE bag**
Polyethylene glycol 20000 **EMPROVE® ESSENTIAL Ph Eur, NF**	Scales	817018.1000	1 kg	PE bottle

** in corrugated cardboard box

Discover our formulation portfolio

Our broad range of GMP products covers pharmaceutical raw materials for the development and manufacture of solid, semi-solid, and liquid dosage forms for small and large molecules. Explore our functional excipients specifically developed for solubility enhancement, improved process efficiency, specific administration routes or release profiles. Benefit from high-quality products with a wide range of functionalities backed by stringent quality control and regulatory support.

For more information, visit:
SigmaAldrich.com/formulation

Product Finder App

Find the right product for your application with our Product Finder App at:

SigmaAldrich.com/formulationapp

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**

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice does not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

For additional information, please visit **SigmaAldrich.com**
To place an order or receive technical assistance, please visit **SigmaAldrich.com/contactAF**

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