

## Think Cognis

Cognis offers premium-quality solutions to match all needs – not only for pharmaceutical companies but also for a wide range of industrial markets.

Leading companies are using Cognis know-how to manufacture successful products all over the world. For our Nutrition & Health business we have been successful in developing a significant number of naturally derived products that are used as building blocks, excipients, active ingredients and drug-delivery agents by the pharmaceutical industry. These include high-purity oleochemicals and derivatives (Pharmaline™), azelaic acid (Dermaz® Line), phytosterols and chitosan (Chitopharm®).

With natural-source ingredients and expertise in relation to healthy nutrition, Cognis also provides products, formulations, and marketing-oriented concepts for functional food, additives, and dietary supplements – from phytosterols and plant extracts to mixed carotenoids and products for active-body composition management. Cognis is also a world-leader in the production of natural vitamin E. Our products meet the requirements both of our customers and the end users in terms of safety, performance of and convenience.

Behind all this is over 160 years of excellence in natural chemistry. Today Cognis is the world's largest producer of natural-source oleochemical basestocks.

As a marketing-oriented specialty chemicals company, we have developed an intensive understanding of our customers' markets. On this basis, Cognis develops innovative products, complete solutions, and concepts that also include marketing messages for important industrial markets, such as personal care, the cleaning products industry, food and nutrition, coatings and inks, textiles, agriculture, mining, the automotive sector and, of course, the pharmaceutical and healthcare industry.

We generate real competitive advantage for our customers in over 100 countries around the world. With a worldwide turnover of approximately € 3,37 billion in 2006, Cognis is a true global player with a presence in 30 different locations and with about 8,000 employees.

[www.cognis.com](http://www.cognis.com)  
[www.pharmaline.com](http://www.pharmaline.com)  
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## PharmaLine™

Oleochemical-derived Pharmaceutical Excipients to Pharmacopoeia Standards and IPEC – PQG GMP



**cognis.**  
 we know how

# The PharmaLine™ Range

Product purity and process integrity are the pillars of the PharmaLine™ concept.



To meet the specific needs of the pharmaceutical industry, we offer you excipients that satisfy all the relevant regulatory requirements.

PharmaLine™ – our product range of premium-quality excipients.

**EP and USP/NF (optionally JP/JPE)**

- Specifications
- Analytical Methods
- US DMF's (type IV)

**Extensive Purity Data**

- Residual Solvents
- Microbiology
- Aflatoxins
- Heavy Metals
- Polycyclic Aromatic Hydrocarbons (PAH)

**Individual Customer Service**

We are able to specify additional parameters according to individual customer requirements and to produce customized excipients



**IPEC\* – PQG\*\* GMP**

- GMP Guide for Bulk Pharmaceutical Excipients
- GMP Conformity Declaration
- Change Control Agreements
- Long-Term Contracts
- Selected Production Lines

**Distribution**

- Direct Deliveries from Cognis or
- Deliveries through an Approved Pharma Distributor

**Auditing System**

- Internal Audits and Assessments according to:
  - ISO 9001
  - ISO 14001
  - IPEC – PQG GMP

**External:**

- Customer Audits
- Questionnaires

PharmaLine™ are oleochemical-derived pharmaceutical-grade excipients such as specialty esters, fatty alcohols, ethoxylates, hard fats, stearic acids, mono- and triglycerides, castor oil derivatives etc., which are used by pharmaceutical companies in their topical, oral, parenteral and other formulations as:

- tableting aids
- solubilizers & solvents
- consistency factors
- emulsifiers
- emollients
- cream bases
- suppository masses
- moisturizers
- surfactants
- drug delivery agents

for solid, semi-solid and liquid pharmaceutical dosage forms. We are also able to produce customized excipients based on our own raw materials and chemical expertise, naturally in line with the relevant safety standards. Thanks to our excellent and constant product quality and process integrity, Cognis enhances safety right down the line.



**PharmaLine™ satisfies the most stringent requirements and complies with the latest pharmacopoeias.** We maintain our high standards through integrated quality management to ISO 9001, ISO 14001 and IPEC – PQG GMP. Our quality system defines in detail the production procedures for our excipients and monitors compliance with the relevant guidelines.

**PharmaLine™ with IPEC – PQG GMP Conformity Declaration** We obtained a conformity declaration for IPEC – PQG Good Manufacturing Practices for pharmaceutical excipients in 2006. This sets strict benchmarks in the areas of training and hygiene, pest control, cleaning of production equipment, documentation of individual process steps, traceability of intermediate products and raw materials, and supplier auditing. This saves our customers from having to carry out numerous individual audits.

**Extensive purity data** covering microbiology, aflatoxins, heavy metals, polycyclic aromatic hydrocarbons, etc. as well as US Drug Master Files (type IV) are available.

**We practice comprehensive quality management to achieve consistently high standards.** All production methods and processes are documented, and finished products are subjected to intensive testing. Through our equipment and safety-conscious, highly trained employees we comply with relevant regulations. We offer you pharmacopoeia-compliant analytics.

**Shipment is made directly by Cognis or through an approved distributor.** This is how we fulfill our own stringent safety specifications, from raw material and packaging through storage, logistics and delivery.

\* IPEC = International Pharmaceutical Excipients Council  
 \*\* PQG = Pharmaceutical Quality Group