Efficacy and Safety: natural MK7 overview

vitaMK7® fermented vitamin K2 as MK7 and the importance of high purity for safety and stability
Naturalness of Gnosis vitaMK7

It is almost two decades since Gnosis launched a first production of vitamin K2 as Menaquinone-7 (MK7), by employing a unique natural microbial source: the bacteria Bacillus subtilis natto.

Its millennial impact on human wellness through consumption of natto food, obtained by spontaneous natural fermentation of soybeans by this bacteria, actually defined its current scientific taxonomic name**.

Peculiarly, at the very beginning of defining modern microbiology, the MK7 itself has been used as one of the first compounds to accurately identify and classify the Bacillus genus, distinguishing it unmistakably among other bacterial species producing other vitamin K like compounds**.

In order to maintain naturalness of vitamin K2, the Gnosis production platform is based on industrial fermentation process***, by using a highly purified natural microbial strain of the B. subtilis natto, grown under strictly controlled conditions following rigorous rules higher than those prescribed by ICH guidelines, allowing it to express its specific evolved naturally occurring biochemical features, including a unique and reliable tool for natural product processes long-term stability and controlled biological techniques.

MK7 is actively absorbed by the organism and plays a role mainly in the extrahepatic tissues in supporting cardiovascular and bone health. Overall, data are not present to support a cooperative or synergistic effect of vitamin MK7 with the other menaquinones - like MK6, MK8 and MK9 - that are practically inactive.

All the clinical trials were performed with vitamin K2 as MK7 from Bacillus subtilis natto (minor extent of MK6) as it is present in the natto food.

**PURITY PROFILE, MUCH MORE CRITICAL THAN OFTEN BELIEVED

MK7 supplementation can last for a variable period, from a few months to several years.

The purity profile of MK7 ingredient, its content of all-trans isomer and the related impurities, represent the first factors of choice of end-manufacturers and consumers for an effective and safe MK7 supplementation.

High levels of impurities, very frequently unknown, are common in some kind of MK7. Their long-term effects given by exposure to these unknown impurities do not generally have a clear evaluation of their safety on humans over the time.

This is why Gnosis is extremely rigorous to deliver vitamín K7 from natto food the most pure. It is almost two decades since Gnosis launched a first production of vitamin K2 as Menaquinone-7 (MK7), by employing a unique natural microbial source: the bacteria Bacillus subtilis natto.

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Unlike other microbes, the Bacillus genus, especially Bacillus subtilis natto, employs specific naturally evolved enzymatic pathways where almost exclusively heptaprenyl pyrophosphate unit is incorporated into the menaquinone structure. This genus specific heptaprenyl incorporation, represents "an undistinguishable natural signature" of vitamin K2 (MK7) produced by the B. subtilis natto, and was recognised by Gnosis scientists as the starting point of setting up vitamin K2 production platform.

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<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>All-trans MK7</th>
<th>Known other compounds</th>
<th>Unknown impurities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gnosis</td>
<td>99.27%</td>
<td>0.18%</td>
<td>0.56%</td>
</tr>
<tr>
<td>Synthetic commercial microencapsulated</td>
<td>92.73%</td>
<td>1.40%</td>
<td>0.00%</td>
</tr>
<tr>
<td>Other fermented derived MK7</td>
<td>93.67%</td>
<td>0.31%</td>
<td>2.50%</td>
</tr>
</tbody>
</table>

Gnosis development of vitaMK7® has aimed to achieve highest purity (all-trans active isomer >99%) and almost no impurities. The purification technologies implemented meet market demand for a "more green" ingredient, with no trace of unidentified impurities.

A pure and stable MK7 ingredient minimizes cross-reactions with other ingredients/excipients included in the formulation during the shelf-life of the product, for 360 degrees quality.

On the contrary, as shown by the analysis carried out, both poor fermentation- and synthetic-derived MK7 are characterized by a large number of unknown impurities with an unknown toxic evaluation and a proper risk-benefit analysis.

**Current taxonomy is based upon sequencing of specific DNA regions in order to classify living organisms, but poor discovery of DNA and subsequent difficulty of modern techniques for its sequencing naturally occurring biochemical reactions within living cells, it has been used as a criteria of classification including classification of the biosynthesis of the different menaquinones.

***In a trail leading to the discovery of vitamin K2 (MK7) and its application for human use, scientists had to overcome the habit of relying on chemical synthesis. Now with the success of Fermentation Technology and Microbiology, a direct connection is established between the concepts of "Naturals Products", as substances produced by living organisms (first of all microorganisms) and "Natural Products", as substances produced by living organisms (first of all microorganisms).

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![Graph showing purity and impurity profile of different fermentation- and synthetic-derived MK7](image-url)
**VitaMK7®** is the unique European fermented vitamin K2 as MK7, produced by Gnosis proprietary patented biofermentation process of *Bacillus subtilis* spp natto, in its own European cGMP manufacturing site.

With more than 10 years of production, we are able to offer the same qualified MK7 raw material because we are the direct manufacturer, with no intermediates or brokers.

The entire supply chain, from the raw material to the finished large range of vitaMK7® powder/oil grades, is tightly controlled and carried out in compliance with the rules of Gnosis’ Quality Management System QMS’s, ISO and HACCP quality systems.

**ENTER OUR FACTORY AND TOUCH THE QUALITY AND THE SAFETY WITH YOUR HAND**

Gnosis works with transparency and offers you the opportunity to control every step of the manufacturing process of the vitaMK7® products, to enable you to understand how we can achieve such a pure, stable, safe, high quality source of vitamin K2 as MK7, suitable also for people with dietary restrictions.

Our customers are invited to visit our approved cGMP plant of 133,000 square meters and view the entire production process that leads from the raw material to our vitaMK7® products.

**DISCOVER GNOSIS EXPERIENCE ON VITAMIN K2**

Whether you want to know more or still feel sceptical, do not hesitate to visit our plant and talk to our experts.

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