



**Request for the authorization of a phospholipase D preparation
from *Streptomyces violaceoruber* pPDN
for use as a food processing aid
From NAGASE CHEMTEX CORPORATION**

**PUBLIC NOT CONFIDENTIAL SUMMARY
OF THE DOSSIER**

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1 Scope of the application

The present dossier documents the compliance of the phospholipase D preparation produced by *Streptomyces violaceoruber* pPDN with the criteria laid out in Regulation (EC) 1332/2008 on food enzymes, i.e.:

- the food enzyme is safe for consumers in its intended uses;
- it fulfils a reasonable technological need in food processing;
- its use does not mislead consumers.

2 Existing authorizations of the food enzyme

The phospholipase D preparation from *Streptomyces violaceoruber* pPDN has never been authorized in Europe. Currently, the phospholipase D preparation is only approved in Japan.

3 Enzyme identification

Phospholipase D is chemically identified as phosphatidylcholine phosphatidohydrolase with the following registry numbers: EC 3.1.4.4 and CAS RN: 9001-87-0.

The enzyme catalyzes the hydrolysis of phosphatidylcholine into phosphatidic acid and choline and/or the transphosphatidylation of phosphatidylcholine into phosphatidylserine.

The phospholipase D preparation has been fully characterized and amino-acid sequence, molecular weight, substrate specificity, inhibitors and activators, optimal conditions and stability during storage are available.

The specifications of the phospholipase D preparation comply with the FAO/WHO recommendations.

4 Production method

The production strain is a self-cloned denominated *Streptomyces violaceoruber* pPDN. It is not genetically modified. Number of species of the genus *Streptomyces* are used and authorized over the world to produce food products including processing aids. No pathogenicity or antibiotics resistance were found in the literature. Thus, the source organism is considered safe.

The whole production process is run according to the requirements of the European Food Law and Food Hygiene Regulation. It also complies with the Japanese Food Sanitation Law on food additives requesting quality assurance certification, good manufacturing practices, HACCP analyses and control measures.

5 Intended uses in food production

The phospholipase D preparation is typically used in phosphatidylserine rich lecithin production and meat processing.

In meat, phospholipase D catalyzes the hydrolysis of phosphatidylcholine into phosphatidic acid and choline. The resulting phosphatidic acid inhibits the bitter taste caused by free peptides.

In phosphatidylserine rich lecithin lecithin production, phospholipase D produces phosphatidylserine from phosphatidylcholine by transphosphatidylation. The resulting phosphatidylserine is a food ingredient approved in EU for special medical purposes.

6 Studies on safety

The phospholipase D preparation was subjected to several toxicological studies to confirm its safety for consumers. Mutagenicity and clastogenicity studies showed that the food enzyme does not have the potential to damage the genetic material of living organisms, including mammals. The repeated administration oral toxicity study showed that the food enzyme does not exhibit signs of toxicity, up to doses that are around three hundreds' times higher than those which are consumed via food.

Studies also demonstrated that the phospholipase D preparation could not be considered as allergenic.

7 Conclusions on the safety of the food enzyme

Based on the safety of the production organism, on the quality of the production process, on the results of the toxicological studies, and on its long history of use in the Japanese food industry, it is concluded that the phospholipase D preparation object of this dossier is safe in its intended uses.

8 The use of the enzyme will not mislead the consumers

The effect of the phospholipase D is the hydrolysis of phosphatidylcholine into phosphatidic acid and choline.

The phospholipase D preparation does not perform any technological function in meat or final food products containing lecithin prepared with the help of this enzyme.

The phospholipase D preparation has been used for the above described technological function in food processes for many years in Japan.

Considering the above, there are no reasons to believe that the use of the phospholipase D preparation in food processing could be misleading for the consumer.