

PureNis™: Natural Preservative for Egg Products and Egg-Based Preparations

An antimicrobial solution based on nisin (E 234) for microbiological control in sensitive matrices within the egg product sector and other egg-based preparations.



Product Definition

PureNis™ is a natural antimicrobial preparation based on **nisin (E 234)**, a bacteriocin produced by *Lactococcus lactis* subsp. *lactis*. The product is formulated on a food carrier (salts and/or carbohydrates) for use as a preservative in sensitive matrices within the egg product sector.

Intabiotech produces this product following a patented formula through an exclusive and unique biotechnological process, providing this product with technical characteristics that make it far superior to conventional nisins.

Main Applications

- Pasteurised liquid egg products
- Omelettes and prepared egg-based dishes
- Cooked eggs and ready-to-eat egg products
- Sauces and emulsions such as mayonnaise/lactonese containing egg



Microbiological Control

Effective against spoilage and pathogenic Gram-positive flora, especially *Listeria monocytogenes*, *Bacillus cereus*, and other spore-forming bacteria

Shelf-Life Extension

Extends preservation under refrigeration with appropriate packaging, optimising the distribution chain

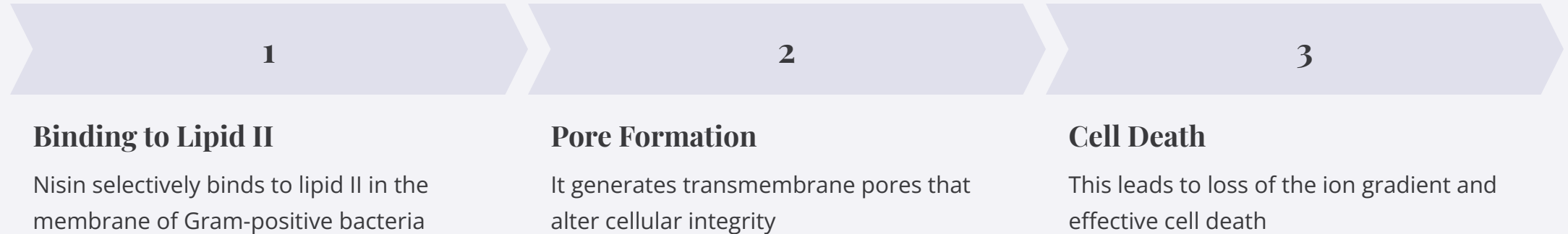
Clean Label

Fits clean label strategies as it is declared as nisin (E234) from natural fermentation

Technical Note: The operational doses in kg/tonne of PureNis™ should be calculated based on the active nisin content specified in the product's commercial technical data sheet.

Mechanism of Nisin Action

Nisin is a **thermostable cationic polypeptide** with a specific and highly effective mechanism of action against Gram-positive micro-organisms.



Spectrum of Activity

Highly effective against:

- *Listeria* spp., especially *L. monocytogenes*
- *Bacillus* spp., including *B. cereus*
- *Clostridium* spp. and other spore-forming bacteria
- Inhibition of spore germination and outgrowth

Limited activity against Gram-negative bacteria, which can be improved by combination with low pH, **ACETIPRO™** or **PreserFood™** **UOVO** or treatments that alter the outer membrane.

Key Efficacy Factors

pH Influence: Higher activity at acidic pH (optimum 3.5–5.5). Efficacy remains relevant up to pH ~6 in certain matrices with adequate dosage and combined hurdles.

Thermal Stability: Resistant to common pasteurisation treatments. It may be partially inactivated in very severe processes, but maintains sufficient residual efficacy if correctly proportioned.

Regulatory Framework in the European Union

Nisin is authorised as a preservative additive **E 234** in the EU according to Regulation (EC) 1333/2008 and derived legislation, for specific food categories. *Note: Post-Brexit, the EU regulations are retained in UK law, with specific UK implementing legislation and guidance.*

01

Base Authorisation

Regulation (EC) 1333/2008 establishes the legal framework for the use of nisin as a preservative in defined food categories (cheeses, creams, desserts, specific applications).

02

Safety Assessment

EFSA has confirmed nisin's safety with an established ADI, supporting its use and extension to new food categories.

03

Liquid Egg Products

Specific authorisation for pasteurised liquid egg products (cat. 10.2) with maximum levels historically defined up to 6.25 mg/L.

Practical Implications for PureNis™

Pasteurised Liquid Egg Products

Direct use covered under category 10.2, respecting applicable maximum levels and labelled as E234 when it has a technological function in the final product.

Tortillas and Ready-to-Eat Dishes

Can benefit from the **carry-over** principle when nisin is legally incorporated into the base egg product and maintains technological function in the overall product.

- ❏ **Conditions for carry-over:** Use must be technologically justified (control of *Listeria/Bacillus* and safety in chilled RTE products), respecting the conditions and categories of use of the additive in the original ingredient and in the final product. Product classification and regulatory fit in the country of destination must be reviewed on a case-by-case basis.

Key Documentation for Control Recommendation:

- Technical and safety data sheet for PureNis™
- Technological justification for use
- Shelf-life studies and challenge tests
- Labelling in accordance with 1333/2008 + 1169/2011

Application in Chilled Tortillas

Target Microbiological Risks

Listeria monocytogenes

Post-processing contamination with potential growth during chilling in ready-to-eat products.

Bacillus cereus and Spore-forming Bacteria

Survivors of heat treatment with possible germination during chilled storage.

Gram-positive Spoilage Flora

Micro-organisms that shorten shelf life and compromise the product's sensory quality.

PureNis™ Application Strategy

The incorporation of **PureNis™** into the egg batter before setting allows for effective and homogeneous microbiological control throughout the product matrix.

Target Dosage

As active nisin in the egg phase: typically **2.5–6.25 mg/kg** of egg product, adjusting according to:

- Final pH of the tortilla
- Intensity of the heat treatment applied
- Target shelf life (e.g. 25–40 days at 0–4 °C)
- Presence of other technological hurdles (PreserFood™ UOVO, buffered vinegar, modified atmosphere, water activity)

Technological Advantages

- Significant reinforcement against *Listeria* in RTE products
- Reduction of risk associated with *B. cereus* in combination with validated heat treatment
- Low sensory impact: active at very low concentration
- No modification of colour, flavour or texture

Recommended Best Practices

- 1** Maintain formulation pH at the lower limit of the usual range where possible (slight controlled acidification improves efficacy)
- 2** Implement vacuum packaging or modified atmosphere packaging (MAP) combined with strict cold chain management
- 3** Validate through counts of mesophiles, psychrotrophs, enterobacteria, *Listeria* spp. (absence) and specific challenge tests
- 4** Monitoring of *B. cereus* with enumeration and toxin analysis where appropriate according to risk profile

Pasteurised Liquid Egg Products



Specific Applications

- Whole liquid egg, albumen, and yolk
- Blends for industrial omelettes
- Bases for sauces and emulsions
- Ingredients for the food industry

Application Objectives



Extend Shelf Life

Significant extension of the storage period under refrigeration



Control of Spore-Forming Bacteria

Inhibition of residual Gram-positive flora and spore-forming bacteria surviving pasteurisation



Microbiological Quality

Maintenance of microbiological standards throughout the product's shelf life

PureNis™ Application Protocol

Dose sizing to comply with the maximum regulatory level of nisin in liquid egg (historically up to **6.25 mg/L**; check updates to Annex II of Regulation 1333/2008). Note: For the UK, refer to retained EU law and relevant Food Standards Agency guidance post-Brexit, with the necessary periodicity to remain within the permitted standard.

1

Time of Addition

Preferably before or immediately after pasteurisation

2

Homogenisation

Homogeneous agitation to ensure uniform distribution throughout the product mass

3

Verification

Control of dosage and homogeneity through representative sampling

Achieved Technological Benefits

- Reduced risk of microbiological swelling
- Prevention of coagulation and quality defects
- Reduction of losses due to premature spoilage
- Secure platform for subsequent processed products
- Reliable base for omelettes, cooked egg products, and sauces
- Optimisation of the supply chain

Cooked Eggs and Ready-to-Eat Egg Products

Cooked egg-based ready-to-eat (RTE) products present specific risks of surface recontamination, requiring differentiated control strategies.

Application Examples

Peeled Hard-Boiled Eggs in Brine

Packaged in a covering liquid that allows for the homogeneous incorporation of PureNis™

Vacuum Packaging

Peeled eggs packaged individually or in groups for direct use in foodservice

Egg Products for Salads

Refrigerated products ready for incorporation into salads, sandwiches, and prepared dishes

PureNis™ Application Methods

1

Incorporation into Brine

When an aqueous covering phase exists, PureNis™ is incorporated directly into the solution, allowing gradual penetration towards the egg surface.

2

Surface Treatment by Immersion

Product bathing in a solution with a controlled concentration of PureNis™ prior to final packaging.

3

Spray Application

Atomisation of the antimicrobial solution onto the product surface using calibrated nozzles.

Common Objective: To maintain an effective concentration of nisin at the product-environment interface, where potential post-process recontamination may occur.

Benefits of Surface Treatment

- Effective control of Gram-positive flora on the surface
- Significant reduction in the risk of *Listeria* in RTE products
- Specific protection in critical recontamination areas
- Compatibility with other preservation systems



Egg-Based Sauces and Emulsions



Applications in Emulsions

- Traditional and light mayonnaise
- Lactonesa (dairy-based mayonnaise)
- Emulsified sauces for foodservice
- Egg-based fillings and creams
- Creamy dressings and condiments

Ideal in combination with our CultraDex™ product in cases where additional or high-profile effectiveness, efficiency, and efficacy protection is required.

Egg-based sauces and emulsions present particularly favourable conditions for the action of **PureNis™** due to their characteristically acidic pH, which enhances the antimicrobial activity of nisin.

Advantages of the Acidic Environment

Naturally Optimal pH

The typical pH of mayonnaise and emulsified sauces (3.5–4.5) coincides with the optimal activity range of nisin, maximising its efficacy

Synergy with Acidulants

The organic acids present (acetic, citric, lactic) enhance antimicrobial action through complementary effects

Stability in Matrix

Nisin maintains its activity for an extended period in these formulations, providing long-lasting protection

Recommended Application Protocol

Dose Adjustment

Dose to achieve **1–12.5 mg/kg of active nisin** according to the final pH, water activity, and target shelf-life of the product

Homogenisation

Process the emulsion according to standard protocol, ensuring uniform distribution of nisin throughout the matrix

Addition Time

Add PureNis™ to the aqueous phase before forming the emulsion, ensuring complete dispersion through agitation

Efficacy Verification

Perform microbiological controls and shelf-life studies to confirm the level of protection achieved

Results Obtained

Microbiological safety: Effective reinforcement against *Listeria* and Gram+ spoilage flora, critical in high-risk chilled products.

Preserved sensory quality: No appreciable impact on flavour, colour, or texture at authorised doses, maintaining consumer acceptance.

Technological Synergies: Multi-Barrier Strategy

PureNis™ achieves maximum efficacy when integrated into preservation strategies based on multi-barrier technology (hurdle technology), allowing for the reduction of the intensity of each individual factor while maximising overall safety and shelf-life.

Recommended Synergistic Barriers



Moderate pH Reduction

Incorporation of organic acids or buffered vinegar (**ACETIPRO™**) which enhance nisin activity and provide their own antimicrobial effect.



Lactate/Acetate Salts (**PreserFood™ M-Egg**)

Where legally applicable, these enhance the control of *Listeria* and other pathogens by altering microbial metabolism. (Note: Current EU regulations apply, with similar principles generally followed in UK food law.)



Water Activity Control

Adjustment using salt, sugars, or soluble solids that limit water availability for microbial growth.



Validated Thermal Treatments

Gentle yet effective pasteurisation processes that reduce initial microbial load without compromising sensory quality.



Protective Packaging

Vacuum or modified atmosphere packaging that limits available oxygen and slows down aerobic spoilage processes.



Other INTABIOTECH Solutions

Combination with **PreserFood™ UOVO** for minimalist SKU schemes with high microbiological robustness.

Advantages of the Synergistic Approach

1

Optimisation of Dosage

Reduction in the required amount of each individual factor, lowering costs and potential sensory impacts.

2

Superior Sensory Profile

Lower individual impact of each technology allows for the maintenance of optimal organoleptic characteristics.

3

System Robustness

Greater resistance to specific process deviations or cold chain issues, increasing overall safety.

Technical Validation and Documentation

Successful implementation of **PureNis™** requires a robust validation and documentation programme to support both technical efficacy and regulatory compliance.

Recommended Validation Programme

Shelf-Life Studies

Evaluation under real process, packaging, and distribution conditions, simulating the entire chain from manufacture to consumption.

Periodic Verification

Continuous monitoring of critical parameters and treatment homogeneity in industrial production.

1

2

3

Targeted Challenge Tests

Controlled inoculation of target pathogens to demonstrate specific antimicrobial efficacy.

Specific Challenge Tests

Listeria monocytogenes in RTE tortillas and cooked egg products:

- Inoculation at 10^2 - 10^3 CFU/g
- Monitoring for shelf-life + 50%
- Demonstration of no growth or reduction

Bacillus cereus and other spore-forming bacteria in liquid egg and tortillas:

- Evaluation of germination inhibition
- Control of post-heat treatment outgrowth
- Verification of safe levels during preservation



Periodic Verification Parameters

Physicochemical Parameters

- pH of the final product
- Water activity (aW)
- Storage temperature

Dosing Homogeneity

- Distribution of PureNis™ in the matrix
- Concentration at critical points
- Stability during processing

Microbiological Controls

- Indicator counts (mesophiles, psychrotrophs)
- Specific pathogens
- Spoilage flora

Essential Regulatory Documentation

01

Technological-Legal Report

Comprehensive justification for the use of nisin (E234) including scientific basis, technological need, and regulatory support.

02

Compliance with Categories 1333/2008

Demonstration of compliance with authorised categories, maximum levels, and specific conditions of use. (Note: Post-Brexit, UK regulations for food additives largely mirror EU Regulation 1333/2008, but specific UK guidance should be consulted for full compliance).

03

Application of Carry-Over Principle

Where applicable, documentation of the carry-over principle from ingredient to final product with maintenance of technological function.

04

Labelling Compliance

Verification of requirements according to EU Regulations 1333/2008 and 1169/2011, including correct declaration of E234 and any voluntary mentions. (Note: Post-Brexit, UK food information regulations, including labelling, largely mirror EU Regulation 1169/2011, but specific UK guidance should be consulted).

Conclusion: Strategic Value of PureNis™

PureNis™ represents a comprehensive, scientifically validated, and regulatory sound solution that addresses critical needs for safety, quality, and commercial positioning in the egg products and processed egg sector.

3

Strategic Pillars

Safety, Shelf Life, and Clean Label

25-40

Days of Shelf Life

Typical extension in chilled omelettes

6.25

mg/L Maximum Regulatory Limit

In liquid egg products (EU). Similar limits apply in the UK under retained EU law.

Value Proposition for INTABIOTECH and Industrial Clients



Enhanced Food Safety

Effective control of *Listeria monocytogenes* and spore-forming bacteria (*Bacillus cereus*, *Clostridium* spp.) in omelettes and processed egg products, significantly reducing microbiological risk in ready-to-eat products.



Extended Shelf Life Under Refrigeration

Significant prolongation of the storage period without compromising the sensory profile, optimising logistics, reducing wastage, and expanding commercial distribution reach.



Integration into Clean Label Strategies

Positioning as a natural preservative (fermented E234) that responds to consumer demand for recognisable ingredients, technically and regulatory supported for responsible commercial argumentation.

- 📄 **INTABIOTECH Commitment:** Comprehensive technical support including dosage dimensioning, validation of specific applications, regulatory documentation, and accompaniment in the development of new products with PureNis™.

The adoption of PureNis™ enables the egg product industry to advance towards higher food safety standards while maintaining sensory excellence and responding to market trends towards more natural and transparent formulations.

PureNis™

Natural Shelf-life for your products.