SPECIFICATION OF NISIN

M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)	FINESHED PRODUCT INFORMATIONS
QUALITY CONTROL AND ASSURANCE	PRODUCT : NISIN (Class II Preservative)
MSDS no. BPPL 119 (Available on Request)	SPECIFICATION NO. FP- 119 (Enclosed)

1.	**NOMENCLATURE**	**:**	Nisitrol.
2.	**CAS NO.**	**:**	1414-45-5
3.	**HS CODE NO. (ITC CODE)**	**:**	29419090 / 29389000
4.	**EMPIRICAL FORMULA**	**:**	$C_{143}H_{228}O_{37}N_{42}S_7$
5.	**MOL. WT.**	**:**	3348.00
6.	**STRUCTURAL FORMULA**	**:**	A Mixture of closely related Antimicrobial Polypeptides , 34 Amino Acid peptides, with characteristic Lanthionine Rings.
7.	**DESCRIPTION**	**:**	Whitish to light Brownish, Micronized Powder
		:	Soluble in Water (50 mg. /ml.) ;
8.	**STORAGE**	**:**	NISIN can be stored at Ambient temp.
		:	It is stable for more than two years from the date of manufacture when stored in the original container, in dry conditions, at 4° C – 25° C and away from Direct Sunlight and Ultra- Violet light.
		:	Keep it tightly closed and stored in cool, Dry and Shady place.
9.	**SHELF LIFE**	**:**	2 Years

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QUALITY CONTROL AND ASSURANCE	PRODUCT : NISIN **(Food Preservative)**
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1.	**DESCRIPTION**	**:**	Whitish to light Brownish, Micronized Powder.
2.	**SOLUBILITY**	**:**	Soluble in Water (50 mg. /ml.) ;
3.	**NISIN CONTENT** (Assay)	**:**	≥ 1150 (IU / mg.)
4.	**LOSS ON DRYING** (Moisture Content)	**:**	NMT 3.0%
5.	**HEAVY METALS**	**:**	NMT 0.002% (20 ppm)
6.	**LEAD CONTENT**	**:**	NMT 2 ppm
7.	**CARRIER** (Sodium Chloride)	**:**	Min. 50%
8.	**ARSENIC**	**:**	NMT 0.0001% (1 ppm)
9.	**PROTEIN**	**:**	Min. 15%
10.	**CARBOHYDRATE**	**:**	Max. 4%
11.	**MICROBIAL LIMIT TEST**	**:**	
	Total Colony Count	**:**	NMT 10 CFU / gm.
	Staphylococci	**:**	Negative.
	E. Coli	**:**	Negative in 25 gms.
	Salmonella	**:**	Negative in 25 gms.
	Listeria	**:**	Negative .
12.	**PACKING**	**:**	500 gms. / 1000 gms Plastic Bottle
		:	10 Bottles / Case
		:	20 Bottle / Case
		:	15 Kgs. / 25 Kgs. Fibre durms.

STABILITY OF NISIN

NISIN IS MOST STABLE UNDER ACIDIC CONDITONS.
THE ACTIVITY IS LOST IN HIGHLY ALKALINE CONDITIONS.

Refer the Table below

MEDIUM	REMARK
pH = 2.0	It can keep the activity intact after the treatment at 121 °C temp. for 30 Min. at pH = 2.0
pH = 3.0	Nisin is dissolved in HCL by 121 °C to sterilize for 15 Minutes. No activity is lost.
pH = 5.0	At 115.6 °C temp. to Sterilize. 40% activity is lost.
pH = 6.5	Nisin is dissolved in skimmed milk by 85° C temp. to pasteurize for 15 Minutes. 15 % Activity is lost.
pH = 7.0	At this period , 90 % activity is lost.
pH = 11.0	Activity is lost completely in 30 Minutes at 63 °C temp. in pH = 11.0

SOLUBILITY AND ACTIVITY

SOLVENT	SOLUBILITY	ACTIVITY
Distilled Water (pH = 5.9)	50.0 (mg. / ml.)	2.0×10^6
Domestic Water (pH = 7.10)	49.0 (mg. / ml.)	1.96×10^6
HCL Solution (0.02 N)	118.0 (mg. / ml.)	4.72×10^6
NaCl Solution (2%)	47.9 (mg. / ml.)	1.91×10^6
Non – Fat Milk	87.5 (mg. / ml.)	3.5×10^6

NOTES :
1. Nisin can be dissolved in Aqueous solution.
2. It is Insoluble in non-polar solvents.
3. The solubility decreases with in increase of pH , and it increases with the rise of temp.

ADVANTAGES OF NISIN

a) The use of NISIN, as a Food Preservative, can

- Greatly **decrease the required Temperature,**
- **Shorten the time in Food Heat processing**,
- It **improves** the **Nutritional value**, Appearance, Flavor and Texture of foods, and significantly **prolong the Shelf-life**.
- It also **saves the Energy** greatly and **lower the product and Production cost.**

b) Now, **NISIN** has been **used in a wide range of Processed foods**, e.g. Cured meat, Dairy products, Plant protein Foods, Canned foods, and Heat-treated/Air-tightly packed foods etc.

c) It can also be used in the **Area of Cosmetics, Medicines and Health products.**

d) It **can replace** or partial replace chemical preservatives and meet consumer demand for Food preserved with Natural Ingredients.

e) It is **Non-Toxic**, the producer strains of L. Lactis are regarded as safe (Food Grade).

f) It is used **alone** or in **combination** with other preservatives e.g. Benzoic Acid, Sorbic Acid and Potassium Sorbate.

DIRECTION OF USAGE

About 5% Aqueous solution is prepared firstly with cold Boiled water or Distilled water (best with diluted acid solution), then, instantly put it into food and stirred well. Or put it directly into food and stirred well.

RECOMMENDED DOSAGE

The general dosage is 0.05 gm / kg. to 0.1gm / kg.

The detail dosage of NISIN depends on End products, Raw material's Quality, Nature of the processes, Shelf Life of End Products and Storage conditions of End Products etc.

APPLICATIONS OF NISIN

NISIN , as an effective **Natural Food Preservative**, can be used in a number of Foods under the permission by local legislation.

Some of the applications of NISIN are listed as follows:

01	**Dairy Products**	**06**	**Meat Products and Marine Products**
02	**Plant Protein Foods**	**07**	**Canned Foods**
03	**Fruit Juice Drinks**	**08**	**Liquid Egg and Egg-Contained Products**
04	**Alcoholic Beverages**	**09**	**Salad Sauce And Dressings**
05	**Sealed Foods With Heat Process**	**10**	**Packed Coconut Water & Idli Batter**

IMPORTANT POINTS TO REMEMBER DURING APPLICATIONS

1. NISIN can **inhibit** the **Gram-positive bacteria**, but has **no action** on **Gram-negative bacteria, Yeasts and Moulds.**

   The usage of NISIN combined with other food preservatives will increase the effect when the products contaminate Gram-negative Bacteria, Yeasts and Moulds.

2. The effect of NISIN, as a Food Preservative is affected by the factors below:

a) **The type of products:** The contaminated microbes vary in products, and NISIN possesses different inhibiting action on different microbes.

b) **The degree of pollution and environment conditions:** The deeper of pollution and the poorer of environment conditions, the more the NISIN should be used. And the usage of NISIN will not be effective for the rotten products.

c) **The pH of products:** NISIN is effective with a wide range of pH level (3.5--8.0). It is stable at low pH value.

d) **The Moisture, Fat and Salt in the products:** the products with high moisture, high fat and low salts will need more usage of NISIN.

e) **The types of flavor additives:** The mixture of oxidizing flavor additives can decrease the effect of NISIN .

f) **The process and the package materials:** The appropriate process and the cleaned package materials will optimize effects for the usage of NISIN.

g) **The homogeneous degree of the mixture of the product and NISIN**: The parts of the product without touch with NISIN are not effective .

h) The amount of NISIN used varies with **Storage Temperature** and the **Shelf life.**

APPROVAL OF NISIN

REGULATIONS: CODEX STANDARDS

NISIN is currently included as a preservative in the following Codex Standards:

1) **Codex Standard A-8(a)**
Codex General Standard for Named Variety **Processed Cheese** and
Spreadable Processed Cheese.

2) **Codex Standard A-8(b)**
Codex General Standard for **Processed Cheese** and
Spreadable Processed Cheese.

3) **Codex Standard A-8(c)**
Codex General Standard for Processed Cheese Preparations, Processed Cheese Food and **Processed Cheese Spread**.

4) **Codex Standard A-6**
Codex General Standard for Cheese

5) The maximum Level of NISIN permitted in all of these standards is 12.5 mg/kg (12.50 ppm).

NISIN is approved as a preservative in specific foods in a number of countries and jurisdictions including the

- **European Union** (e.g. 12.5 mg/kg in cheese),
- **USA** (a **GRAS** (generally recognized as safe) notice),
- **China** (500 mg/kg in meat products) and
- **MERCOSUR** countries (Argentina, Brazil, Paraguay, Venezuela and Uruguay) (e.g. 12.5 mg/kg in cheese).
- **India**, as per **FSSAI** rules, 12.5 ppm in Cheese and Processed Cheese.