

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

1. **NOMENCLATURE** : Nisitrol .
2. **CAS NO.** : 1414-45-5
3. **HSN CODE** : 29181190
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 peptide with characteristic Lanthionine rings.
7. **DESCRIPTION** : Whitish to light Brownish, Micronized Powder.  
: Soluble in Water (50 mg. /ml.) ;  
: 118 mg / ml. in 0.02 M HCL  
: 47.9 mg / ml. in skimmed milk .  
: 87.5 mg. / ml. in non – fat milk .  
: 47.9 mg. / ml. in 2% NaCl Solution.  
: Insoluble in non – polar solvents.
8. **APPLICATIONS** : NISIN is used as a Food preservative in a number of Thermal processed foods, particularly in Dairy products, Canned foods, Plant protein Foods and Cured Meat products and Marine Products.  
: Beer & related Products.  
: Liquid Egg and Egg Contained Products.  
: Processed fruits and vegetables.  
(Tomato Products (Juices) Ph <4.5).  
: Alcoholic Beverage .

<b>M/S. BIMAL PHARMA PVT. LTD . MUMBAI (INDIA)</b>	<b>FINISHED PRODUCT PHARMACOPOEIAL SPECIFICATIONS</b>
QUALITY CONTROL AND ASSURANCE	PRODUCT : NISIN <b>(Food Preservative)</b>
MSDS no. BPPL 119 (Available on Request)	SPECIFICATION NO. FP- 119

1. **DESCRIPTION** : Whitish to light Brownish, Micronized Powder.
2. **SOLUBILITY** : Soluble in Water (50 mg. /ml.) ;  
: 118 mg / ml. in 0.02 M HCL  
: 47.9 mg / ml. in skimmed milk .  
: 87.5 mg. / ml. in non – fat milk .  
: 47.9 mg. / ml. in 2% NaCl Solution.  
: Insoluble in non – polar solvents.
3. **NISIN CONTENT** :  $\geq 1150$  (IU / mg.)  
(Assay)
4. **LOSS ON DRYING** : NMT 3.0%  
(Moisture Content)
5. **HEAVY METALS** : NMT 0.002% (20 ppm)
6. **LEAD CONTENT** : NMT 2 ppm
7. **CARRIER** : Min. 50%  
(Sodium Chloride )
8. **ARSENIC** : NMT 0.0001% (1 ppm)
9. **PROTEIN** : Min. 15%
10. **CARBOHYDRATE** : Max. 4%

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**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 .

<b>12. PACKING</b>	:	100 gms. / 250 gms Aluminium Foil Bags
	:	500 gms. Plastic Jar
	:	1000 gms. (1.0 Kg) Plastic Jar
	:	10 Bottles / Case
	:	20 Bottle / Case
	:	15 Kgs. / 25 Kgs. Fibre durms.

<b>13. STORAGE</b>	:	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 .

<b>14. SHELF LIFE</b>	:	2 Years
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## STABILITY OF NISIN

**NISIN IS MOST STABLE UNDER ACIDIC CONDITIONS.  
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

### The Relations of pH Value and NISIN Activities

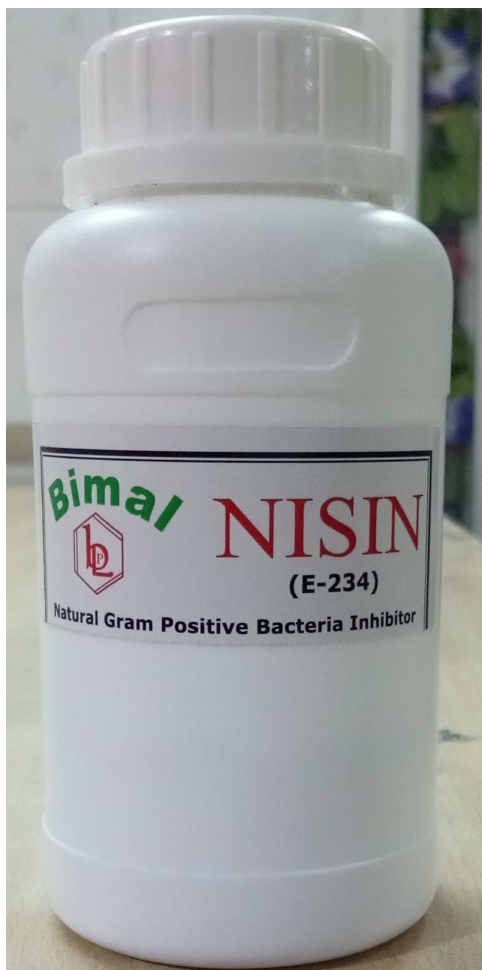
pH	IU / mg
02.4	1032
03.0	995
04.0	944
05.0	608
06.0	475
07.0	355
08.0	242
09.0	195
10.0	125
11.0	21
12.0	00

**Note:** Above Results obtained after 24 hrs of adjusting pH

# SOLUBILITY AND ACTIVITY

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

- 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.



**R & D Packing  
100 Gms**



**Commercial Packing  
500 gms / 1000 gms**