



M/s. Bimal Pharma Pvt. Ltd., Mumbai, India
(ISO 9001 : 2015 & AEO T1 Certified Co.)



URS : UKAS

M/S. BIMAL PHARMA PVT. LTD. MUMBAI (INDIA)	FINISHED PRODUCT INFORMATION
QUALITY CONTROL AND ASSURANCE	PRODUCT : NISIN, E -234 (Food Preservative)
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** :
 - : Very Slight Brownish to White Powder, 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.

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: Insoluble in non – polar solvents.
3. **NISIN CONCENTRATION** : ≥ 1150 (IU / mg.)
(IU / mg)
4. **CARRIER** : Min. 50%
(Sodium Chloride)
5. **LOSS ON DRYING** : NMT 3.0%
(Moisture Content)
6. **HEAVY METALS** : NMT 0.001% (10 ppm)
7. **LEAD CONTENT** : NMT 1 ppm
8. **ARSENIC** : NMT 0.0001% (1 ppm)
9. **PROTEIN** : Min. 15%



सत्यमेव जयते

MSME

MICRO, SMALL & MEDIUM ENTERPRISES

सूक्ष्म, लघु एवं मध्यम उद्यम

Udyam MSME No. : UDYAM-MH-18-0061131



Cert. No. : INAABCB9186E1F220



International Customs Cert.

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11. MICROBIAL LIMIT TEST

Total Colony Count : NMT 10 CFU / gms.
Staphylococci : Negative
E. Coli (MPN/ 100 gms)
(Coli Form Bacteria) : Less than 3
Escherichia (MPN/ 100 gms) : Less than 3
Salmonella : Negative in 25 gms.

12. PACKING

: 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 Drums.

13. 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.

14. SHELF LIFE

: 2 Years



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

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.

Notes :

NISIN product itself is Acidic with its pH Range, 2.8 to 3.8.

So, with increase of pH, its Heat Treatment stability Decreases.

So, the stability of NISIN is closely related to pH value of the process solution.

For example :

- When NISIN was dissolved in Skimmed Milk with pH = 6.5, then after pasteurization at 85°C Temp., for 15 minutes, only 15% of its Activity was lost.
- When NISIN was dissolved in Dilute Hydrochloric Acid (Dil. HCL) with pH=3, it remained 100% Active, even after high pressure sterilization at 121°C Temp.

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 within increase of pH, and it increases with the rise of temp.

SOLUBILITY IN WATER

pH Value	Solubility
Less than 2.5	50 mg/ml
2.5	12%
5.0	4%
7.0	Almost Insoluble
More than 8.0 (Alkaline)	Almost Insoluble

Note :

- Solubility of NISIN increases with the decrease of pH value.
- Water solution of NISIN is slightly Turbid due to the presence of milk protein.