

Specification

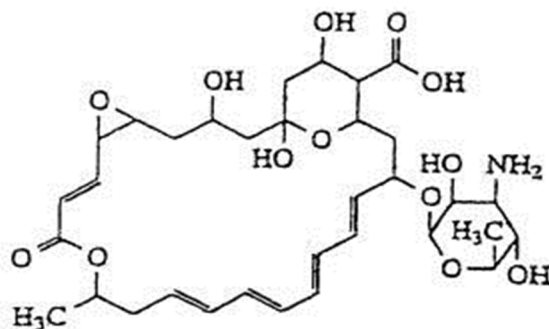
FINISHED PRODUCT INFORMATIONS

Product : Natamycin, 50% (Class II Preservative)

MSDS No. BPPL 121 (Available On Request)

Specification No. FP- 121

1. **NOMENCLATURE** : Pimaricin
2. **CAS NO.** : 7681-93-8
3. **MELTING POINT** : 280°C (Decomposed)
4. **HS CODE NO. (ITC CODE)** : 29419090
5. **EMPIRICAL FORMULA** : $C_{33}H_{47}NO_{13}$
6. **MOL. WT.** : 665.73
7. **STRUCTURAL FORMULA**



8. **DESCRIPTION** : White to Yellow Crystalline Powder.
(Cream –coloured to slightly Yellow Powder.)
: No Taste or Odour.
9. **PACKING** : 250 gms./ 500 gms. Plastic Bottle
: 1000 gms. (1.0 Kg) Plastic Bottle
: 10 Bottles / 20 Bottles / Case
: As per customer's requirement.
10. **STORAGE** : To keep in sealed & cool place where
there is no direct sunshine exposure
and the temp. is 2°C to 15°C.
: It is sensitive to oxidant and Ultraviolet
Radiation. (U.V)
11. **SHELF LIFE** : 2 Years.

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|---------------------------------|---|---|
| 1. DESCRIPTION | : | White to Yellow Crystalline Powder.
(Cream –coloured to slightly Yellow Powder.)
No Taste or Odour. |
| 2. SOLUBILITY | : | Not soluble in Water. |
| 3. MOISTURE CONTENT | : | 6.0 % to 9.0 % |
| 4. pH | : | 5.0 to 7.5 |
| 5. NATAMYCIN CONTENT | : | More than 50% |
| 6. ARSENIC (As) | : | NMT 1 ppm |
| 7. HEAVY METALS (Pb) | : | NMT 0.002% (20 ppm). |
| 8. SPECIFIC ROTATION | : | + 2760° to + 2800° |
| 9. ASH | : | NMT 0.5% |
| 10. MERCURY (Hg) | : | NMT 0.0001% (1 ppm). |
| 11. MICROBIAL LIMIT TEST | : | |
| Count of Colony | : | NMT 100 cfu/gm. |
| Pathogen | : | Absent |
| E. Coli | : | Negative (in 25 gms.) |
| Salmonella | : | Negative (in 25 gms.) |

STABILITY OF NATAMYCIN

MANY FACTORS CAN INFLUENCE THE STABILITY OF NATAMYCIN, AS UNDER

1. pH VALUE
2. TEMP.
3. LIGHT
4. OXIDANTS
5. HEAVY METALS etc.

1. **pH VALUE** : Natamycin is Most Stable Under Acidic Conditions, preferably between pH Range of 4.0 To 7.0 The activity is lost in highly Alkaline conditions. (Refer the Table below)

MEDIUM	REMARK
pH, Less than 3.0	30% activity is lost .
pH = 3.0 to 5.0	10% activity is lost.
pH = 5.0 to 7.0	No activity is lost .
pH More than 9.0	30% activity is lost.

2. **TEMPRETURE** : Natamycin is **stable** at Room Temp., **more stable** under dry condition. The desiccated Natamycin could endure 100°C in short-time. But the activity will be decreased when it is kept for more than 24 hours at more than 50 °C temp. .
3. **LIGHT** : Natamycin in powder or solution is sensitive to UV (Ultra Violet (Gamma Rays) γ Rays, which will cause the lose of activity. So, the direct sunlight exposure should be avoided.
4. **OXIDANTS** : Natamycin is sensitive to oxidants, such as Peroxide, Chlorine Dioxide, and Bleaching powder etc, which will decrease the activity of Natamycin. The use of antioxidants, e.g. Vitamin C, could prevent it.
5. **HEAVE METALS** : The Pb (Lead), Hg (Mercury), Fe (Iron) , and Ni (Nickle) etc. could affect the stability of Natamycin. So, Natamycin or its solution should be stored in container made of Glass, Plastic or Stainless Steel.

The EDTA could also be mixed with it to prevent the lose of activity.

SOLUBILITY OF NATAMYCIN

SOLVENT	SOLUBILITY
Distilled Water . [(pH) = 4.0 to 8.0] pH More than 9.0 / Less than 3.0	Practically Insoluble . Very low soluble. 0.005 gm – 0.01 gm /100 ml. water. (30 mg. to 100 mg. / lit. water at RT). Solubility increases, but it decreases the Anti fungal activity .
High Alcohols, Ether and Ester	Very low soluble .
Methanol	Very slightly soluble.
Glacial Acetic Acid and DMSO	Completely soluble. 18.50 gm – 100 ml. Glacial Acetic Acid.

ADVANTAGES OF NATAMYCIN 50% FOOD GRADE

- a) It extends the Shelf Life of the Food and save the Logistic Cost.

Natamycin and shelf life

Natamycin can significantly extend the shelf life of many products. The first and most widely approved application areas for Natamycin are cheese and fermented meat. These food categories require preservation against yeasts and molds, but need to allow cultures (i.e. bacteria) to remain active. For example, a white cheese in Latin America can have a shelf life of 38 days following the application of liquid Natamycin and 26 days with Natamycin powder. Without preservation, its shelf life is less than two weeks.

- b) It can successfully prevents the growth of potentially harmful Molds and Yeasts.

c) **No Color, Taste or Odor deviations**

Unlike many other preservation options, the application of Natamycin in foods does not produce changes in Taste, Color or Odor. This makes it suitable as a food preservative in a wide range of products.

It has no adverse flavour to Foods (Unlike Sorbic acid which can impart a Bitter Taste). It has a stronger inhibitability compared to Sorbic Acid.

d) **Effective at Low Doses and stable at a wide pH range**

Natamycin remains stable at a wide pH range (3-9).

As most Foods have a pH value between pH 4 to pH 7, this makes Natamycin a very **Versatile** food preservative.

In order to prevent spoilage in food applications, it works at low dosages between 3 ppm to 20 ppm. This means 3 mg to 20 mg of Natamycin in 1 kg of a final product.

It has high efficacy at low concentrations and, thus, replacing chemicals preservatives. It does not act against Bacteria – unlike Sorbic Acid . This makes it useful for Food Products such as Cheese and dry sausages in which Bacteria are key to the ripening process .

It meets the consumers demand for Food Preserved with Natural Ingredients.

e) **Health and Safety information (The most safe Natuaraal Preservative)**

No health concerns have been raised by the consumers, supported by numerous safety studies – (Reviewed by Independent Authorities) which show no negative impact on human health.

Furthermore, Natamycin helps to protect consumers from potentially harmful Mycotoxins, responsible for a variety of adverse health effects.

Mycotoxins

Molds are able to produce Toxins, called **Mycotoxins**, which are harmful to Human and Animal health. Mycotoxins have been found on a wide variety of foods such as Cheese and Bread. The use of Natamycin for food preservation reduces the Health Risks related to Mycotoxin exposure.

Natamycin has a long history of safe use as a Natural Mold Inhibitor in Cheese, Meat, and many other food products.

In 1967, Natamycin was approved worldwide as a Food Additive to be applied on the surface of (specific) cheese(s), preventing the growth of unwanted Molds and Yeasts.

- f) It reduces product (Food Product) being recalled resulting from Spoilage (and reduces manufacturing costs)

DIRECTION AND RECOMMENDED USAGE

The recommended dosage depends on the number of viable yeasts. Natamycin should be diluted 50 or 100 times with juice or wine before addition and then mixed with the juice or wine equably.

Spray Natamycin 4.0 gm. / Lit. suspended solution on the surface of the Meat or dip Meat into the solution. It can prevent the Mould .

If used in Cheese, there are two Methods to prevent the Mould :

1. Dip the piece of the Cheese.
2. Spray on the surface of the Cheese

If choose Dipping and Spraying method, the recommended usage is 5.0 gm. / Lit. Natamycin suspended solution .

APPROVAL OF NISIN

REGULATIONS: CODEX STANDARDS

Permitted worldwide

Natamycin is a food preservative that is approved and used in more than 150 countries around the world.

Natamycin has been Tested and Approved thoroughly as a Food preservative suitable for human consumption and all list it as safe for human consumption, by, amongst others,

- The European Safety Authority (EFSA),
- World Health Organization (WHO) and,
- Food and Drug Administration (FDA).
- The permitted applications differ per country/region.
- Latest notification: FDA approves Natamycin in Non-Alcoholic beverages.
- COFEPRIS (Mexico) approves Natamycin in Yogurt and Non-Alcoholic beverages.

USA

Example: Use in Cheese, including shredded Cheese (max. use level 20 mg/kg in the finished product).

Mexico

Example: Use in Non-Alcoholic Beverages (max. use level of 5 mg/L), Bread (max. use level of 14 mg/kg) and Tortills (max. use level 20 mg/kg) .

Europe

Example: Use on the surface of semi-soft to hard Chees and Dried, Cured sausage. (max. use level of 1 mg/sq dm, not present at a depth of 5 mm).

Use in the EU

In the European Union, the application of Natamycin is permitted for the surface treatment of semi-soft and semi-hard cheeses, as well as cured meats. As it has no effect on bacteria, Natamycin helps ensure optimal fermentation while protecting products from adverse effects related to the growth of molds and yeasts. Natamycin does not enter a products if used on casings or on rind.

China

Example: Use on Pastries (max. 300 mg/kg in spray or for dip such that residue level in the food shall be less than 10 mg/kg).

South Africa

Example: Use in fruit juices (max. use level 5 mg/kg) and in yogurt (max. use level 10 mg/kg).

Codex General Standard for Natamycin	
Cheese analogues, processed Cheese, Ripened cheese, Whey protein cheese.	Max. level 40 mg/kg (40 ppm)
Cured (including Salted) and dried non-heat treated processed comminuted Meat, poultry, and Game Products.	Max. level 20 mg/kg (20 ppm)
Cured (including Salted) and dried non-heat treated processed meat, poultry, and Game Products in whole pieces or cuts	Max. level 6 mg/kg (06 ppm)

Based on different applications, most countries in the world have approved Natamycin for preserving food products: from Canada to China and South Africa.

Natamycin and Food Wastages

Food spoilage and Food waste

Close to one third of the world's food supply is wasted annually. Besides physical damage, browning and staling, molds and yeasts cause significant food waste.

Why foods need protection

We have been preserving our foods for centuries using sugar, salt and acid or by heating or chilling them, for example. Protecting foods from spoilage is essential in order to reduce food waste and ensure safety for consumers, especially in humid and tropical climates.

Natamycin and food waste

With more than 1.5 million different varieties of molds and yeasts, food spoilage remains a constant risk factor – during manufacturing, storage, transportation, in the supermarket and in the home of the consumer.

The natural mold inhibitor Natamycin helps reduce food waste by protecting a wide variety of products and thereby extending shelf life. The application of Natamycin in yogurt, for example, has increased shelf life from two weeks to over 35 days.

APPLICATIONS OF NATAMYCIN

Natamycin possesses Antifungal activity to most all Moulds and Yeasts.

The Activity of Natamycin is **500 times higher** than that of Sorbic Acid, very little amount of Natamycin shows the Antifungal activity.

Generally, the growth of most moulds and yeasts could be inhibited by 1.0 ppm to 6.0 ppm of Natamycin, only few Moulds are inhibited by 0.10 to 25 ppm of Natamycin.

The appropriate pH value for the activity of Natamycin is **pH, 3.0 to 9.0**. and it does not change the Nutritional value, Appearance, Flavor and Texture of Foods.

It is very adaptable to use as Food preservative. But note that, Natamycin could not inhibit the growth of Bacteria.

Some of the **Applications of NATAMYCIN** are listed as follows:

1. **Cheese, Surface treatment of Cheese.**
2. **Guangdong-flavor-moon Cakes.**
3. **Bread and Cakes, baked Foods.**
4. **Meat products, Jam, Jelly, Marinated Food, Fish , Chicken**
5. **Salad Sauce**
6. **Soy Sauce**
7. **Fruit Juice, Drinks**

Types of Natamycin, Food Grade

Natamycin Food Grade is available under following types.

- a) Natamycin 50%
- b) Natamycin 95%

Natamycin 50% is available as under

- Natamycin 50% in NaCl (Salt)
- Natamycin 50% in Glucose
- Natamycin 50% in Lactose

Natamycin 50% in NaCl (Salt)

Natamycin 50% in NaCl (Sodium Chloride) (Salt) is made of 50/50 blend of NaCl and Natamycin for Sausage, Ham, Roti and mainly for Meat and Meat products etc.

Natamycin 50% in Glucose

Natamycin 50% in Glucose is made of 50/50 blend of Glucose and Natamycin for use in Juices and Drinks and Fresh Fruits.

Natamycin 50% in Lactose

Natamycin 50% in Lactose is made of 50/50 blend of Lactose and Natamycin for Dairy and Baked food etc.