

Niacin and Niacinamide

A Commitment to Quality



Niacin **B₃**

Niacinamide **B₃**

What is Niacin/Niacinamide?

Niacin (nicotinic acid) and Niacinamide (nicotinamide) comprise the two forms of Vitamin B3; both of which provide equivalent vitamin activity. The significance of Vitamin B3 in humans was established in the 1930's when scientists discovered that foods rich in this vitamin helped cure pellagra, a disease characterized by dermatitis, diarrhea and dementia. If left untreated, pellagra eventually leads to death. Since its discovery, Vitamin B3 deficiency in developed countries has nearly been eradicated thanks to its addition to enriched foods, such as flour.

As an essential component of the enzyme system of living cells, Vitamin B3 is essential for protein, carbohydrate and fat metabolism. Niacin and Niacinamide are precursors in the synthesis of the pyridine coenzymes NAD and NADP involved in cell metabolism, and as such play a key role in the production of energy. Vitamin B3 is needed in all living cells, and as it is not produced naturally in the body, it must be taken up through diet or supplementation. Vitamin B3 can be found in various foods, however, its bioavailability is often limited depending greatly on the source. Therefore, Niacin and Niacinamide are critical supplements in the human food industry. Niacin is also used in dietary supplement applications to help maintain cholesterol level in the normal range while Niacinamide is increasingly important as an active ingredient in cosmetic products used to promote the appearance of healthy skin and hair.

Lonza offers both Niacin and Niacinamide in different forms to meet the needs of the dietary supplements, food, personal care, pharma and animal nutrition markets.

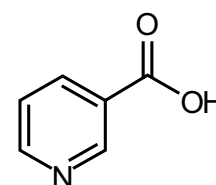
« Our commitment to quality comes from our belief that our products are an extension of yours »

Lonza – Your Reliable Supplier for Vitamin B3 Value

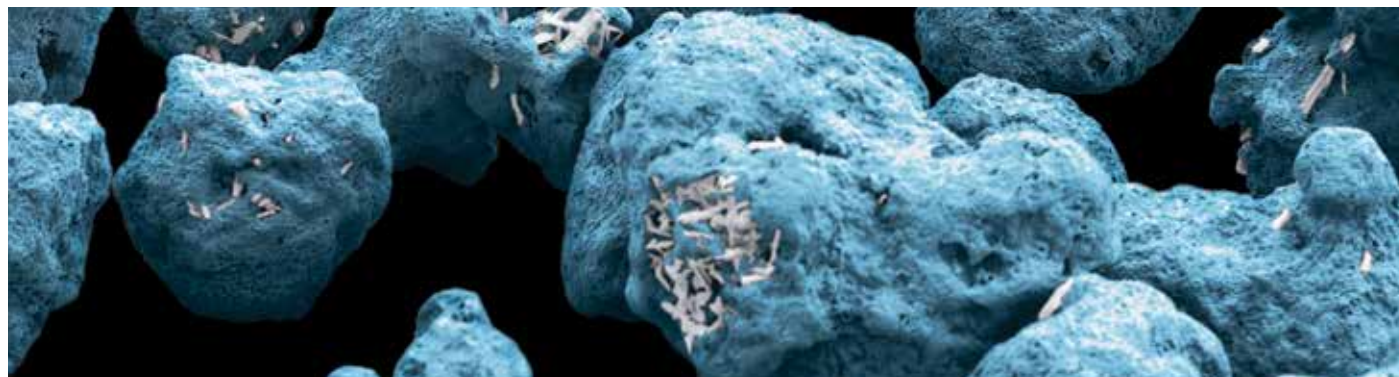
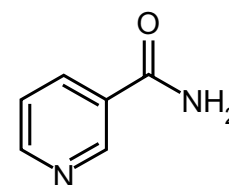
Lonza has been a leading supplier of Vitamin B3 for over 40 years, producing Niacin and Niacinamide in different forms for the dietary supplements, food, personal care, pharma and animal nutrition markets. Lonza is committed to providing unsurpassed quality nutritional products, stemming from our belief that our products are an extension of yours.

We believe working with suppliers who meet our business standards is beneficial to our customers and suppliers, as well as to Lonza. Therefore, we continually review and improve our internal processes necessary to help our customers succeed. For example, Lonza offers full traceability, superior customer service and logistical support. We offer high flexibility in delivery, packaging and efficient order processing, including automated order confirmations, CoAs, and licenses. Our local warehouses in the United States offer excellent proximity to our customers. Our regulatory experts collaborate with authorities and organizations around the world to establish successful regulatory affairs for Niacin and Niacinamide products, wherever they are manufactured. We have many years of experience supporting regulatory dossiers and a track record of successful regulatory initiatives.

Niacin	
Chemical name:	3-Pyridinecarboxylic acid
Other names:	Nicotinic acid, Pyridine-3-carboxylic acid
Chemical formula:	C ₆ H ₅ N ₂ O ₂
CAS No:	59-67-6



Niacinamide	
Chemical name:	3-Pyridinecarboxamide
Other names:	Nicotinamide, Nicotinic acid amide, Pyridine 3-carboxylic acid amide, Vitamin PP
Chemical formula:	C ₆ H ₆ N ₂ O
CAS No:	98-92-0



Niacin REM: Niacin min. 99.5%



The world's largest supplier of Vitamin B3 (Niacin and Niacinamide) and L-Carnitine (Carnipure™) in the Food, Dietary Supplement, Feed and Pharmaceutical markets.

- Swiss life-science company founded in 1897
- One of the world's leading suppliers to the pharmaceutical, healthcare and life-science industries
- Global leader in the production and support of chemical and biological active pharmaceutical ingredients (API's)

Niacin 

Niacinamide 

Niacin and Niacinamide from Lonza, the leading manufacturer of free flowing Vitamin B3 ingredients, is produced without any additives.

Production Process

We have several production routes and facilities which allow us the flexibility to produce a number of grades that serve the food, pharma, dietary supplement, animal nutrition and personal care markets. This flexibility gives our customers confidence in our reliability to provide high quality products and service.

Niacinamide Production Process in Guangzhou

Advantages of the process:

- Robust and selective continuous process in dedicated plant with well controlled catalytic reaction, product purification and drying step.
- In-house developed catalyst for 3-picoline and 3-cyanopyridine.
- Synthesis of 3-picoline contrasts other picoline/nicotinate producers independent of pyridine market.
- Integrated waste treatment concept.

Properties of Niacinamide USP Product Quality

Feature	Quality
Particle Size	
Mean diameter d0.5 (Malvern laser diffraction)	130–150 µm
Mean diameter d0.5 (Alpine air jet)	100–120 µm
Mass fraction > 50 µm	min. 90%
Mass fraction > 250 µm	max. 8%
Particle Shape	spheres
Bulk Density	
Poured	0.56 g/cm ³
Tapped (2500 taps)	0.64 g/cm ³
Flow Properties	
Angle of repose	33
Jenike flow function ffc	> 10 (free flowing)
Storage Characteristics	
Caking	No (In dry/moderate climate)

Niacinamide Features and Benefits

Product Handling

Excellent flowability and no caking of the product due to special downstream processing including spray drying, thermal treatment and temperature/humidity controlled packaging.

Stability

100% pure substance affords excellent stability in vitamin premixes or in multivitamin/multi-mineral tablets.

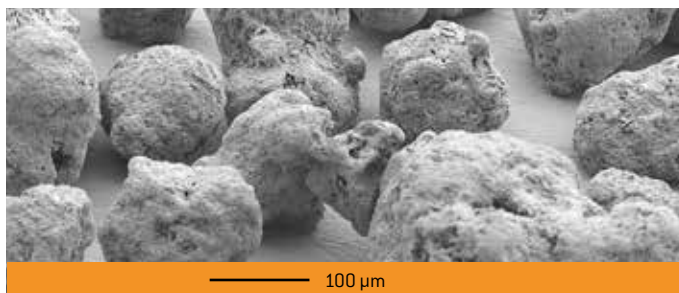
Particle size

Narrow particle size distribution, covering the needs of the industry (food, pharma, personal care, and feed).

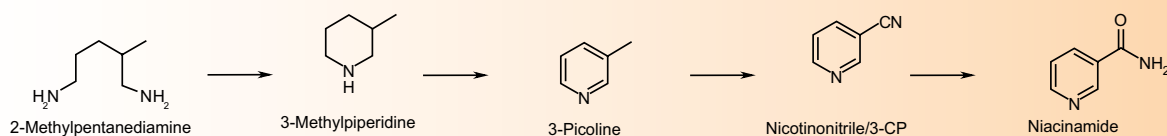
Suitability for direct compression

Excellent

Niacinamide enlarged 150 times



Lonza's Niacinamide Process in Guangzhou



Niacin Production Process in Visp

Advantages of the process:

- Robust production network/backward integrated to cracker with LPG(LVN) as feedstock (Visp).
- Long term, dedicated experience for many years with product and process.
- Industrial production process of Niacin in Visp since 1956.
- Consistent high quality.
- Dedicated plant with world scale economy.
- Unique process with continuous operations.

Properties of Niacin

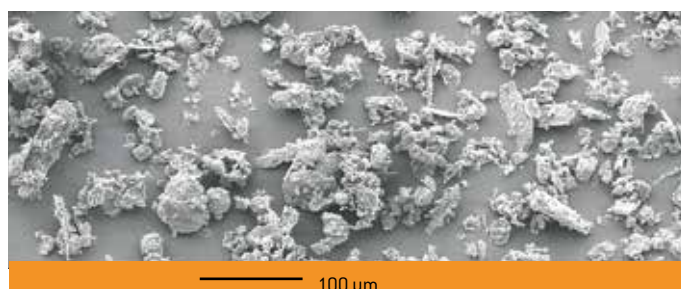
Feature	Niacin USP	Niacin USP granular
Particle Size	20	
Mean diameter d0.5 (Malvern laser diffraction)	20 $\mu\text{m} \pm 10 \mu\text{m}$	350 $\mu\text{m} \pm 70 \mu\text{m}$
Particle Shape	powder (grinded needles)	spheres
Bulk Density		
Poured kg/m^3	350–450	650–750
Tapped (2500 taps) kg/m^3	620–700	800–850
Flow Properties		
Angle of repose	~50	33
Storage Characteristics		
Caking	No	free flowing

Niacin Features and Benefits

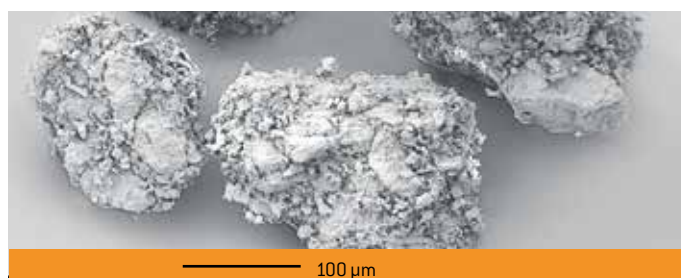
Stability

Product is very stable as a pure substance, in vitamin premixes and in processes such as baking.

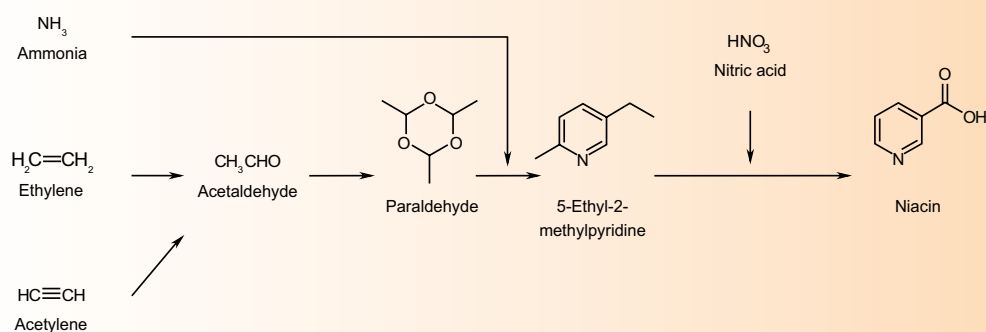
Niacin USP enlarged 150 times



Niacin USP granular enlarged 150 times



Lonza's Niacin Process in Visp



Health Benefits

Biochemical Function

Niacin and Niacinamide are required by all living cells. They are essential components of two coenzymes, Niacinamide adenine dinucleotide (NAD), and Niacinamide adenine dinucleotide phosphate (NADP). More than 40 biochemical reactions dependent on them have been identified. NAD and NADP are involved in reactions of the metabolism of carbohydrates, lipids and proteins.¹

Endogenous Synthesis and Natural Occurrence

Niacin is converted to Niacinamide in the body as part of the metabolic process. Many vitamin formulations use Niacinamide instead of Niacin. When this is done, the FDA requires that the product label list the amount of Niacin in terms of its Niacinamide equivalent—which is essential in order to know how much Niacin you're actually getting. Another interesting fact is that our bodies can make Niacinamide from Tryptophan, which is an amino acid commonly found in foods. It is estimated that approximately 60 mg of Tryptophan can be used to make 1 gram of Niacin which is referred to as 1 Niacin Equivalent (NE).¹ In the USA, the RDA for Vitamin B3 for adults is 16 mg NEs for men and 14 mg NEs for women.

Niacin and Niacinamide are naturally present in various foods. The natural presence of Niacin/Niacinamide does not mean, however, that these quantities are available to the human body or even sufficient to cover daily requirements. Some foodstuffs contain chemically bound Niacin which result in its bioavailability being low. In cereal grains, as much as 70 to 100 percent of the Niacin is biologically unavailable because of the structure of the compounds in which it is bound. Niacin in corn, for example, is fully unavailable.¹ When considering cereal/corn-based diets, it is necessary to make allowance for poor bioavailability.



Niacin production plant, Visp, charcoal filtration of Niacin

Blood Lipid Management

Unlike Niacinamide, nicotinic acid is also utilized in pharmaceutical applications for maintaining sound heart function and healthy cholesterol levels in humans. In higher dosages typically used in pharmaceutical applications, Niacin has been shown to raise levels of HDL (high density lipoprotein), or “good” cholesterol, and lower elevated LDL (low density lipoprotein), or “bad” cholesterol, as well as triglyceride levels in the blood.²⁻⁶

Daily Recommendations

The Food and Nutrition Board, part of the National Academy of Sciences in the United States, has recommended dietary allowances (RDA) for Niacinamide. The Niacinamide requirements vary, depending on sex, age and pregnancy. The importance of Vitamin B3 is demonstrated by its recommended daily intake, as defined by the “Dietary Guidelines for Americans”. These guidelines recommend daily intake of Vitamin B3 and its equivalents by foods of 16 mg/d for men and 14 mg/d for women.

Quality and Regulatory Standards/Certificates

Lonza holds various certificates which guarantee the highest quality of Niacin and Niacinamide. State of the art, dedicated plants in Switzerland (Visp) and in China (Guangzhou and Nansha) produce Niacin and Niacinamide.

Niacin Quality and Regulatory Standards/Certificates

- Kosher
- Halal
- HACCP
- GMP
- ISO 9001:2008
- FSSC 22000:2010
- FAMI-QS and others
- CEP
- US-DMF

Niacinamide Quality and Regulatory Standards/Certificates

- Kosher
- Halal
- HACCP
- GMP
- ISO 9001:2008
- FSSC 22000:2010
- ISO 140001:2004
- OHSAS 18001:2007
- CEP

Process/Batch to Batch Consistency

Strict SOPs which ensure our quality also support our production stability and long-term business focus. They enable Lonza to provide the most consistent product with minimal batch-to-batch variation.

Traceability and Product Recalls

Lonza has implemented a traceability system and recall procedure that fully complies with industry requirements for product and batch tracking.



At Lonza, we have the expertise to identify from whom and to whom a product has been supplied within a short time period. Our systems allow this information to be forwarded to the national authorities responsible for the control and safeguard measures. The frequently tested procedures include:

- Formation of recall management team
- Creating a compliance file
- Tracing of products
- Analysis of distribution records
- Maintenance of recall product records
- Establishing recall procedures with periodic test recalls

Regulatory Affairs

Regulatory Affairs at Lonza ensures that the company complies with all of the regulations and laws pertaining to their business. Regulatory Affairs prepares dossiers and maintains communication with the relevant authorities.

Lonza relies on a broad network of contacts as well as our own extensive experience accumulated over the years to efficiently handle all kind of regulatory related tasks and problems.

References

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