Niacin and Niacinamide
A Commitment to Quality
**What is Niacin/Niacinamide?**

Niacin (Nicotinic acid) and Niacinamide (Nicotinamide) comprise the two forms of Vitamin B3; one of the water-soluble B vitamins. Both forms 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 supplement, food, personal care, pharma and animal nutrition markets.

**Lonza – Your Reliable Supplier for Vitamin B3 Value**

Lonza is one of the world’s leading suppliers of Vitamin B3 for over 40 years, producing Niacin and Niacinamide in different forms for the dietary supplement, 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, certificates of analysis, 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 conditions 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.

<table>
<thead>
<tr>
<th>Niacin</th>
<th>Niacinamide</th>
</tr>
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<tbody>
<tr>
<td>Chemical name: 3-Pyridinecarboxylic acid</td>
<td>Chemical name: 3-Pyridinecarboxamide</td>
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<tr>
<td>Other names: Nicotinic acid, Vitamin B3, Vitamin PP, Pyridine-3-carboxylic acid</td>
<td>Other names: Nicotinamide, Nicotinic acid amide, Vitamin B3, Vitamin PP, Pyridine 3-carboxylic acid amide</td>
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<tr>
<td>CAS No: 59-67-6</td>
<td>CAS No: 98-92-0</td>
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About Lonza
- Swiss life-science company founded in 1897
- One of the world’s leading and most-trusted suppliers to the pharmaceutical, biotech and specialty ingredients markets
- The global leader in the production and support of active pharmaceutical ingredients (API’s) based on both chemical as well as biotechnological platforms
- One of the world’s leading suppliers of Vitamin B3 (Niacin and Niacinamide) and L-Carnitine (Carnipure®)
Production Process

We have several production routes and facilities which allow us the flexibility to produce a number of Vitamin B3 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, Nansha

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

<table>
<thead>
<tr>
<th>Feature</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Particle Size</td>
<td></td>
</tr>
<tr>
<td>Mean diameter d0.5 (Malvern laser diffraction)</td>
<td>130–150 µm</td>
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<tr>
<td>Mean diameter d0.5 (Alpine air jet)</td>
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<tr>
<td>Mass fraction &gt; 50 µm</td>
<td>min. 90%</td>
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<td>Bulk Density</td>
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<tr>
<td>Jenike flow function ffc</td>
<td>&gt; 10 (free flowing)</td>
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<tr>
<td>Storage Characteristics</td>
<td></td>
</tr>
<tr>
<td>Caking</td>
<td>No (in dry/moderate climate)</td>
</tr>
</tbody>
</table>

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 animal feed).

Suitability for direct compression
Excellent

Lonza’s Niacinamide Process in Guangzhou, Nansha
**Niacin Production Process in Visp**

**Advantages of the process:**
- Robust production network/backward integrated to cracker with LPG (Liquefied Petroleum Gas) / LVN (Light Virgin Naphtha) as feedstock (Visp).
- Long term, dedicated experience for many years with product and process.
- Industrial production process of Niacin in Visp since 1956.
- Dedicated plant with world scale economy.
- Unique process with continuous operations.

**Properties of Niacin**

<table>
<thead>
<tr>
<th>Feature</th>
<th>Niacin USP</th>
<th>Niacin USP granular</th>
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</thead>
<tbody>
<tr>
<td>Particle Size</td>
<td>Mean diameter d0.5</td>
<td>20 µm ± 10 µm</td>
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<tr>
<td>(Malvern laser diffraction)</td>
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<td>350 µm ± 70 µm</td>
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<td>Particle Shape</td>
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<td>Bulk Density</td>
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<td></td>
<td>Tapped (2500 taps)</td>
<td>620–700</td>
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<td>Flow Properties</td>
<td>Angle of repose</td>
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<td></td>
<td>Storage Characteristics</td>
<td>33</td>
</tr>
<tr>
<td></td>
<td>Caking</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td>free flowing</td>
</tr>
</tbody>
</table>

**Niacin Features and Benefits**

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

**Lonza’s Niacin Process in Visp**
Significance of Vitamin B3

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 milligram of Niacin which is referred to as 1 mg 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.

Blood Lipid Management
Unlike Niacinamide, nicotinic acid is also utilized in pharmaceutical applications for helping maintain 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 indicates the highest quality of Niacin and Niacinamide. Lonza has state of the art, dedicated plants in Switzerland (Visp) and in China (Guangzhou, Nansha district) producing Niacin and Niacinamide.

Niacin Quality and Regulatory Standards/Certificates
- Kosher
- Halal
- Pharma cGMP
- ISO 9001
- FSSC 22000

Niacinamide Quality and Regulatory Standards/Certificates
- Kosher
- Halal
- Pharma cGMP
- ISO 9001
- FSSC 22000
- ISO 14001

Process/Batch to Batch Consistency
Lonza has 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.

Niacin production plant, Visp, charcoal filtration of Niacin
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 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 matters.

References
Nutrition – Niacin and Niacinamide – 09/16

Review and follow all product safety instructions. This brochure is for professional use only. The statements made in these materials have not been evaluated by the U.S. Food and Drug Administration or any other regulatory authority. Lonza’s products are not intended for use to diagnose, treat, cure or prevent any disease. All product information corresponds to Lonza’s knowledge on the subject at the date of publication, but Lonza makes no warranty as to its accuracy or completeness and Lonza assumes no obligation to update it. Product information is intended for use by recipients experienced and knowledgeable in the field, who are capable of and responsible for independently determining the suitability of ingredients for intended uses and to ensure their compliance with applicable law. Proper use of this information is the sole responsibility of the recipient. This information relates solely to the product as an ingredient. It may not be applicable, complete or suitable for the recipient’s finished product or application, therefore republication of such information or related statements is prohibited. Information provided by Lonza is not intended and should not be construed as a license to operate under or a recommendation to infringe any patent or other intellectual property right. No claims are made herein for any specific intermediate or end-use application. All trademarks belong to Lonza or its affiliates or to their respective third parties and are used here only for informational purposes. Copyrighted material has been produced with permissions or under license, all other materials belong to Lonza.

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FiberAid™
The premium prebiotic fiber
Composed of larch arabinogalactan, FiberAid™ prebiotic is an all-natural, multifunctional dietary fiber and is approved as such by the US FDA and other authorities. It is extracted by Lonza from larch trees that grow in abundance in the United States via a patented process (US 5756098, EP 866808 and other patents).

Larch arabinogalactan consists of galactose and arabinose in a 6:1 ratio. It is a long, densely-branched non-starch polysaccharide consisting of a galactan backbone and galactose and arabinose side-chains.

What is FiberAid™?
FiberAid™ is a premium soluble prebiotic fiber manufactured by the Swiss life-science company Lonza. FiberAid™ prebiotic offers superior benefits for gastrointestinal health combined with excellent digestive tolerance and technological properties. Products displaying the FiberAid™ quality seal on the packaging show the consumer that they contain the premium prebiotic fiber from Lonza.

What are prebiotics?
The term prebiotics was coined in 1995 and defined as “non-digestible food ingredients that beneficially affect the host by selectively stimulating the growth and/or activity of one or a limited number of bacteria in the colon.” It is therefore believed that prebiotics will improve health in a way similar to probiotics (live microbial food supplements).

FiberAid™ offers superior health benefits combined with excellent digestive tolerance.
Gastrointestinal Health

Positive influence on the microflora
Results from human and in vitro studies indicate that FiberAid™ ingestion enhances gut microflora significantly by specifically increasing anaerobes such as Bifidobacteria and Lactobacilli.8–13

The intestinal microflora comprises various microbial species that are mostly bacterial and are influenced by the diet.14,15 Addition of FiberAid™ to the diet can deliver prebiotic benefits.

Increase in the production of short chain fatty acids
FiberAid™ was reported to increase short chain fatty acids (SCFAs) in the gut.16,17 These acids lower the colon pH and create an environment favoring the development of beneficial bacteria.2,18–20

The majority of the strictly anaerobic bacteria in the large intestine derive their energy from fermentation of carbohydrates, which results in the production of volatile SCFAs.21,22

Acetate, propionate and butyrate are the major SCFAs produced by friendly gut microflora.16,18 They can stimulate salt and water absorption in the gut and are important metabolites of intermediary metabolism in the colonic epithelium.19 Acetate and propionate are reported to be taken up from the gut to provide energy for brain, muscle and heart, while butyrate provides about 50% of the daily requirements of the gastrointestinal mucosa.23

Reduction of ammonia in the gut
FiberAid™ has been shown to decrease the generation and absorption of ammonia in the gut.3,11,16 The deamination of amino acids by the microflora is reported to be the major contributor to ammonia levels in the large intestine. High ammonia levels in the large intestine appear to contribute to detrimental health conditions.2

Excellent digestive tolerance
All of the gastrointestinal benefits mentioned above are provided without the typical side effects, such as gas and bloating, which are commonly associated with other dietary fiber ingredients.24 Due to its highly branched structure, FiberAid™ is slowly fermented.10 FiberAid™ was shown to have a high digestive tolerance at dosages up to 15 g/day, whereas effective dosages are already achieved at 4.5 g/day.11 FiberAid™ prebiotic is a low calorie additive (1.4 kcal/g) and is reported to have no glycemic response.11,25

Summary of the gastrointestinal functions of FiberAid™

– Increases Lactobacilli and Bifidobacteria
– Increases short chain fatty acids
– Decreases ammonia levels
– Ferments slowly
Superior Technical Properties of FiberAid™

FiberAid™ has a number of technical properties which make it unique as a food ingredient: it is a dry, free-flowing powder. FiberAid™ can be taken in standalone form or combined with other products to increase functionality.

**High solubility in water**
As FiberAid™ has a highly branched structure it is freely soluble, dissolving completely in hot or cold water.

**Stable to temperature and low pH value**
FiberAid™ is stable at a wide range of temperatures and pH, which provides for use in various applications. In beverages it keeps its functionality and neither degrades nor hydrolyzes.

**Low viscosity and excellent mouthfeel**
Along with its high solubility, FiberAid™ provides very little sensory impact, offering minimal mouthfeel and viscosity. Testing has also shown that FiberAid™ has a minimal aftertaste.

**Moisture retention and increased shelf life**
FiberAid™ can be easily formulated into food and beverage systems. It retains moisture in baked goods and has improved dough-handling characteristics. It helps to contribute to a finer, more uniform grain and can improve the taste and aroma of baked goods, such as tortillas. FiberAid™ is also effective in lowering water activity in sweetener compositions. It provides film-forming properties for extended shelf life and tack-on aid.
FiberAid™
Production Process

FiberAid™ is produced by steam-heating larch wood chips and evaporating the extract. This procedure is unique as it does not require any harsh chemicals to release the polysaccharide from the plant matrix. Therefore, the product remains pure and structurally unaltered².

Quality and Safety of FiberAid™

FiberAid™ quality at a glance
– Solvent free, water based extraction process
– Manufactured according to HACCP principles
– GMP audited by American Institute of Baking
– Kosher certified by United Mehadrin
– GMO free
– Monograph in Food Chemicals Codex (FCC)
– Consistent quality and free of batch-to-batch variation – not affected by seasonal variability or extreme weather conditions

FiberAid™ safety at a glance
– Self-affirmed GRAS with US FDA notification²⁸,²⁹
– Approved by the US FDA as direct food additive³⁰
– Allergen free
– No reported side effects, no adaptation period required⁴,¹¹

Due to its excellent technical properties FiberAid™ can be used in many different types of products.
Like all of Lonza’s nutritional ingredients, the health benefits derived from FiberAid™ are based on scientific evidence.

References

5 Ekman KH et al. (1962). Tappi 45(6): 477–481
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18 Cummings JH et al. (2001), Am J Clin Nutr 73:415S–420S
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26 Tungland B et al. (2002). ORFSFS 3:73–92
27 American Institute of Baking (1997), unpublished data
Lonza is a life-science-driven company headquartered in Switzerland. Founded in 1897, Lonza today is one of the leading custom manufacturers of chemical intermediates, active pharmaceutical ingredients and biopharmaceuticals. In the Life Science Ingredients division, Lonza creates among other products value-added solutions for the food and dietary supplement industries.

For more information please visit www.lonzanutrition.com
www.fiberaid.com

Europe

Czech Republic
Lonza Biotec sro
Okružní 1/4
CZ-281 61 Kouřim
Tel +42 0321 738 654
contact.cz@lonza.com

France
Lonza France Sârli
55, rue Aristide Briand
FR-92309 Levallois-Perret Cedex
Tel +33 1 40 89 99 00
contact.fr@lonza.com

Germany
Lonza Cologne AG
Nattermannallee 1
DE-50829 Köln
Tel +49 221 99 1990
info.cologne@lonza.com

Hungary
Lonza Ltd Representation Office
Dunaház III. lépcsőház II. em 2
Boráros tér 7
HU-1095 Budapest I
Tel +36 1 215 94 19
contact.hu@lonza.com

Netherlands
Lonza Benelux BV
Aluminiumstraat 1
NL-4823 AL Breda
Tel +31 76 542 51 00
contact.nl@lonza.com

Poland
Lonza Ltd Representation Office
ul. Sniatynskiego 4 m 15
PL-01-698 Warsaw
Tel +48 22 833 87 45
contact.pl@lonza.com

Russia
OOO Lonza Rus
Ordonnikidze Street 11
(Bldg 11, Office 807)
RU-Moscow 115419
Tel +7 495 721 23 39
contact.ru@lonza.com

Spain
Lonza Ibérica SA (Unipersonal)
Via Augusta, nº 18, 2a Pta, Izda
ES-08006 Barcelona
Tel +34 93 239 54 60
fiberaid@lonza.com

United Kingdom
Lonza Biologics plc
Suite 3, Building A
The Courtyard, Severn Drive
GB-Tewkesbury GL20 8GD
Tel +44 1684 292 728
contact.uk@lonza.com

Asia

China
Lonza Guangzhou Ltd
39, Jinhuil Road
Haizhu District
CN-Guangzhou 510288
Tel +86 20 8433 8998
contact.cn@lonza.com

Japan
Lonza Japan Ltd
Kyowa Shinkawa Bldg 8F
2-20-8, Shinkawa, Chuo-ku
JP-Tokyo 104-0033
Tel +81 3 5566 0612
contact.jp@lonza.com

Note: This document is an overview of published scientific information on larch arabinogalactan and published scientific information on clinical and nutritional trials with larch arabinogalactan. No claims are made herein for any particular consumer product, nor can these statements be used on such consumer products. The recommended use for FiberAid™ prebiotic is as a nutrient or dietary supplement.

The statements in this document have not been evaluated by any Food and Drug Administration. Lonza’s FiberAid™ prebiotic is not intended to diagnose, treat, cure or prevent any disease.

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