



– amixon® whitepaper –

Mixing the next generation of infant nutrition

amixon® mixers and infant formula manufacturing

The key role of mixing equipment in producing safe and
healthy powdered infant formula



INTRODUCTION

Ensuring the highest standards for the next generation

It is the most natural thing in the world for parents to want the very best for their children. But ideas about what is actually best for children differ throughout history as science, cultural attitudes, and society have evolved.

Over the past few decades, the field of infant and pediatric nutrition has benefited tremendously from enhanced scientific knowledge and innovative technology. But while we now know more than ever about what babies need to grow up strong and healthy, there remain significant challenges in both manufacturing infant formulas that can fulfill these needs and marketing baby nutrition products in a way that is discerning to the diverse needs of new parents.

Entrusted to nourish the most vulnerable among us, baby nutrition products must be developed and manufactured with the utmost care and transparency. High-performance, hygienic mixing equipment plays a key role in ensuring that these products live up to the science behind their development.

This whitepaper from amixon GmbH examines some of the dominant forces currently shaping the market for infant formula and baby foods and explores their impact on the manufacturing process. Our evolving scientific understanding of the composition of breast milk is opening new possibilities for infant nutrition products to better nourish babies. But without sophisticated processing technology, scientific knowledge can only go so far in improving products. Industrial mixing technology is key in developing and manufacturing infant formulas and baby foods that can live up to health claims and guarantee safety.



ABOUT AMIXON

Industrial mixing technology made in Germany

For nearly 40 years, amixon® has been a market leader in the manufacture of sophisticated, high-precision mixing equipment for diverse processing needs. Made in Germany from food grade materials, outfitted with hygienically optimized proprietary technology, and customized to the exact specifications of your products, amixon® mixers offer state-of-the-art bulk material processing solutions for manufacturers of infant formula, baby foods, nutraceuticals, and pharmaceuticals.



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amixon® Vertical Twin-Shaft Mixer HM



Growing awareness of the benefits of HMOs and probiotics



Allergen prevention and cow-free products: the rise of niche market segments



Synthesizing HMOs and proving their efficacy



Preserving bioactive ingredients in shelf-stable products



The crucial importance of hygiene and traceability



The role of mixers in fulfilling health and safety claims

1

A new generation of infant nutrition

In grocery stores around the world, parents can choose between dozens of products formulated to meet the nutritional needs of their infants and young children. As wide as this selection already is, it is continuously growing. Formula and baby food manufacturers are in constant collaboration with researchers to develop and test new formulas.

Driving the continued growth in the variety of baby nutrition products is scientific advancement on the one hand, and changing attitudes about health and parenting on the other. The past few decades have seen drastic changes in our understanding of the composition of breast milk and its different components' roles in infant growth and development. Furthermore, consumers are more conscious of the health and environmental consequences of their purchasing decisions than ever before. As such, manufacturers of infant formula and baby food have a responsibility to create products that address both the latest science and generational attitudes about parenting.

1.1 The evolving science of baby nutrition

Since the mid-1990s, commercial infant formulas have been able to replicate breast milk in terms of its ratio of proteins, fats, vitamins, and minerals (Callahan 2019). But modern science has shown that breast milk has not only evolved to have a nutrient composition specific to the rapid growth that babies experience during their first year of life, but that it is also bioactive.

The last decade has produced numerous studies confirming that breast milk is filled with hundreds of living microscopic components, each with a unique and as of yet not completely understood role in infant development – from protecting babies from pathogens to building their immune systems.

Though commercial infant formula may never achieve an exact replication of breast milk at the molecular level, this growing scientific knowledge is helping to make infant nutrition products better. Afterall, not all babies can be breastfed, and there is an ethical imperative to ensure the availability of safe and efficient formulas that meet babies' nutritional needs.



The scientific community's growing understanding of the complexities of breast milk has encouraged continuous research and development on the part of infant formula manufacturers. In particular, the past few years have seen the addition of the following ingredients to infant formulas:



Human milk oligosaccharides (HMO)

After lactose and fat, the third-most plentiful component in breast milk is a group of over 150 different sugar molecules known as HMOs – none of which are actually digestible by the infants themselves. Studies have shown HMOs to play a number of beneficial roles in infant development. Primarily, this family of sugar molecules act as a prebiotic food source for *Bifidobacterium*, a beneficial microorganism found in the gut microbiomes of infants. HMOs have also been shown to confer a number of other benefits including protecting infants from pathogens (Triantis, et al. 2018), modulating cell growth (Ray, et al. 2019), and reducing inflammation (Wickramasinghe, et al. 2015).



Milk fat globule membranes (MFGM)

The mammary glands of breastfeeding mothers secrete fat droplets packaged in an intricately structured three-layer membrane. The membrane of the globule contains a plethora of proteins, cholesterol, and phospholipids that are thought to aid in infant brain development and immune function (Lee, et al. 2019). MFGMs have historically been absent from infant formulas, but researchers have in recent years taken to adding a cow-derived version of the structure to their products.



Lactoferrin

Lactoferrin is a protein that combats pathogens and harmful bacteria and is found in much higher quantities in human milk than in cow's milk. Levels of lactoferrin rise in a mother's milk when her baby is ill, and its powerful antiviral and immunomodulatory properties have even made this protein the subject of research as a potential preventative and adjunct treatment for COVID-19 (Chang, et al. 2020).

1.2 Conscientious parenting and the growing spectrum of infant nutrition products

In recent decades, scientific progress and the wide availability of information have made the public more critical and conscientious about the potential health implications of their consumption than ever before.

Especially when it comes to purchases that could impact the health of their babies, consumers are understandably anxious and seek to be as informed as possible when making decisions. Millennials, who comprise 90% of today's new parents, are nearly twice as likely to express concern about what their children are eating than Gen X parents were, and nearly three times more likely than Baby Boomer parents were (Steinmetz 2015).

To be certain, conflicting information abounds and expanding access to information does not necessarily equate with a better-informed public. But growing awareness about health topics such as the gut microbiome and allergens, as well as an increasingly environmentally-conscious generation of parents, are giving rise to new sorts of baby nutrition products beyond traditional infant formula and baby foods. Here are some of the emerging infant nutrition products fueled by changing attitudes about health and parenting:



Probiotic supplements

Scientists warn that the growing prevalence of antibiotic use, c-section delivery, and formula feeding is leading to a "generational loss" of the critical gut bacteria *B. infantis* among infants in industrialized nations (Watson 2017). Even for breastfed babies who were delivered vaginally, a growing number of new mothers no longer have any *B. infantis* to pass on to their infants. This issue has led some life science companies to develop special supplements containing activated *B. infantis* that parents can mix with pumped breastmilk or formula. The development of products such as these corresponds with rising public interest in probiotics generally. A 2019 analysis of product reviews in 19 countries revealed a huge boom in consumer interest in probiotics, and that probiotic supplements for children generated more customer engagement than any other category (Cutler 2019).



Allergen prevention products

In industrialized nations, childhood food allergies are on the rise. In the United States, for instance, food allergies among children increased 50% from 1997 to 2011 (Jackson, et al. 2013). Both genetics and environmental factors influence the development of childhood food allergies, but many researchers point to the early integration of small amounts of common allergens into babies' diets as having the potential to prevent food allergies. As such, the past few years have seen a surge of new allergen introduction products, ranging from powdered supplements to be mixed with baby foods to toddler snack foods like puffs and crackers.





Plant-based baby nutrition

Historically, the vast majority of infant formula has been made with cow's milk, with a few alternative options made from soy, goat or sheep's milk. But growing awareness of animal welfare and environmental issues as well as health concerns relating to lactose and soy intolerance have fueled the growth of an emerging market segment for alternative baby nutrition products. 2020 saw the launch of the first vegan and soy-free infant formula on the U.S. market as well as steady growth in the global market for vegan baby food products. Other plant-based ingredients for infant formula, such as DHA algae oil, are projected to see impressive annual market growth rates as high as 8.5% in the coming years (Global Market Insights, Inc. 2020).

2

The evolving responsibility of infant formula manufacturers

Science is expanding what we know about the composition of breast milk and its importance to the health and development of growing babies, but translating these findings into a safe and effective infant formula product is no easy task. Much remains unknown about how different molecules interact at different ratios, and preserving probiotic ingredients while simultaneously minimizing harmful bacterial risks proves challenging.

When new insights into the composition of breast milk come to light, it is not enough for infant formula manufacturers to simply synthesize these ingredients to the best of their ability and add them to products. Manufacturers must also carry the burden of proof in validating that these ingredients are safe, tolerable for the delicate infant digestive system, and actually confer benefits to growing babies. Doing so necessitates a robust research and development infrastructure for conducting product trials, as well as a sophisticated production line capable of manufacturing such complex products in the first place.



2.1 Adding ingredients: the question of ratio

Though the presence of components such as HMO, MFGM, and lactoferrin in breast milk have been shown to benefit infant development, it is not always clear how safe or effective their replication in formula is.

For instance, microbial engineering has made it possible to manufacture a handful of HMOs for addition to infant formula, with 2'-FL and LNnT being the most common (Zeuner, et al. 2019). But given that over 150 different types of HMOs are present in breast milk, there remain questions about which HMO types should be added to infant formula and in what concentration.

After all, even in the gold standard of breast milk, certain ratios of HMOs have been shown to be less than ideal for infant health. One study on nursing mothers in India found that elevated levels of 2'-FL and LNnT in breast milk correlate with greater incidence of rotavirus and gastrointestinal infections in infants (Ramani, et al. 2018). Other studies have shown that specific HMO compositions in breast milk may cause infants to gain weight excessively (Larsson, et al. 2019) or develop food allergies (Miliku, et al. 2018).

These studies point to the risk that too-high concentrations of just one or two HMOs in infant formula may have unintended negative effects. Though development trials of infant formulas containing HMOs have shown promising results, further research is needed in order to design an HMO mixture that is optimally balanced. Furthermore, sophisticated processing equipment is necessary to ensure that these delicate ingredients are homogeneously incorporated into infant formula at precise and scientifically validated concentrations.

2.2 Ensuring purity and added ingredient effectiveness

Hygiene is a top priority for any food manufacturer, but nowhere is this focus more pronounced than in the field of infant and young child nutrition. Because a baby's immune system will only develop over the course of the first year of life, manufacturers of infant formula must take exceptional caution to ensure product purity and include clear and transparent labeling about how their products are to be safely stored and prepared.

The abundance of caution with which infant formula manufacturers must operate can however prove challenging in the development of products containing beneficial bio-active ingredients. In their powdered form, infant formulas are shelf-stable products. But they are not sterile, and so minuscule amounts of naturally occurring pathogens may proliferate in packaged products with prolonged storage and caregiver handling (Cho, et al. 2019). Of particular concern in infant formula are *Cronobacter sakazakii*, *Salmonella enterica*, and *Staphylococcus aureus*, which together have caused hundreds of documented cases of illness and dozens of infant deaths over the years.

In order to destroy these bacteria and ensure safe consumption, WHO advises that caregivers reconstitute powdered infant formula with water no cooler than 70° C. However, this high temperature will also kill any probiotic bacteria, nullifying the benefits of these added and often expensive ingredients. Solving this dilemma requires the development of rigorous in-line detection processes (Song, et al. 2018), an exceedingly hygienic manufacturing operation, and sophisticated batch tracing capabilities, as well as innovative approaches to developing products designed for safer handling by consumers.



3

The role of mixers in the production of safe and healthy infant formulas

The high health and safety standards to which infant nutrition products are held can only be fulfilled if raw material components are prepared in quality-controlled systems. As the vessel in which diverse components come together, mixers are crucial to both product quality and processing efficiency.

The final section of this whitepaper discusses three central ways in which high-performance mixing equipment is critical to the cost-effective production of powdered infant formula that is both safe and nutritionally optimal. As a decades-long partner to businesses in the food, nutraceuticals, and pharmaceuticals industries, amixon® has extensive knowledge and experience in engineering sophisticated powder mixers to meet demanding health, safety, and performance standards.

3.1 Creating precise and nutritionally effective mixtures

As discussed in the previous chapters, replicating the complexities and enigmatic properties of breastmilk in powdered infant formula no easy task. This is true both from the standpoint of research and product development and from the standpoint of manufacturing technology.

Once researchers have developed a beneficial recipe with a proven composition of delicate, microscopic components, the recipe must then undergo technical implementation on the production floor. Mixing is among the most critical and challenging processing steps in ensuring that the resulting infant formula contains precise concentrations of beneficial components and can fulfill health claims.

From minerals, to probiotic bacteria, to HMO molecules, many components in infant formula are only present in very small concentrations. To make the mixing task even more challenging, these components have especially delicate particle structures and can lose their efficacy with exposure to heat, shear, or oxidation.





The construction of the HM twin shaft mixer from amixon®.

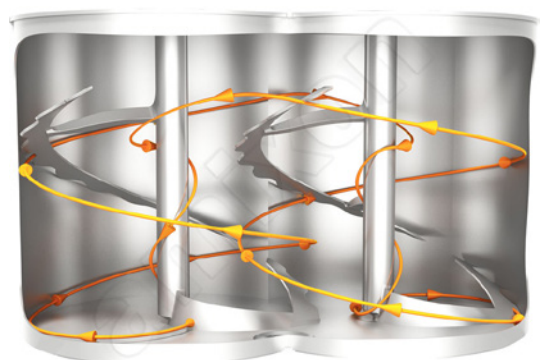
The HM vertical twin-shaft mixer from amixon® offers a particularly gentle yet effective solution for incorporating such small and sensitive components into bulk ingredients. The mixing vessel consists of two cylinders that have been fused together, each housing a helical mixing tool. Both mixing tools rotate in the same direction and are designed with a slight incline of 30°. The diameter of the mixing tool is wide enough to convey nearly a quarter of all the goods within the vessel in just a single rotation. The peripheral speed of the mixing tool is typically adjustable between 0.5 m/s to 3 m/s.

The helical mixing blades gather the powdery contents at the periphery of the mixing vessel, conveying them upwards. Once the powders have reached the top, they then flow back down along the center of the mixing shaft. A three-dimensional current is created in the space between the upward flow at the periphery and the downward flow in the center. The actual mixing, i.e. particles changing places with one another, happens between these two macro flows.

This three-dimensional mixing flow ensures technically ideal mixing results in as few as 20 to 90 rotations, thus requiring only minimal energy input and shear. Even at extremely low filling levels, the HM twin-shaft mixer

can effectively create this current, resulting in perfectly homogenous mixtures even when filled to just 10 to 15 percent its capacity.

The mixing results of the HM mixer are so consistent that only a single sample analysis must be performed per batch in order to ensure that the powdered infant formula has a precise nutrient composition validated by the latest pediatric science.



Flow principle HM

3.2 Exceptional hygiene and construction

Any facility that manufactures infant formula can only reliably prevent microbial contamination and allergen-free processing by means of thorough wet-cleaning protocols. amixon® mixers are designed to simplify the wet-cleaning process in a number of ways:



Hygienic design

amixon® mixing vessels and blades are made from food-grade stainless steel with a smooth, sanitary finish to minimize the build-up of material residues. The mixing shaft is driven and mounted only from the top, out of contact with the mixing goods. The ergonomic doors provide easy access to the mixer interior for simplified maintenance and inspection. Furthermore, the doors are produced using the CleverCut® method, during which an O-ring is inserted into the groove, creating a gastight, dust-free seal that is both close to the product and free of deadspace.



Innovative technology for complete discharging

amixon® mixers with conical floors can quickly discharge flowable bulk materials without segregation. But ComDisc® technology makes it possible to achieve up to 99.997% discharge even in flat-bottomed mixers. Installed at the bottom of the mixing shaft, this flexible mechanism floats through the product during the mixing process and lowers to the vessel floor upon discharging. There, it sweeps the bottom of the mixer in a radial fashion, pushing the mixing goods towards the discharge outlet. The result is less product loss and a cleaner mixer interior.



Automated WaterDragon® wet-cleaning and drying mechanism

A series of retractable washer nozzles are installed at strategic points within the mixing vessel. After discharging, the nozzles automatically protract from behind their air-tight closure flap. Driven by the pressure from the wash water, the washing heads rotate to spray down the interior of the mixing vessel. The system is designed to automatically drain itself of residual rinse water before funneling warm air into the vessel via the nozzles to completely dry the mixer interior.

3.3 Continuous mixing on high-volume production lines

A modern powder filling and packaging machine can process a flow volume of roughly 20 m³ (roughly 10 tons) per hour. In order to work at this pace, infant formula manufacturing facilities must have a logistic concept capable of coordinating the various processing stages and equipment involved.

In our experience, there are two primary ways to approach mixing on a high-volume infant formula production line. In one scenario, a precision mixer (such as the amixon® HM twin-shaft mixer) with a batch volume of 10 m³ or more is implemented such that it feeds into multiple filling machines. In another scenario, multiple smaller mixers with batch volumes ranging from 1 to 2 m³ are implemented with each mixer feeding into its own dedicated filling machine.



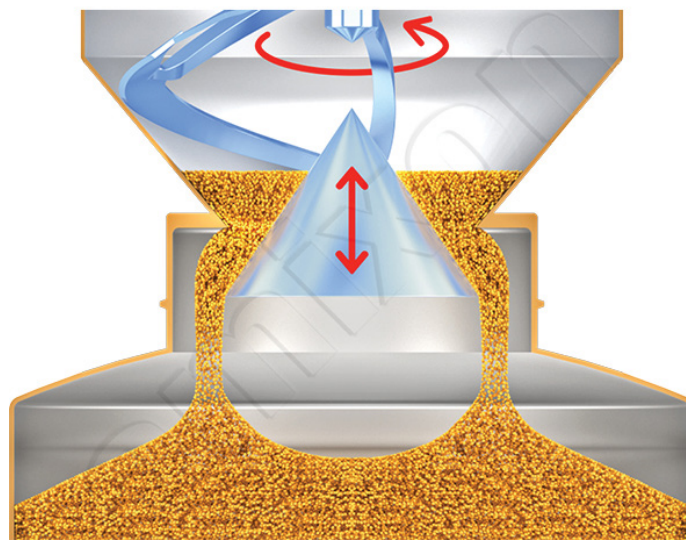
This second concept is known as an end-of-line operation and involves a vertical arrangement of processing equipment in which the materials flow gravimetrically and continuously to the next processing stage.

There are several benefits to end-of-line mixing. For one thing, by eliminating batch changeovers and intermediate cleanings, continuous processes can operate at higher production speeds than batch processes. Another benefit of end-of-line mixing especially germane to infant formula production is the fact that each category of product gets its own dedicated production line. As such, end-of-line operations are ideal for products where cross-contamination may be an issue – such as soy-free or dairy-free infant formula for babies with food allergies.

An example of an end-of-line mixing operation featuring a spray tower at the top level, KoneSlid® precision mixers in the center, and packaging machines at the bottom.

But a downside of conventional end-of-line mixing is a certain amount of product loss at the beginning of each campaign. Typically, when a continuous mixer is started up, the first of its contents to be discharged do not conform to the overall recipe. This is because the flow rates of each individual feeding mechanism still need to be calibrated.

amixon® offers an innovative solution to this challenge. The KoneSlid® precision mixer was specially developed for processes with a high degree of variables. Even at low rotational speeds, KoneSlid® mixes gently and precisely, achieving ideal homogeneity in as few as 20 to 30 revolutions, and often eliminating the need for preparing premixes. The unique mixing flow generated within the vessel makes it possible to completely account for the calibration phase within the mixture. Furthermore, the inverted cone floor of the KoneSlid® mixer ensures rapid and complete discharge without segregation or material piling – another feature that helps to ensure the infant formula composition remains consistently homogenous.



The innovative design of the KoneSlid® mixer floor enables flowable goods to be discharged in a matter of seconds without segregation.

4

Conclusions

Infant formula: a product at the intersection of nutritional science, technology, and parenting

For the health of the next generation, manufacturers of infant formula have a responsibility to make the best product they can according to the latest nutritional science, technological capabilities, and the changing needs of parents. As cultural attitudes shift and research advances our knowledge, formula companies must be able to rely on effective processing equipment that can empower them to develop products that are as beneficial as possible to infant health.

In the production of powdered infant formula, high-performance mixing equipment is crucial for the manufacture of safe baby nutrition products that can live up to the science behind their development. Our unparalleled expertise in powder processing has made amixon® a partner to many global market leaders in infant nutrition.

Each infant nutrition manufacturing facility has its own unique production line. As such, every piece of industrial mixing equipment must be engineered for the customer's specific needs. To arrange a meeting with an amixon® powder processing expert to discuss your specific mixing requirements, simply e-mail us at: sales@amixon.com

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