



**EFSA Claims
Approved**

5 Reasons

Why It's the #1 Ingredient Opportunity



5 Reasons Why You Need

VitaCholine®

The global market for supplements continues to grow, with the Nutrition Business Journal (NBJ) reporting dollar sales growth of 7.0% in 2012 and estimated at 7.2% in 2013. This growth represents a major opportunity for companies that are poised to launch new products in the marketplace. For manufacturers, the best product opportunities in the supplement market all share these common characteristics:

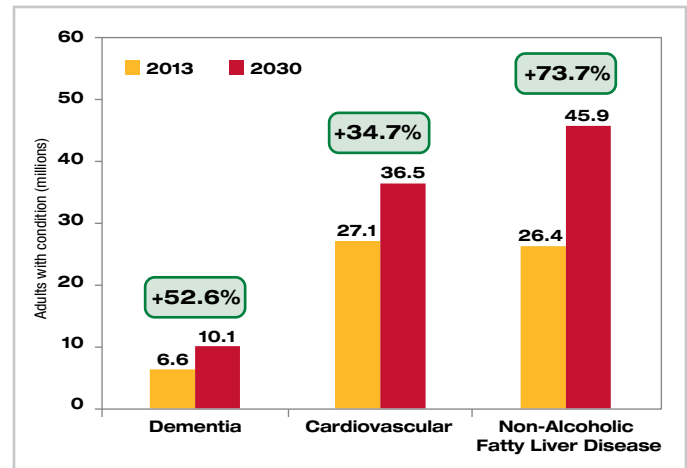
- A clear solution to an emerging market need
- Product claims backed by strong scientific support and
- Branded high quality ingredients

VitaCholine®, from Balchem Corporation, is the only choline salt that can deliver on all three of these factors to help drive your products to sustainable growth. Here are the top five reasons why VitaCholine should be part of your future plans for success.

Reason #1 - A Rapidly Emerging Market for Choline

The degree of success for a new ingredient rests largely upon how well that ingredient meets an existing or emerging consumer need. Successful products not only provide benefits backed by science, but they also most often address an emerging health need. In the case of choline, the need may very well be driven in part by remarkably low levels of choline intake in the average person's diet. According to data from the National Health and Nutrition Examination Survey (NHANES) in the U.S., 90% of individuals don't get enough choline in their diet. Compounding the problem is that many of the richest sources of dietary choline, such as liver and eggs, are frequently viewed as unhealthy themselves. This means that choline deficiency is likely to get worse before it gets better and the need for supplementing dietary intake will become even more critical.

Another important market factor is the role that demographics and health trends play in defining changing consumer needs. When these factors are driving a consumer need in an area where ingredients provide a clear and relevant benefit, the potential market increases significantly. Here, the market is undeniably moving towards a strong need for the benefits choline can provide in the areas of liver health, cardiovascular health and memory and brain function.



Despite a concerted effort by the health and nutrition community to implement preventive measures, poor lifestyle choices mean that more and more people are at risk for developing health issues. According to research projections, by 2030 there will be a significant increase in the number of adults who have health concerns in these areas:

- Dementia sufferers will increase by 52.6% to 10.1 million adults 65+¹
- 36.5 million adults will suffer from cardiovascular disease, up 34.7% from present²
- Liver health, a growing area of concern, will see an increase of +73.7% to a total of 45.9 million adults with non-alcoholic fatty liver disease³

Reason #2 - A Growing Body of Scientific Support for Choline

Choline is not a new ingredient, but it is most certainly an emerging essential nutrient with more and more research supporting the important role it plays in several body systems. Numerous studies have shown the benefits that choline can deliver in many key areas of human health:

Prenatal / Cognition / Memory

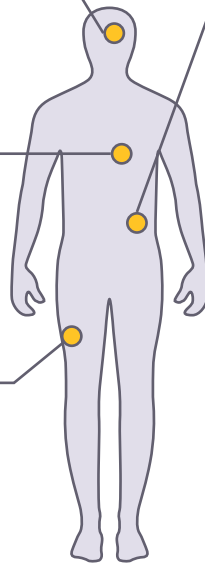
As a precursor of acetylcholine, a powerful neurotransmitter, choline may boost cognitive function by enabling messages to move faster in the brain.

Cardiovascular Health

Choline defends against homocysteine, a pro-oxidant associated with negative impact on heart health, by converting it to the beneficial amino acid methionine.

Fitness / Energy

Choline reduces the onset of fatigue during exercise by speeding up messages from the brain to the muscles. It also protects nitric oxide, enabling muscles to get more nutrients and energy.



Liver / Fat metabolism

Choline defends against fat accumulation in the liver by enveloping lipids and transporting them out of the liver.

Reason #3 - Relevant Claims that Consumers Understand and Believe

Ultimately, the success or failure of a product rests on the consumer and whether they will actually pick the product off the shelf and put it in their shopping basket. This is the critical decision point and is highly dependent upon how relevant the claim is to them and also how

effectively the message is communicated. Consumers don't purchase products they don't need and they won't purchase products unless they believe that they provide benefits that will meet their needs. VitaCholine has a number of claims in areas that are important to consumers and can easily be communicated in marketing materials.

VitaCholine excels at multi-tasking within the body and is appropriate for inclusion in both general and benefit specific formulations. Here are just a few of the areas where VitaCholine can add significant value to new and existing products:

Balchem® has summarized the research behind each of these key benefit areas in a comprehensive set of scientific summaries that provide a detailed description of the inner workings of the nutrient choline.

Balchem actively supports clinical research on choline at leading academic institutions, such as the University of North Carolina and Cornell University, by providing research funding and assistance in developing dosage forms for interventional studies. VitaCholine® was the choline chloride used to supplement dietary intakes in

recent interventional studies that have led to promising new findings in prenatal nutrition. Balchem has worked with leaders in the meat and soy industries in promoting awareness of the nutrient via the Choline Coalition. In addition, Balchem is at the forefront in working with governmental agencies to highlight the need for additional choline in the diet. We have submitted a dossier to the Institute of Medicine in support of defining an RDI for choline and have provided comments to the Dietary Guidelines for Americans Committee in the US.

- *Digestive Health* – as a key driver of fat metabolism, choline is critical to maintaining a healthy liver
- *Prenatal* – similar to folate, choline is essential to help babies develop healthy brains and improve long-term memory
- *Heart Health* – choline lowers levels of homocysteine, which is commonly associated with negative impact on cardiovascular health
- *Cognitive* – choline plays an important role in developing and maintaining healthy memory function
- *Men's and Women's Formulas* – choline requirements are particularly high among men, women of child-bearing age and post-menopausal women
- *Energy* – choline is highly synergistic with the B vitamins and plays a key role in making fats available for conversion to energy

As the #1 global supplier of choline, Balchem has led claims approvals for the nutrient in both the US and Europe. Balchem led the way by submitting dossiers to the Panel on Dietetic Products, Nutrition and Allergies of the European Food Safety Authority (EFSA). After review, EFSA determined that three new claims were sufficiently substantiated. In 2013, these three choline claims were adopted into the EU Approved Health Claims Register. They can now be used on products containing at least 82.5mg choline per 100g per 100mL or per serving.

Much has changed in recent years. In 2016, the EU has established Adequate Intake (AI) value of 400 mg for adults, recognizing the importance of Choline as an essential nutrient. In the USA the FDA has established a Reference Dietary Intake (RDI) of 550mg. Products with claims on choline content or benefits will now show choline and its percent Daily Value (DV) on the label.

Commission Regulation (EU) No 432/2012⁴ established a list⁵ of general function ('Article 13.1') health claims for vitamins, minerals and other nutrients. It was published on 25 May 2012 in the Official Journal of the European Union, and applies from 14 December 2012.

The following claims are authorised for products containing choline:

| EU Adequate Intake (AI) / US Reference Dietary Intake (RDI) for Choline | | | | |
|---|--------------|--------------|--------------|--------------|
| Age | Male | Female | Pregnancy | Lactation |
| Birth to 6 months | 125 mg (US) | 125 mg (US) | | |
| 7–12 months | 160 / 150 mg | 160 / 150 mg | | |
| 1–3 years | 140 / 200 mg | 140 / 200 mg | | |
| 4–8 years | 170 / 250 mg | 170 / 250 mg | | |
| 9–13 years | 250 / 375 mg | 250 / 375 mg | | |
| 14–70 years | 400 / 550 mg | 400 / 550 mg | 480 / 450 mg | 520 / 550 mg |

| | European Union (Product must contain at least 82.5 mg choline per 100g, per 100 mL, or per single portion.) | U.S. |
|-----------------------------------|---|---|
| Liver & Fat Metabolism | <ul style="list-style-type: none"> • Contributes to normal lipid metabolism • Contributes to the maintenance of normal liver function | <ul style="list-style-type: none"> • May promote healthy liver function |
| Cardiovascular | <ul style="list-style-type: none"> • Contributes to normal homocysteine metabolism⁶ | <ul style="list-style-type: none"> • May help reduce levels of plasma homocysteine |
| Fitness & Energy: | <ul style="list-style-type: none"> • Contributes to normal fat metabolism | <ul style="list-style-type: none"> • May reduce fatigue and increase vigor during strenuous exercise |
| Cognition & Memory | | <ul style="list-style-type: none"> • Supplementation during infancy and childhood may lead to improved lifelong memory • May help memory problems associated with aging • Prenatal use may lead to lifelong improvement of visuospatial memory in children born of the pregnancy |

Reason #4 - Multiple Benefits Across Multiple Product Applications

Ingredients that can be delivered across a broad range of product platforms enjoy a higher degree of success than those that have more limited applications. This is particularly critical in the current market, where new product formats are gaining a greater degree of market share and are helping to expand the reach of nutritional supplements. According to Mintel's 2013 global overview of vitamins, minerals and supplements, global sales are valued at US\$ 25 billion and are forecast to grow to US\$ 31 billion by 2016. Their research also indicates strong interest in alternative delivery formats such as chews, dissolvable and liquid products. To drive that point home, NBJ reported that according to SPINS data, for the 52 weeks ending 4/13/13, dollar sales of gummies increased by 35.4%, more than any other format. Liquids and powders also grew, by 7.5% and 10.2% respectively, while tablets were relatively flat at -0.3%. These trends suggest show that consumers are embracing new formats and that manufacturers are working to find ways to satisfy the demand.

Long recognized as safe, stable, proven and versatile, water-soluble choline salts can be used as an important component of a wide range of supplement and food applications. VitaCholine has been successfully added to tablets, powders, gummies, chews, drinks, emulsions, and capsules and is stable through processing operations. In addition, VitaCholine is flavorless at appropriate dosage levels, is compatible with other nutrients and remains highly bioavailable.

VitaCholine has been successfully incorporated into a number processed foods and fortified beverages including, but not limited to:

- Cereals
- Fortified Waters
- Baby Food
- Infant Formula
- Energy Drinks
- Nutrition Bars



VitaCholine is available in a number of different choline salts such as choline chloride, choline bitartrate and choline dihydrogen citrate, each of which has advantages in different applications.



Reason #5 - VitaCholine - Quality That Can Set You Apart

VitaCholine from Balchem is produced to the highest quality standards and is used across a broad range of product applications that demand superior quality such as infant formulations. In addition to using only natural tartaric acid in the production of choline bitartrate, Balchem also has halal and kosher pareve certifications on the vast majority of products. Balchem manufactures VitaCholine according to Good Manufacturing Practices (GMPs), and is Generally Recognized As Safe (GRAS) in the U.S. All products distributed in Europe are manufactured in compliance with EC directives and regulations and meet purity requirements for special food applications.

To further differentiate your product in the market, you can communicate to consumers that you are using a high quality ingredient in your product by using the VitaCholine logo on your package.





- Recognized by EFSA with three health claims
- Superior quality
- From 100% Natural Tartaric Acid
- Highly bioavailable
- Easily applied to liquids, powders, tablets & capsules

1. Dementia incidence data and projected growth rates are from Plassman BL *et al*, *Neuroepidemiology*. 2007 November; 29(1-2): 125-132, Table 2. National prevalence of dementia, AD and VaD, by age categories. Population projections are based on U.S. Census Projections from NP 2012 Table 2. Projections of the Population by Selected Age Groups and Sex for the United States: 2015 to 2060.
2. Cardiovascular incidence data and projected growth rates are from Global atlas on cardiovascular disease prevention and control. Geneva, World Health Organization, 2011 and from Mathers, CD and Loncar D. 2006 November; 3(11):e442. Population projections are based on U.S. Census Projections from NP 2012 Table 2. Projections of the Population by Selected Age Groups and Sex for the United States: 2015 to 2060.
3. Non-alcoholic fatty liver disease (NAFLD) incidence data and projected growth rates are from a study presented at the International Liver Congress, Berlin, Germany, March 30 – April 11, 2011. Population projections are based on U.S. Census Projections from NP 2012 Table 2. Projections of the Population by Selected Age Groups and Sex for the United States: 2015 to 2060.
4. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:136:0001:0040:EN:PDF>
5. EU Register of claims: <http://ec.europa.eu/nuhclaims/>
6. Normal homocysteine metabolism has been identified as being related to cardiovascular health:
EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Guidance on the scientific requirements for health claims related to antioxidants, oxidative damage and cardiovascular health. *EFSA Journal* 2011;9(12):2474. [13 pp.]. doi:10.2903/j.efsa.2011.2474.

