



Ferrochel[®] *“The gentle iron”*

Albion Human Nutrition's patented iron bisglycinate chelate

SUPPORTING HEALTH FOR ALL STAGES OF LIFE



ALBION[®]
HUMAN NUTRITION

From its beginnings as a veterinary pharmaceutical supplier to its current position as a supplier of the highest quality mineral chelates to the human, animal and plant industries. Albion has been at the leading edge of scientific investigations into minerals. Harvey H. Ashmead, Ph.D., founded Albion in 1956; the company started experimenting with chelation in an attempt to increase absorption of minerals in animal feed. The company's findings – that chelation enhanced mineral absorption and animal performance – have served as the bedrock for further investigation and development of new applications, which have resulted in Albion receiving more than 100 patents in the United States and around the world.

Albion's research on its patented amino acid chelates was reviewed by the Food and Drug Administration in the 1970s, as the agency was concerned that unscrupulous companies were making false claims about bioavailability and chelation. After its review, FDA and Albion signed an agreement acknowledging Albion's chelates were safe and effective. In the ensuing years, Albion has led the effort to clear marketplace confusion about the process of chelation.

Nature already supplies bioavailable minerals in a chelated form – for example, the iron in meat is bound to its amino acids, ensuring safety and efficient absorption. Inorganic mineral salts (i.e., carbonates, sulfates, etc.) are not used efficiently by the body because they must be converted to an absorbable form and assembled with protein to assist uptake. Albion's patented chelation process binds a metal ion to at least one non-metallic ligand, usually an amino acid. These

totally reacted, nutritionally functional amino acid chelates possess the absorption advantages of natural chelates present in food.

Albion chelates possess several important features. Most importantly, Albion monitors the reaction process to ensure the chemical bonds form between metal and ligand. Albion chelates are electrically neutral to ensure they neither bind to nor are repelled by intestinal cells. The chelate's molecular weight never exceeds 800 daltons, and the ligands used possess biological usefulness.

Its state-of-the-art production facility in Ogden, Utah, is a human-grade, Kosher (KOF-K) certified spray-drying facility. Albion is prepared for implementation of FDA's good manufacturing practices (GMPs), and has certificates of analysis (C of A's) and specification sheets to guide quality control personnel. Albion welcomes audits by leading suppliers in the dietary supplement, food and pharmaceutical industries. The company now offers almost 30 exclusive, scientifically supported mineral products.

With a host of intellectual property, including patents, trademarks and peer-reviewed published research, Albion has positioned itself as the expert in the field of amino acid mineral chelation. It continues to set the standard for companies seeking quality, efficacious amino acid chelates.

Albion's state-of-the-art production facility is nestled against a backdrop of the Wasatch mountain range in Ogden, Utah



Understanding Ferrochel®

Iron is an essential nutrient in human health, playing a role in immune function, cardiovascular health and cognitive development. Its importance was first recognized about 1500 BC, and by the 16th century, a relationship between iron and blood was well-known. Iron is a constituent of hemoglobin, myoglobin, ferritin and a number of endogenous enzymes.

While iron can be found in vegetables (spinach, corn) and beans (soybeans, kidney beans), its bioavailability is poor. Although iron in meat is much more bioavailable, it is in scarce supply in many places around the world. These factors, combined with physiological reasons, account for the more than 1.3 billion people suffering from iron deficiency anemia, according to the World Health Organization. As a result, iron supplements have been widely used in an attempt to raise ferritin levels to correct this deficiency; however, inorganic iron supplements such as ferrous sulfate still have low bioavailability and typically produce undesirable side effects such as gastric upset and nausea.

There is a better alternative

Albion Human Nutrition developed a patented form of non-heme iron with bioavailability and tolerance similar to heme iron. Characterized by a ferrous cation bonded to two glycine molecules, this ferrous iron amino acid chelate is sold under the brand name Ferrochel. In this chelated form, there is a highly significant improvement in iron bioavailability with a reduction in gastric irritation and unwanted reactions with other food nutrients.

Ferrochel boasts many unique attributes that support its superior

role as an iron supplement in humans. These include molecular size and ionic charge, stability, non-reactivity, bioavailability, safety and tolerability.

In their ordinary form, minerals are difficult for the body to absorb through the intestine due to their charge and the limited intestinal absorptive area, pH, other intestinal contents, and availability of absorptive cofactors. Small protein peptides are easier for the body to absorb. In the stomach, inorganic minerals are solubilized and may combine with amino acids to take advantage of the intestine's affinity for

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- 1956** Harvey H. Ashmead Ph.D., founds Albion in Ogden, Utah
- 1965** Albion receives first U.S. patent and first international patent
- 1970** Albion relocates to Clearfield, Utah, and starts Human Nutrition division
- 1974** Comprehensive research summation on mineral chelates is published in the Journal of Applied Nutrition
- 1977** Harvey Ashmead addresses the United Nations on children's nutrition
- 1985** Ferrochel is developed
- 1986** Ferrochel awarded U.S. Patent No. 4, 599, 152, "Pure Amino Acid Chelates"
- 1994** First clinical study published of Ferrochel on human beings
- 1995** Albion holds its First International Conference on Human Nutrition
- 1996** Albion works with the national Nutritional Foods Association (NNFA) to develop the definition of "chelate"
- 2000** Ferrochel affirmed GRAS in the United States. Door open for expanded, state-of-the-art production facility, Albion
- 2008** Albion works closely with CRN to establish new SIDI protocols

Understanding Ferrochel® *continued*

protein absorption. Albion does the stomach's work in advance by producing low molecular weight mineral compounds where the minerals are bound to amino acids to produce nature-identical chelates that can pass easily through the intestinal wall.

Furthermore, the process of chelation results in the mineral compound carrying no electrical charge. (See Figure 1) Ordinarily, when a mineral is cleaved from its carrier in the stomach, the mineral becomes a charged ion that can block absorption of other nutrients or combine with other dietary factors to form unabsorbable compounds. This is particularly true of iron, which can deactivate nutrients such as vitamin E and ascorbic acid and block uptake of minerals like calcium. (See Figure 2) However, the patented chelation process for Ferrochel ensures the iron does not react with other nutrients and is delivered to the intestine for absorption.

Evidence supports the non-interaction of Ferrochel with other nutrients

A trial in France monitored vitamin A activity in solution alone, with Ferrochel and with iron chloride for almost a year (Bourdonnais, 1994). While the iron chloride caused extensive vitamin A degradation, there was no interaction between Ferrochel and vitamin A; vitamin degradation of the mixture was identical to vitamin A alone. In another trial in Canada, several

samples of a multivitamin and multi-mineral dietary supplement formulation were tested for vitamin and mineral activity over 17 months (McCausland, 1995). There was no interaction between Ferrochel and any of the vitamins or minerals; all vitamins remained within their original USP ranges after 17 months of storage.

Increased tolerability

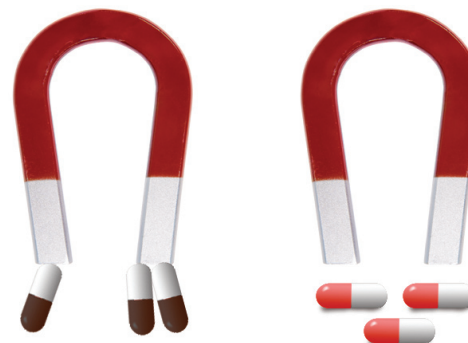
Another benefit of Ferrochel is its increased tolerability compared to inorganic iron, which is associated with gastric side effects such as constipation and nausea. A double blind, crossover trial at the University of Chicago compared the tolerability of 50 mg/d of Ferrochel to 50 mg/d of ferrous sulfate in 38 premenopausal women. (Coplin, 1991). A significant number of the subjects preferred the Ferrochel formulation, and reported fewer instances of gastrointestinal (GI) upset with that formula. These findings are supported by a trial out of the Universidad de San Carlos, Guatemala, in which iron deficient anemic adolescents were given ferrous sulfate or Ferrochel at varying levels (Ponce-Lemus, 1991). At a dosage of 120 mg of iron, 40 percent of subjects taking the dosage as ferrous sulfate reported significant GI effects, while only 15 percent of those taking Ferrochel reported such effects. When the dosage was decreased to 30 mg of iron as Ferrochel, there were no complaints of gastric side effects, and the dosage was still bioavailable enough to correct anemia.

Electrical Charges

Figure 1.

Ordinary iron carries a positive electrical charge. If a magnet is held over most iron salts, they are attracted to the magnet's electrical field.

Ferrochel is chelated and electrically neutral; it is not attracted to a magnetic field.



Iron Sulfite

Ferrochel

Increased bioavailability and extremely safe

It is in the area of bioavailability that Ferrochel truly shines compared with other forms of supplemental iron. Albion's iron amino acid chelate has been effectively used in feed supplementation since 1966; therefore, a great deal of the research has been in the animal field. Researchers from England compared the effects of ferrous sulfate and Ferrochel in weaning rats, and found Ferrochel was significantly more effective (Fairweather-Tait et al, 1992). "Ferrous sulfate is often used as a standard with which to compare the bioavailability of different dietary sources of iron, and it is unusual to find a compound that has iron of higher bioavailability, but clearly [Ferrochel] was more readily utilized than ferrous sulfate," they concluded. In vitro research from Brigham Young University in Provo, Utah, researchers found microvilli exposed to Ferrochel showed dark streaking of absorbed iron, whereas microvilli exposed to inorganic iron showed no streaking (Ashmead et al, 1985).

Even with Ferrochel's enhanced bioavailability, it is extremely safe. Ferrochel absorption is controlled

by body iron stores with greater amounts generally being absorbed by individuals with lower iron status. A woman suffering iron-deficiency anemia may have uptake of 90 percent of the iron, while a healthy young male may only take up 10 percent--enough to offset losses in metabolism.

Ferrochel has been found to be safer than typical iron salts

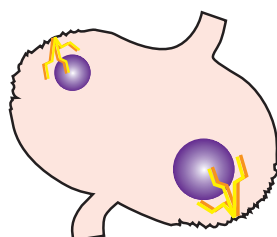
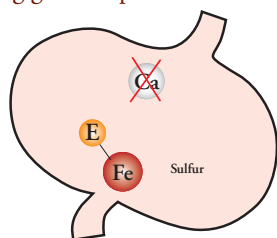
Ferrochel has been found to be safer than typical iron salts found in foods and dietary supplements, and does not produce any pathological effects in test animals, even after long-term feeding. An LD-50 trial in rats at the University of Utah, Salt Lake City, found Ferrochel's LD-50 value was 825 mg iron as iron amino acid chelate/kg of rat weight, compared to 300 mg iron as ferrous sulfate (Larson, 1982). Thus, iron amino acid chelate was 2.6-times safer to use than iron sulfate. An assessment of long-term supplementation of iron amino acid chelate was made through a multi-generational animal study in Canada (Jeppsen, 1993). The trial investigated the effects of iron amino acid chelate in

swine, which are used in such nutritional trials due to the similarity of their digestive tracts and iron metabolism to humans. Supplementation occurred over five filial generations, and histopathological testing was conducted on animals from each generation. The scientists found no tissue alterations or teratogenic effects; in fact, the only notable differences between the

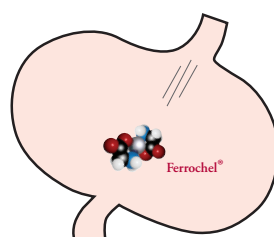
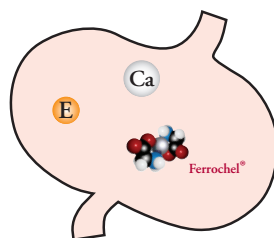
Stomach Reactivity

Figure 2.

When stomach acid breaks an iron salt molecule, electrically-charges iron oxidizes vitamin E and blocks calcium uptake. Unbound iron further impacts the stomach lining, causing gastric upset.



Because **Ferrochel** is a neutral, fully-reacted molecule, it doesn't break down in stomach acid and is delivered intact to the intestine, where it is easily absorbed.



supplemented and control groups were improvements in the treatment group that included increased piglet weight at weaning and lower piglet mortality.

A more recent study investigated the subchronic 90-day toxicity of ferrous bisglycinate in rats (Jeppsen, 1999). There was no mortality in any group, even up to 500 mg/kg body weight/d, and no evidence of compound-related dose-dependent adverse effects. In fact, the researchers found ferrous bisglycinate was both bioavailable and showed absorption rates were regulated by *in situ* iron stores.

Supporting Overall Health

Iron deficiency is the most commonly occurring nutrient deficiency. In the United States alone, the Centers for Health Statistics estimates 12 percent of women of child-bearing age are anemic, while 10 percent of seniors have iron-deficiency anemia. Nutritional surveys estimate the prevalence of subclinical iron deficiency may be as high as 27 percent of the population. In healthy people, iron deficiency can occur in infancy, during periods of rapid growth, from menstruation and in pregnancy. Additional amounts of iron are needed during these periods. Blood loss and disorders of the GI tract can also lead to deficiency. Severe iron deficiency can result in anemia.

A 2003 overview on the consequences of iron deficiency was published in the Food and Nutrition Bulletin from the United Nations University. It noted, "Iron deficiency is considered to contribute to death and disability as a risk factor for maternal and perinatal mortality, and also through its direct contributions to cognitive impairment, decreased work productivity and death from severe anemia." Author Rebecca

Ferrochel Certifications

Kosher-Parve	CAS No. 20150-34-9
Vegetarian	GRAS affirmed
GMO-Free	EFSA approved
FCC	

Stoltzfus presented data showing not only death rates, but disability-adjusted life year (DALY) information to reveal the years of life spent in less than full health. Globally, 841,000 deaths and 35 million DALYs are attributed to iron-deficiency anemia each year.

Ferrochel has been clinically shown to **restore iron levels** in anemic subjects. In a human clinical trial in Germany, 30 patients suffering iron-deficiency anemia received 24 mg/d of iron as Ferrochel (Kirchoff, 1983). After one month, some patients had total correction of the deficiency, while all patients showed significantly increased serum iron, erythrocyte number, hemoglobin and hematocrit values. Similarly, in the Guatemalan trial involving 88 adolescents with severe anemia, those who received Ferrochel showed increased ferritin levels, with only 30 mg/d of iron as Ferrochel increasing hemoglobin values as effectively as 120 mg/d of iron as ferrous sulfate.

Another clinical trial was conducted by the Department of Public Health in San Paulo, Brazil, to investigate the effects of Ferrochel in reversing iron-deficiency anemia in children under 5 years of age (Name, 1995). The children received 1 liter of milk per day that had been fortified with 3 mg of iron



as Ferrochel. After one year, there was an overall reduction in iron-deficiency anemia of 58 percent. Children who were diagnosed with severe anemia showed a reduction of 75 percent in anemia incidence. The researchers calculated the bioavailability of Ferrochel in the milk was 40 percent. Furthermore, this study supported the safety of Ferrochel, as children who were fed the same dosage of iron responded selectively depending on their initial individual hematological condition. Lower hemoglobin levels corresponded to higher relative increases in hemoglobin levels from Ferrochel ingestion; when the levels were higher, ingested Ferrochel produced a lower relative hemoglobin increase.

Importance in children

These studies show both the safety and efficacy of Ferrochel in treating iron-deficiency anemia. This is of particular **importance in children**, as the condition is tied to higher mortality, delayed physical development and impairment of **cognitive function**. Animal studies have shown many parts of the brain are myelinated in the first two years of life, and iron deficiency adversely affects this process (Beard, 2003). In addition, brain iron is acquired early in postnatal life and has a slow turnover; thus, iron deficiency in infants negatively influences psychomotor development. Studies have shown placental transfer, indicating usefulness in preventing fetal iron deficiency anemia (Jeppsen, 1993).



Studies in Children Show Ferrochel Benefits

Physical fitness

Studies in children have shown the benefits of iron supplementation on nutritional status, **physical fitness** and cognitive performance. Researchers in the Philippines provided 800 children with a micronutrient fortified beverage, which contained Ferrochel, and examined the effects on various markers (Solon, 2003). They found children who were moderately to severely anemic who received the fortified beverage showed significant improvement in nonverbal ability scores.



The Philippines study further supported data showing iron's impact on physical fitness. The researchers noted anemia produces lethargy with decreased physical capacity for activity. They noted the children who received the fortified beverage showed “dramatic and consistent” beneficial effects in reducing post exercise heart rates and increasing fitness index scores. Previous clinical studies showed a strong relationship between increased hemoglobin levels and physical fitness indicators such as work productivity, heart rate, blood lactate and oxygen intake.

These findings are not only important in children, but also in adults. Clinical work at Pennsylvania State University found resistance training in older adults increased skeletal muscle strength, but also significantly impacted iron status (Murray-Kolb, 2001). Women showed significant decreases in serum ferritin concentrations, while men's transferrin saturation increased but their iron binding capacity decreased.

Immune function

Finally, iron also plays an important role in **immune function**. Iron deficiency adversely affects the lymphoid system and causes alterations in cellular immune function; this is due in part to iron's role in producing tissue enzymes (Chandra, 2003). In addition, lack of iron impacts the ability of macrophages to kill invading microbials through a free-radical generating process using iron.

increased costs for higher levels of those nutrients that will be impacted. Because Ferrochel does not cause such adverse nutrient reactions and loss of potency, formulators avoid the associated cost of “planned losses.” This means Ferrochel is a more **cost-efficient** way to deliver products that meet label claims now and down the road.

In addition, Ferrochel has been self-affirmed GRAS (generally recognized as safe), is CAS and FCC listed and was sponsored by the FDA at the Codex Alimentarius meeting to have its monograph included in the Codex listing. European deregulation has mandated new regulatory approval in the EU and we are proud to have EFSA approved glycinate chelates. Ferrochel's most recent international approval was recognition from China's Ministry of Health as a food additive.



Ferrochel's Applications

Ferrochel already can be found in a range of pharmaceutical, dietary supplement and food products around the globe. The benefits to product formulators in these areas are clear. As mentioned earlier, Ferrochel has been found non-interactive with other vitamins and minerals. One recent study examined the mean percent loss of vitamins over 180 days when mixed with 4,000 mg of iron/kg (as ferrous sulfate or as Ferrochel) (Marchetti, 2000). The ferrous sulfate mixture showed a 64.7-percent loss in retinol, 48.3-percent loss in pyridoxine, 26.4-percent loss in folic acid and 62.3-percent loss in ascorbic acid. Comparatively, the Ferrochel solution showed only a 46.7-percent loss in retinol, 18.8-percent loss in pyridoxine, 12.9-percent loss in folic acid and 43.8-percent loss in ascorbic acid.

Supplements/Pharmaceutical

As formulators develop multivitamin/multi-mineral products, they must often consider loss of potency due to nutrient interactions. Planning for lost potency means

Ferrochel Applications

Dietary Supplements/Pharmaceuticals:

- Solid dosage forms (i.e., tablets, capsules, soft gels, chewables, etc.)

Foods:

- Beverages
- Confectionery (i.e., nutrition bars, candies)
- Dairy Products
- Grains/Cereals (i.e., rice, cereals, bread, pasta, tortillas, etc.)
- Staples (i.e., flour, sugar, etc.)





Food fortification

Food fortification has been a special area of focus for Albion, since applications have shown Ferrochel has significantly better bioavailability than iron salts when mixed with food and is also less reactive in the food matrix. For example, unlike inorganic iron, Ferrochel does not cause taste or color changes in milk, does not cause fat oxidation, survives the pasteurization process and retains its bioavailability without interacting with other nutrients. Results from a sensorial study presented at the First International Dairy Congress in Brazil (1996) showed milk fortified with Ferrochel retained its flavor (indicating a lack of fat oxidation) compared to milk fortified with ferrous sulfate. Today, UHT milks from Parmalat and Nestle in several Latin American markets use Ferrochel as their iron source. The South African Government Anemia Intervention Program selected Ferrochel as the iron source in the cookies it provides school children to prevent iron-deficiency anemia.

Iron-Source Characteristics

*Pro-Oxidant effect is a negative characteristic of the vast majority of iron salt. This reactive tendency is what gives these other iron forms many of their undesirable effects.

Benefits	Ferrochel	Iron Salts
High bioavailability	✓	
Electrically neutral	✓	
Well-tolerated, easy on the gut	✓	
Viable for dairy products, even with pasteurization	✓	
Drawbacks		
Pro-oxidant effect*		✓
Cause off flavor in foods		✓
Cause color changes in foods		✓
Interferes with other nutrient absorption		✓
Requires vitamin C for absorption		✓

Marketing Opportunities with Ferrochel®

Companies are selecting Ferrochel for their dietary supplement and food products because of its benefits in formulation, safety profile and bioavailability. Marketers have an additional opportunity to reach consumers - who may be reluctant to take iron-containing products because of GI side effects - by promoting Ferrochel as the “gentle” iron. Albion Human Nutrition is supporting this effort with a consumer awareness advertising campaign. Advertisements run in various mainstream publications to educate consumers on the importance of iron and the availability of a more user-friendly form, and advise them to look for Ferrochel on the label. It is important to remember there is no generic equivalent to Ferrochel. While labels may identify this unique molecule in many different ways (e.g., ferrous bisglycinate, iron glycinate, iron amino acid chelate, etc.), Ferrochel is the identifiable consumer trademark for product labels. Given the state of the dietary supplement labeling regulations, Albion customers can sign a licensing agreement to use Ferrochel on the label, avoiding consumer confusion and benefiting from marketplace identification.

“There is no generic equivalent to Ferrochel.”

How to Become a Gold Medallion® Program Member

Albion Human Nutrition also offers its customers the chance to participate in its Gold Medallion program. There are two levels of participation: Gold Medallion products and Gold Medallion companies.

Gold Medallion product status - To receive Gold Medallion product status, minerals must be supplied by Albion, unless Albion does not offer that item (i.e., strontium). Albion also reviews the formulation with the company to ensure the product makes good scientific sense and it is providing customers with efficacious levels of ingredients. Gold Medallion formulations reassure consumers that the minerals are provided by Albion, guaranteeing the company’s quality assurance backing.

Gold Medallion company status - For Gold Medallion company status, manufacturers must offer a complete selection of products containing Albion minerals-both individual items (such as Ferrochel) and multi-mineral formulations. Albion again reviews the product formulations and concepts, and supports its Gold Medallion companies with special discount pricing and marketing promotions. Albion’s Preferred Customer Pricing Program and Gold Medallion

Company Pricing Program offer participating customers a variety of ways to save money through a series of special terms, performance rebates and bonuses.

In addition, manufacturers and marketers who are interested in learning more about the scientific benefits of using Albion chelated minerals such as Ferrochel can request a CD-ROM of published, peer-reviewed studies from the company.

Albion continues to support clinical studies on the safety and efficacy of Ferrochel, as well as research into new applications for this highly bioavailable source of iron. This unique iron amino acid chelate affords marketers the chance to use a stable, non-reactive iron source in their products that shows low toxicity and excellent bioavailability.





Nobody talks Chelates like Albion talks Chelates!

Mineral Amino Acid Chelates – the mineral language the body truly understands.

Albion Human Nutrition's patented chelation processes form mineral compounds that have a multitude of advantages!

- **Nutritionally Functional**

- Easily absorbed, bioavailable, and 100% nutrient content.

- **Kosher-Parve and Vegetarian Friendly**

- All of Albion's human grade nutritional products are certified Kosher-Parve! Meets the guidelines for vegetarian products.

- **Chemically Validated**

- Laboratory tested to be structurally valid. Real mineral amino acid chelates – beyond so-called proteinates or complexes.

- **CAS Registered**

- Only Albion's Chelazome® mineral amino acid chelates have been granted CAS Registry Numbers.

- **Clinically Proven**

- Safe and effective. Predictable positive results!



ALBION® Minerals • Science • Chelates™
HUMAN NUTRITION

Find out about our full TRAACS® range of mineral amino acid chelates
go to www.AlbionMinerals.com or call us at 1-800-222-0733