

## IRON PRODUCTS SAFETY ISSUE / A NON-ISSUE FOR ALBION'S FERROCHEL!

### The Trouble with Iron

Recently, some researchers have interpreted data on iron tissue levels as evidence that too much stored iron can be a health hazard. Salonen, *et al.*, (Circulation 86: 803-11, 1992) reported a correlation between high ferritin levels and the risk of myocardial infarction which was subsequently refuted by other scientists. Nevertheless, in other ways, intake of large doses of iron can be harmful, and in some cases, deadly. Acute iron over dosage is one of the leading causes for pediatric emergency room visits every year. Ferrous sulfate has a recognized LD 50 in rats of 1584 mg/kg (equal to 319 mg elemental iron/kg.) The LD 50 is a recognized statistic that can be used for judging a compound's potential for abrupt toxicity. It is not too difficult for a 20 kilogram child to ingest enough tablets or capsules to produce potentially toxic body levels for iron. The National Poison Control Center Network states that intake of more than 40 mg/kg of elemental iron is cause for grave concern. One can see why scientists, historically, have had concerns about safety issues surrounding iron intake. Ferrochel, from Albion Laboratories, is much safer.

### Research on Ferrochel

Published studies conducted by well known researchers throughout the world, such as Mervyn, Kirchoff, Pineda, Name, Fairweather-Tate, etc., have consistently shown Ferrochel to be more bioavailable than other forms of iron, as shown in Figure 1. In a recent study on a group of 40 anemic children ranging from 6 to 36 months of age, Pineda, *et al.*, found Ferrochel

to have an apparent absorption of 70-75%, a bioavailability that is 3.7 times that of ferrous sulfate.

In most cases, high bioavailability is a desirable feature in a nutrient. However, given the concerns of scientists over the safety of iron intake - abrupt (accidental overdose) and long term, one might question whether the high bioavailability of Ferrochel is then a positive feature.

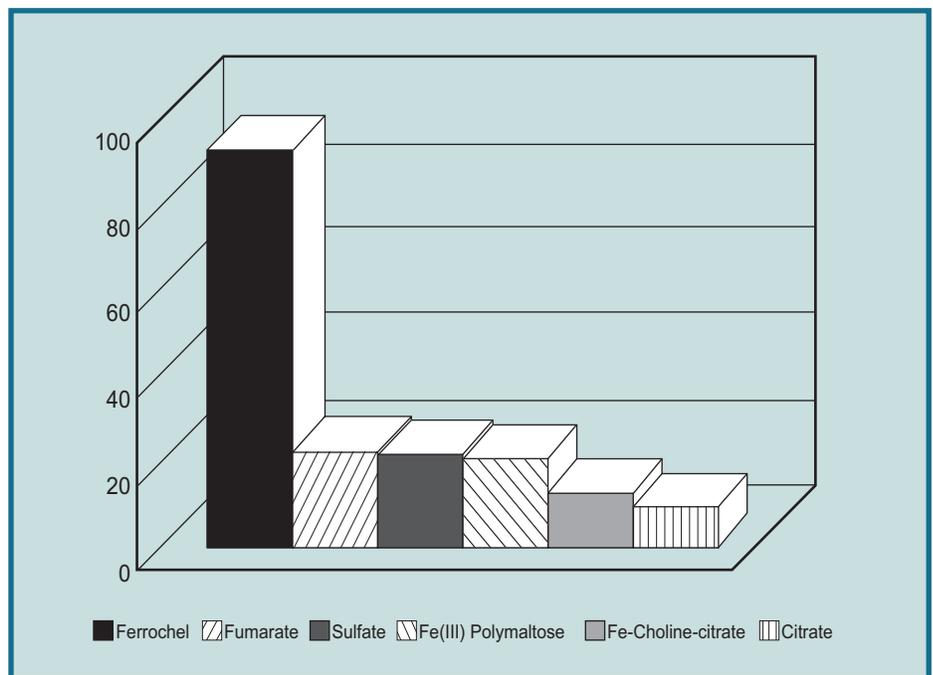


Figure 1.

Relative absorption of different iron compounds as compared to iron amino acid chelate(Ferrochel).

*Brian & Hallberg, Acta Med Scand, Supp 368, 1960, Pineda & Ashmead, J Appl Nut, 1994.*

## Ferrochel - Higher Margin of Safety Against Overdose

When Albion Laboratories develops a new nutritional ingredient, one of its priorities is to determine its safety. In the 1970's, Professor Austen Larson at the University of Utah conducted acute toxicity studies on iron amino acid chelate and compared it to ferrous sulfate toxicity. (Table 1.)

The LD 50 for iron from the Albion amino acid chelate was found to be 2.6 times higher than

the iron from ferrous sulfate. This is a very significant safety margin, particularly when one considers, as mentioned earlier, that Pineda has found Ferrochel to be absorbed at a rate that is 3.7 times that of ferrous sulfate. An extrapolation of these data that compares safety on the basis of absorbed iron would give Ferrochel an even greater theoretical safety advantage of almost 10 times (2.6 X 3.7) that of ferrous sulfate.

Compound	mg/kg	Mg Fe/Kg
Ferrous Sulfate	868	319
Iron Amino Acid Chelate	5000	825

*Chelated Mineral Nutrition in Plants, Animals, and Man, D. Ashmead, ed., Charles C. Thomas Pub p. 163, 1982.*

## Ferrochel - Safety in Long Term Usage

The high absorption rate of Ferrochel has raised some concern over its regular use for long periods of time. Is it safe to take in a multiple formulation on a daily basis? To evaluate the safety, Albion conducted multi-generation studies on pigs. The pigs were fed a diet containing 500 mg of iron, as Albion's amino acid chelate, per day for four consecutive filial generations. The researchers who evaluated these animals could not detect any biochemical,

physiological, or histological changes in these animals compared to normal animals. Histochemical analysis found no abnormal accumulation of hemosiderin, which means that there was no evidence of excess iron accumulation in the animal's tissues. This is evidence that even at this high dose (500 mg/day), Albion's amino acid chelate form of iron is able to be metabolized - strong evidence of low toxicity and safety for long term use.

## Ferrochel - Safety by Nature

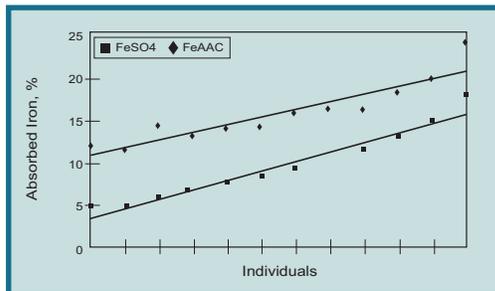
The overall safety found with Ferrochel may be a function of its unique patented chemistry: a chemistry that permits the body to handle this form of iron with an ease and efficiency not seen with other forms of iron. Ferrochel is preferentially absorbed in the jejunum with some absorption in the duodenum. Iron salts are primarily absorbed in the duodenum. Ferrochel's absorption is not inhibited by dietary components such as phytates, phosphates, other metals, phenols, and tannins that generally reduce absorption is thought to be carried out in three stages. Stage one is the uptake of the iron into the mucosal cell from the lumen. Stage two is the storage/metabolism of the iron in the mucosal cell. Stage three is the release of the iron into the serosal for transport throughout the body. Ferrochel excels at Stage one. Ferrochel's movement from the lumen into the mucosal cells is several times more rapid and in greater quantity than that of inorganic iron because it does not enter into the chemical reactions normally associated with iron salts. It is believed that Ferrochel's efficiency at this stage one movement results in its bioavailability advantage over other forms of iron.

Once Ferrochel is in the mucosal cells, it remains there until it is called upon to fill its physiological functions. When in stage three, it moves from the mucosal cells, isotopic studies show that most of the iron is preferentially channeled to erythropoietic tissues. The iron that remains in the intestinal

mucosal cell for a longer period of time is harmlessly passed out of the body by normal shedding of the mucosal epithelia.

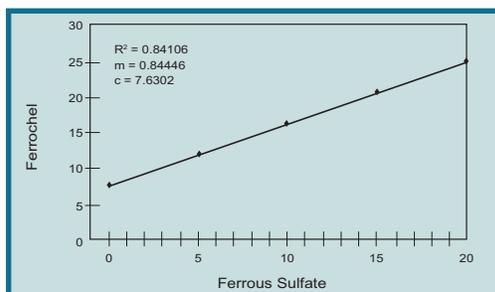
Oscar Pineda, M.D., Ph.D., has analyzed absorption data in a study with human volunteers conducted at Mt. Sinai Medical Center (Mt. Sinai School of Medicine, New York). In this iron absorption study, the volunteers were given ferrous sulfate (18 mg Fe) for seven consecutive days, followed by seven days without treatment, and ten were given Albion's iron amino acid chelate (18 mg Fe) for seven days. In Figure 2, the regression lines of absorbed iron were calculated for all individuals. The absorption of each form of iron was compared in each individual. The slopes for both components are similar, and the only difference is the magnitude of absorption. This indicates that both compounds are subject to similar iron regulatory mechanisms in the mucosal cells. (Figure 3.) Subsequently, Pineda examined the research data gathered in a study by

.....  
**Figure 2.**  
 Relative absorption of iron from either ferrous sulfate or FeAAC in the same non-anemic individuals.  
 .....



Prepared with data from Marvin L. Proc Intl Conf Human Nutr, Salt Lake City, 1995

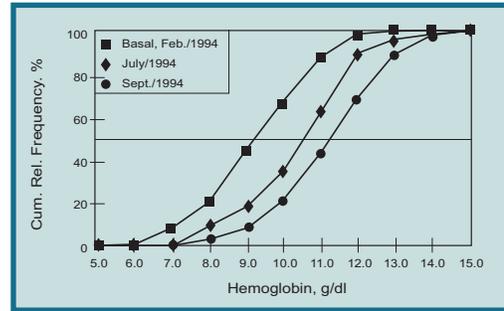
.....  
**Figure 3.**  
 Linear regression of absorption iron from either ferrous sulfate or FeAAC in non-anemic individuals.  
 .....



Prepared with data from Marvin L. Proc Intl Conf Human Nutr, Salt Lake City, 1995

.....  
**Figure 4.**  
 Effect of consumption of milk fortified with ferrochel (3mg Fe/L) on hemoglobin level.  
 .....

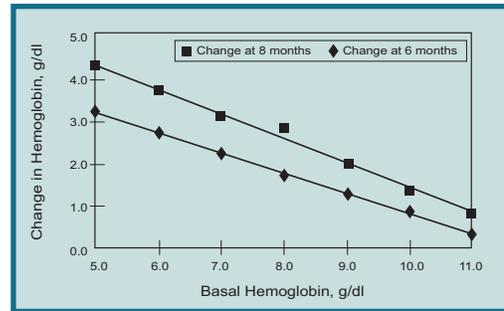
*Children of Tuba, Sao Paulo, Brazil*



Secretaria de Estado da Saude. Escritorio Regional de Tuba, Sao Paulo, Brazil

.....  
**Figure 5.**  
 Regression of change in hemoglobin on basal hemoglobin values after consumption of milk fortified with ferrochel.  
 .....

*Children of Tuba, Sao Paulo, Brazil*



Secretaria de Estado da Saude. Escritorio Regional de Tuba, Sao Paulo, Brazil

Dr. Jose Name at the Basic Health Unit in the city of Tupa, Sao Paulo, Brazil (1994). A total of 185 children ranging in age from six months to two years were involved in this study. All the children in this study received one liter of milk per day fortified with 3 mg of iron from Ferrochel. The hemoglobin levels were monitored

in these children. The changes in hemoglobin levels at six and eight months of the study can be seen in Figure 4. The mean hemoglobin change at six months was +2 g/dl, and at the end of eight months, it was +3 g/dl. The regression analysis of these data (Figure 5) further demonstrated the safety of Ferrochel because Ferrochel absorption was regulated. When the hemoglobin levels were low, the absorption of the iron from the mucosal cells was greater, as reflected by the greater changes in hemoglobin. The more efficient the movement of Ferrochel at stage one of iron absorption allowed more of this iron to be taken up to the mucosal cells in response to the body's demand for iron. As the hemoglobin levels elevated, Ferrochel movement from mucosal cells to the serosa dropped. This natural regulation of Ferrochel's movement into the bloodstream points to its high degree of safety against iron overload on long term use.

## **Ferrochel - An Iron That's Easy To Swallow**

Albion's Ferrochel is a patented, nutritionally functional amino acid chelate form of iron. Human clinical studies have shown it to be an iron of great bioavailability and tolerance (easy on the system). Additional research has further shown that Ferrochel is an extremely safe form of iron. With the concerns of many about the safety of many iron products, it is good to know that a most effective form of iron - Ferrochel - has been found to be a very safe form.

.....

---

### **Albion Human Nutrition**

100 Maple Park Blvd., Suite 110  
St. Clair Shores, Michigan 48081 USA  
[P] 586•774•9055 | [TF] 800•222•0733  
[F] 586•774•8838  
[e] [info@AlbionMinerals.com](mailto:info@AlbionMinerals.com)

© 2008 Albion Human Nutrition. All rights reserved.