Technical Bulletin #S-13

Summary of Bioavailability Study Results Comparing Foodform® Vitamins and Minerals with Ordinary (USP and FCC) Vitamins and Minerals

By IntraCell Nutrition Inc.

USP (and FCC) vitamins and minerals are the free-state chemicals used by vitamin companies to make supplements. USP vitamins and minerals are synthesized by a handful of pharmaceutical companies (Roche, Kodak, Takeda etc.) according to strict federal standards known as the USP (United States Pharmacopoeia) and the FCC (Food Chemicals Codex). Vitamin companies purchase these materials in bulk, blend them together into formulations, make tablets, capsules or powders, and market them under hundreds of brand names. They are also added to flour, breakfast cereals and other prepared foods. The vitamins sold as "natural" or "natural source" or "food based" in the health food store are the same USP (and FCC) vitamins and minerals sold in the drug store or supermarket. Only the labels are different. Supplements formulated with these free-state chemicals and mineral salts may be poorly utilized by the body. They are frequently misused and abused by a confused public. Excesses and therapeutic doses can cause toxic side effects and metabolic imbalances. Studies indicate that Foodform® Vitamins and Minerals, an alternative to USP and FCC vitamins and minerals, may provide a more natural form, lower toxicity and greater utilization.

VITAMINS AND MINERALS IN FOOD ARE NOT ISOLATED CHEMICALS

There is strong evidence that, in food, vitamins and minerals are not in a free state (isolated). They are bound up in highly-complex, macro-molecular structures of proteins, carbohydrates, lipids and other food factors—the "food matrix." Abram Hoffer, M.D., Ph.D., wrote "Components [of food] do not exist free in nature; nature does not lay down pure protein, pure fat or pure carbohydrate. Their molecules are interlaced in a very complex three dimensional structure which even now has not been fully described. Intermingled are the essential nutrients such as vitamins and minerals, again not free, but combined in complex molecules."[1]

TAKING A NEW LOOK AT THE DIGESTION OF FOOD

Among scientists, it is commonly believed that, during digestion, food is completely broken down. This theory holds that, as part of the digestive process, vitamins and minerals become isolated from the food matrix prior to absorption and then somehow become re-combined into the highly complex structures utilized by the body.

The research team that developed Foodform® vitamins and minerals did not accept the common belief that vitamins and minerals are completely broken off from the food matrix during digestion. This was because their experience in isolating constituents of plants in order to assay them made it abundantly clear that plants do not break apart easily, as evidenced by the steps (eg. application of heat and acids) necessary to break them apart. It seemed unlikely, therefore, in the conditions of the stomach (temperature, acidity etc.) that vitamins and minerals could be completely broken away from the substances in the food matrix.

Perhaps the substances in the food matrix to which vitamins and minerals are bound, or with which they are associated, work with them in some way to help them perform their functions more efficiently. Since humans evolved on foods, not on free-state chemicals, it seems reasonable to conclude that it is the larger, more complex structures containing the nutrient, rather than the isolated nutrient, that the body wants.

It is important to remember that USP vitamins were originally developed to be used as drugs, to treat symptoms of nutritional deficiency diseases. But what if it were possible to develop nutrients which would provide the body with the concentrated nourishment it needs to help prevent susceptibility to disease...as a healthy food would do? This line of reasoning was the theoretical basis for the development of Foodform® Vitamins and Minerals.

Therefore, while most scientists and chemists start with foods and then isolate away

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the desired nutrient or constituent from the food matrix so an analog of it can be synthesized, the decision was made to start with the isolated or synthesized nutrient and try to develop a method to put it back into the food matrix (containing proteins, lipids, carbohydrates and bioflavonoids).

THE MANUFACTURING PROCESS FOR FOODFORM® VITAMINS AND MINERALS

After several years of research and development, two proprietary processes were developed with the intention of converting the commercially available USP and FCC isolates into a more natural form. One process is for vitamins (except vitamin D-3) and the other process is for minerals and vitamin D-3.

Foodform® Vitamins are produced by combining free-state USP and FCC vitamins with active vegetable and yeast concentrates, under specific conditions, providing them an opportunity to react with the constituents of the food matrix. The concentrate must have a natural "affinity" for the vitamin being processed (citrus with vitamin C, alfalfa with vitamin K, carrot with vitamin A and Beta Carotene, etc.). The vitamin is then spray dried and assayed for potency. If resulting batches have varying potencies, they are blended together to arrive at a standard potency.

The process for Foodform® Minerals and Foodform® Vitamin D-3 uses a process of growing the mineral in active yeast. Saccharomyces cerevisiae (baker's yeast) is added to water and cultured. The mineral (or vitamin D-3) is fed to the active, growing yeast. After a period of growth and digestion, proteolytic enzymes are added to break the cell walls of the yeast. In the case of certain minerals the insoluble cell walls are removed. The finished product is spray dried and assayed for potency. All finished batches, with various resulting potencies, are blended to arrive at a standard potency.

As part of a rigid quality control program, detailed microbiological tests are performed on each batch of Foodform® Vitamins and Minerals to insure purity.

PRODUCTS CONTAINING USP VITAMINS AND MINERALS BLENDED WITH NATURAL BASES

In health food stores, supplements are often sold which contain USP vitamins and minerals blended with bee pollen, spirulina, herbs, rice and other foods, and labeled "food based", "whole food vitamins", "whole food concentrates", "complete nutritional systems", "vitamins with whole food concentrates", "rose hips vitamin C", B vitamins "fortified" with yeast, etc.

These are not the same as Foodform® vitamins and minerals. Simply mixing USP vitamins and minerals with food bases in a blender does not change them from being free-state USP vitamins and mineral salts. The body is not fooled.

ARE FOODFORM® VITAMINS AND MINERALS BOUND?

It is our opinion that the proprietary processes used to produce FOODFORM® nutrients result in vitamins and minerals which have become bound or associated in some way to constituents of the food matrix. However, this is difficult to prove to a scientific certainty.

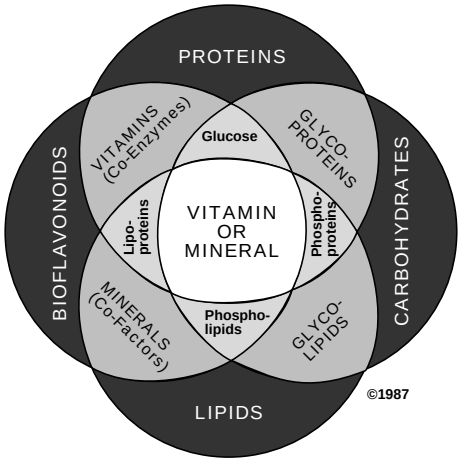


Fig. 1. — FOODFORM® Vitamins and Minerals in a food matrix containing proteins, lipids, carbohydrates and other food factors.

A number of tests have been conducted by independent researchers to try to determine if Foodform® vitamins are bound. These tests include Nuclear Magnetic Resonance analyses (NMR), Fourier Transform-Infra Red analyses (FT-IR), UV-Visible analyses, and Infra Red analyses.

All of the researchers came to the same conclusion: that Foodform® Vitamins are (A) not identical to standard free-state USP and FCC vitamins, (B) not a simple mixture of USP or FCC vitamins and food and (C) bound in the food matrix.

We believe this preliminary investigation into the structure of Foodform® vitamins is a very promising beginning. More research is planned and we hope at some future date to be able to come to a definite conclusion that the vitamins are bound to constituents of the food matrix.

THE IMPORTANCE OF BIOLOGICAL STUDIES

Today there are so many vitamin and mineral products on the market claiming superior absorption or bioavailability. Consumers have understandably become more and more confused and even cynical about absorption claims.

IntraCell Nutrition believes it is the responsibility of supplement manufacturers to support bioavailability claims with biological study results indicating actual, comparative absorption and retention levels.

Even while Foodform® Vitamins and Minerals were being developed, it was decided to have biological studies performed in order to determine if the processes resulted in a better product. Over the years, independent researchers have performed dozens of studies comparing Foodform® Vitamins and Minerals to various USP forms with regard to absorption, retention, utilization and toxicity. Many of these studies have been published in prestigious scientific journals and presented, by invitation, before international scientific gatherings.

THE USE OF ANIMAL STUDIES HAS BEEN ELIMINATED

During the past twelve years, independent researchers have performed both human and animal studies on Foodform® raw material ingredients. This was, and still is the customary scientific procedure for doing studies and is also often required by the FDA, with regard to toxicity studies, in order to insure the public safety.

In recent years, out of respect for the rights of the animal subjects, there has been a growing movement away from animal testing. IntraCell Nutrition fully supports this more compassionate view. Therefore our current policy is not to utilize animals for any future testing.

The results of some of the studies done in the past have been published recently, and more may be published in the future in order to make this data available for evaluation by the scientific community. However, there has not been any funding of new animal studies on Foodform® vitamins and minerals during the past several years.

CONCLUSIONS

These studies may not conform to peer review standards. Therefore, the results are not conclusive. The studies indicate there may be overall increased absorption and retention of Foodform® Vitamins and Minerals. Foodform® Trace Minerals also showed decreased toxicity.

A report on these studies, A New Nutrient Bio-Availability Innovation by HealthComm, Inc., directed by Jeffrey S. Bland, Ph.D., concludes that this animal and human research indicates Foodform® vitamins and minerals "...may represent a significant improvement in bioavailability and tissue retention of specific nutrients.

The clinical implication of these observations could be of significance in facilitating proper nutrient utilization in individuals who suffer from a variety of nutrient malabsorption problems or who require optimal potentiation or nutrient availability."[2]

We believe this biological study research is an exciting beginning. As time goes on we hope to have larger studies performed to yield results which are of greater statistical significance.

SUMMARY OF STUDY RESULTS

The following is a summary of the results (protocols available) of some of the many individual vitamin and mineral studies on human and animal subjects. Also presented are the results of a multiple vitamin/mineral growth study on weanling animals.

The term "absorption" refers to the relative increase over baseline in the amount of the vitamin or mineral in the blood. The term "retention" refers to the relative increase in the amount stored in the liver.

The graphs of the results of the studies performed at University of Scranton by Dr. Joe A. Vinson et. al. show the data, as provided by the researchers, which indicates comparative levels by assigning the USP group an arbitrary value of 100% bioavailability and plotting the Foodform® group's relative level.

The graphs of the results of the human studies performed at New Jersey College of Medicine and Dentistry by Dr. Herman Baker and Dr. Oscar Frank show the data, as provided by the researchers, which plots the mean Δ% increase over base line of the vitamin in the blood, for Foodform® and USP, at various times over a 24 hour period.

The reference for each study is given on pages 6 and 7 at the end of this bulletin. Also shown is information pertaining to where many of the studies have been presented and/or published.

The list of references also includes physiological studies performed at University of Scranton. These studies were performed in the interest of scientific curiosity and to investigate the physiological utilization of Foodform® nutrients.

We are proud that some of these physiological studies have been published in prestigeous, peer-review journals such as Diabetes (the journal of the American Diabetes Association) and The American Journal of Clinical Nutrition.

No drug claims are made or implied on our products.

MULTIVITAMIN–MULTIMINERAL BIOAVAILABILITY STUDY

Baby Animal Growth Study[3] (Fig. 2):

Foodform® group showed significant weight gain reflecting normal, healthy growth of baby animals. The USP group showed growth well below the weight accompanying normal, healthy growth levels.

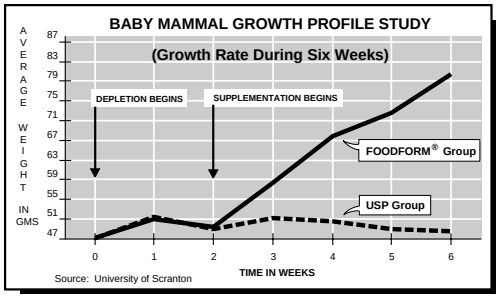


Fig. 2

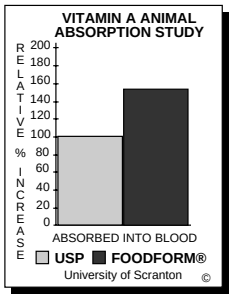


Fig. 3

FOODFORM® VITAMIN A

Animal Study[4] (Fig. 3):

1.54 times more absorbed into blood than USP

Animal Blood Toxicity Study:

Both Foodform® and USP showed depressed values of parameters indicating toxicity. However, the Foodform® group had slightly less depressed values than USP, implying less toxicity for Foodform® Vitamin A.

Human Study[5]:

2.58 times more absorbed into blood than USP after 2 hours

FOODFORM® VITAMIN B-1

Animal Study[6] (Fig. 4, 5):

1.38 times more absorbed into blood than USP

1.27 times more retained in liver than USP

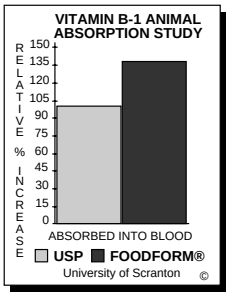
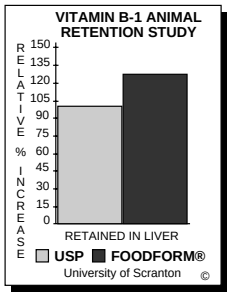


Fig. 4



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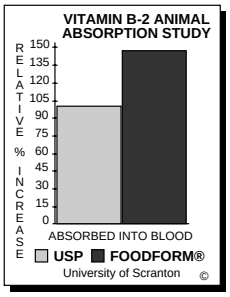

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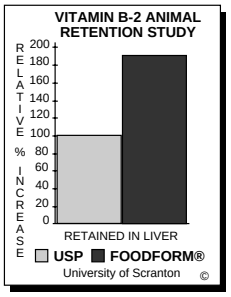


Fig. 7

FOODFORM® VITAMIN B-2

Animal Study[7] (Fig. 6, 7):

1.49 times more absorbed into blood than USP

1.92 times more retained in liver than USP

Human Study[8] (Fig. 8):

1.76 times more absorbed into blood than USP after 2 hours,
1.70 times more after 4 hours, 1.76 times more after 8 hours

FOODFORM® VITAMIN B-6

Animal Study[9] (Fig. 9, 10):

2.54 times more absorbed into blood than USP

1.56 times more retained in liver than USP

Human Study[10] (Fig. 11):

1.29 times more absorbed into blood than USP after 2 hrs, 1.35 times more after 4 hrs

FOODFORM® VITAMIN B-12

Animal Study[11] (Fig 12, 13):

2.56 times more absorbed into blood than USP

1.59 times more retained in liver than USP

Human Study[12] (Fig 14):

1.90 times more absorbed into blood than USP after 2 hrs, 1.66 times more after 24 hrs

FOODFORM® NIACINAMIDE

Animal Study[13] (Fig 15, 16):

3.94 times more absorbed into blood than USP

1.7 times more retained in liver than USP

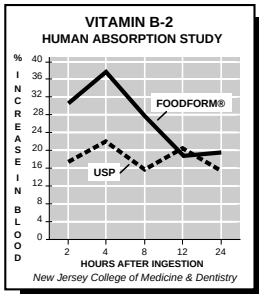
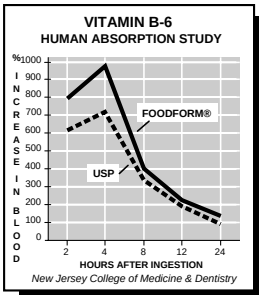


Fig 8.



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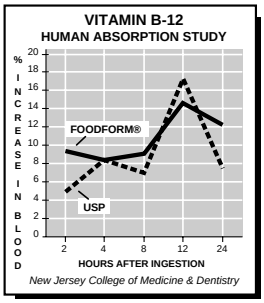

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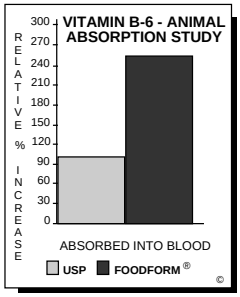

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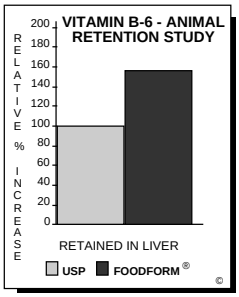

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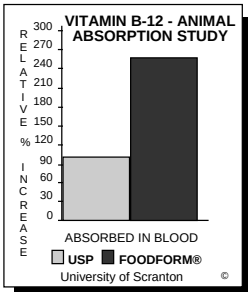

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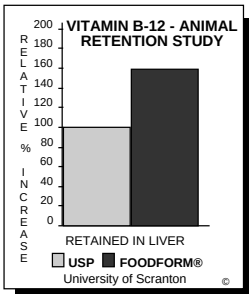

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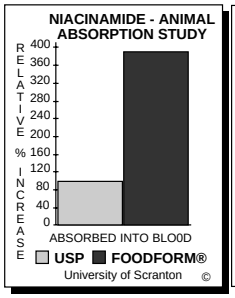

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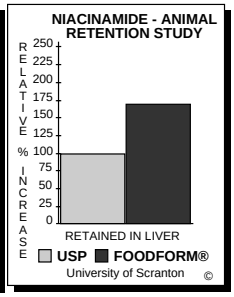


Fig 16.

FOODFORM® PANTOTHENIC ACID

Human Study[14] (Fig 17):

1.38 times more absorbed into blood than USP after 4 hrs, 1.57 times more after 8 hrs

FOODFORM® FOLIC ACID

Animal Study[15] (Fig 18, 19):

1.07 times more absorbed into blood than USP

2.13 times more retained in liver than USP

FOODFORM® BIOTIN

Human Study[16] (Fig 20):

1.06 times more absorbed into blood than USP after 4 hrs, 1.19 times more after 8 hrs

FOODFORM® VITAMIN C

Animal—Short Term Study[17] (Fig 21):

1.48 times more absorbed into blood than USP

Animal—Long Term Study[18] (Fig 22):

1.33 times more absorbed into blood than USP

Human Study[19]:

1.35 times more absorbed into blood than USP

Human Study[20] (Fig 23, 24):

1.55 times more absorbed into blood than USP

1.74 times more absorbed into red blood cells than USP

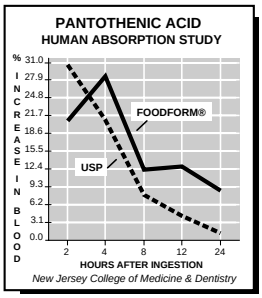
Human Study[21] (Fig 25):

5.01 times more absorbed into blood than USP after 2 hours, 5.86 times more after 4 hrs, 7.88 times more after 8 hrs, 18.37 times more after 12 hrs

FOODFORM® VITAMIN D-3

Analytical Study[22]:

It was found that Foodform® Vitamin D-3 contains significant amounts of vitamin D metabolites—the active pro-hormone (25-hydroxy D-2 and D-3) and the active hormone (1, 25-dihydroxy D-2 and D-3)



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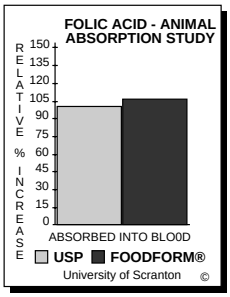

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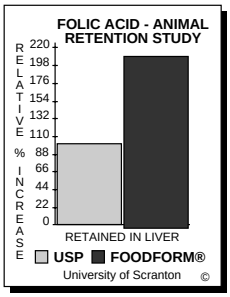

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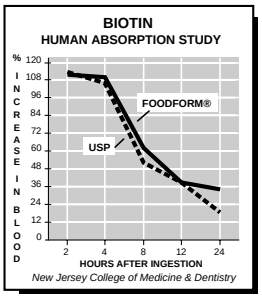

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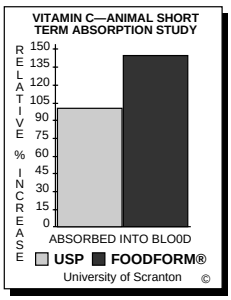

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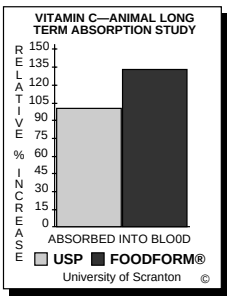

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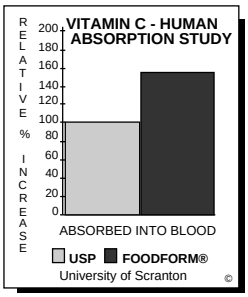

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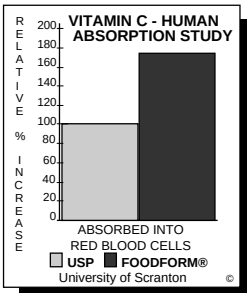

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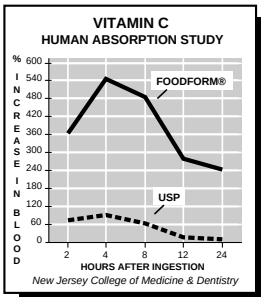

Fig 25.

FOODFORM® VITAMIN E

Animal Study$_{23}$ (Fig. 26):

2.6 times more retained in liver than d alpha tocopheryl acid succinate

Human Study$_{24}$:

7.04 times more absorbed into blood than USP after 2 hours

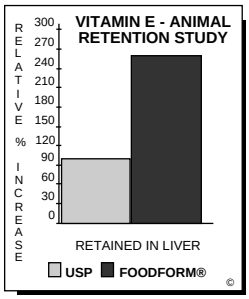

Fig 26.

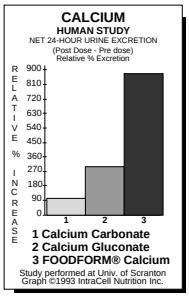

Fig 27.

FOODFORM® CALCIUM

Human Study$_{25}$ (Fig 27):

2.97 times more bioavailable than calcium gluconate, 8.79 times more than calcium carbonate

Human Study$_{26}$:

3.18 times more bioavailable than calcium gluconate

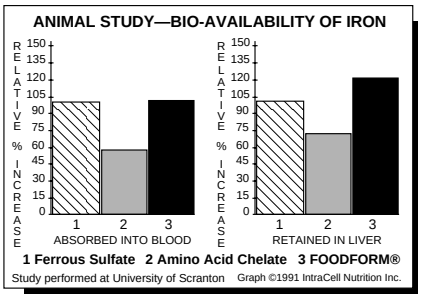

Fig 28.

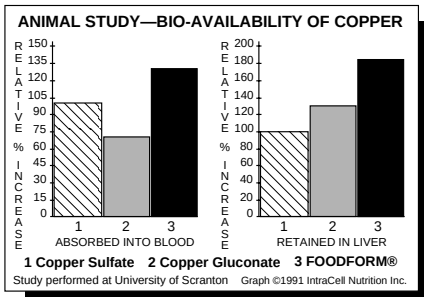

Fig 29.

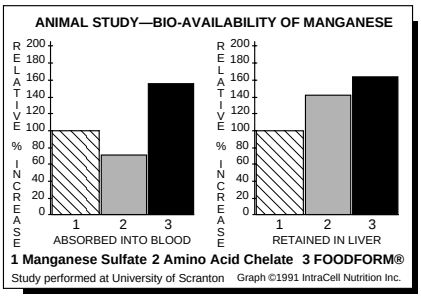

Fig 30.

FOODFORM® MAGNESIUM

Human Excretion Study$_{27}$:

1.83 times more excreted than magnesium oxide, 1.45 times more than amino acid chelate, 2.08 times more than magnesium glycinate

FOODFORM® IRON

Animal Study$_{28}$ (Fig. 28):

1.01 times more absorbed into blood than ferrous sulfate, 1.77 times more than amino acid chelate

1.21 times more retained in liver than ferrous sulfate, 1.68 times more than amino acid chelate

FOODFORM® COPPER

Animal Study$_{29}$ (Fig. 29):

1.29 times more absorbed into blood than copper sulfate, 1.42 times more than copper gluconate

1.85 times more retained in liver than copper sulfate, 1.42 times more than copper gluconate

Human Study$_{30}$:

1.44 times more absorbed into blood than copper sulfate, 1.43 times more than copper gluconate

FOODFORM® MANGANESE

Animal Study$_{31}$ (Fig. 30):

1.56 times more absorbed into blood than manganese sulfate

1.63 times more retained in liver than manganese sulfate

FOODFORM® ZINC

Animal Study$_{32}$ (Fig. 31):

1.72 times more absorbed into blood than zinc sulfate, 1.71 times more than amino acid chelate

1.87 times more retained in liver tahn zinc sulfate, 1.45 times more than amino acid chelate

Animal Study$_{33}$ (Fig. 32):

6.46 times more absorbed into blood than zinc gluconate, 3.11 times more than zinc orotate

3.68 times more retained in liver than zinc gluconate, 1.50 times more than zinc orotate

Human Study$_{34}$:

1.75 times more absorbed into blood than zinc sulfate, 1.58 times more than zinc gluconate

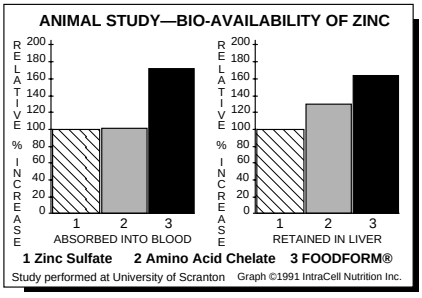

Fig 31.

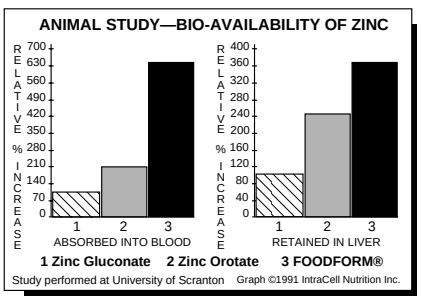

Fig 32.

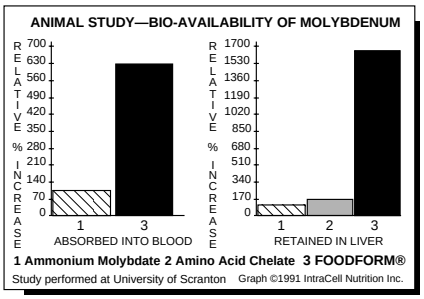

Fig 33.

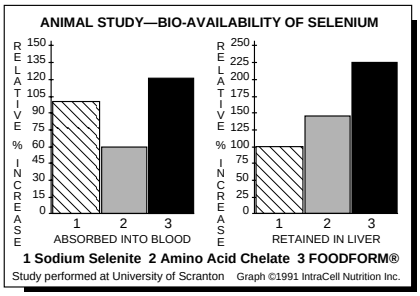

Fig 34.

FOODFORM® MOLYBDENUM

Animal Study[35] (Fig. 33):

6.28 times more absorbed into blood than ammonium molybdate

16.49 times more retained in liver than ammonium molybdate

FOODFORM® GTF CHROMIUM

Animal Toxicity Study[36]:

FOODFORM® GTF Chromium was found to be virtually non-toxic, whereas inorganic chromium is highly toxic (see Merck Index) plus it may be against the Delaney Clause as it has been found to cause cancer in animals.

Human Studies[37, 38]:

Two published human studies indicate that the GTF Complex may be present in highly significant amounts.

FOODFORM® SELENIUM

Animal Study[39] (Fig. 34):

1.22 times more absorbed into blood than sodium selenite

2.26 times more retained in liver than sodium selenite

Animal Toxicity Study[40]:

Foodform® Selenium was approximately 3 times less toxic than sodium selenite.

Sodium selenite is approximately 8 times more toxic when based on the Merck Index.

Human Study[41]:

1.22 times more absorbed into blood than sodium selenite

FOODFORM® VANADIUM

Animal Toxicity Study[42]:

Foodform® Vanadium had low toxicity, similar to inorganic vanadium pentoxide.

FOODFORM® GERMANIUM

Animal Study[43] (Fig. 35):

2.88 times more retained than germanium oxide,

5.30 times more than germanium sesquioxide

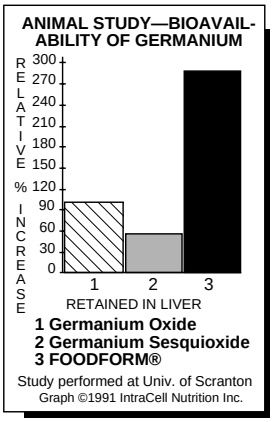

Fig 35.

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