Daily Detox *Plus* (DDP) Overview (White Paper)

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Introduction: Daily Detox *Plus* (DDP) is a colloidal suspension of activated zeolite produced, marketed and distributed by Navan Global. DDP contains primarily clinoptilolite as the constituent zeolite, a naturally-occurring sodium aluminosilicate.

This product is classified as a dietary supplement under US-FDA guidelines.

This monograph will outline the following:

- The history of use and safety of clinoptilolite in animals and humans
- Published clinical data on clinoptilolite
- The history of use and safety of clinoptilolite after nuclear disaster
- The micronization and activation process for DDP
- Quality assurance / product analysis
- Clinical Trials
- Clinoptilolite health benefits

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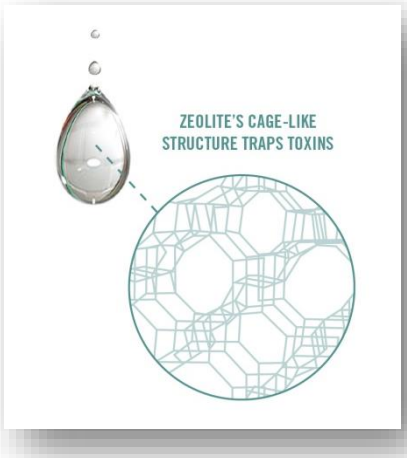
BACKGROUND OF CLINOPTILOLITE

Zeolites are a family of crystalline aluminosilicate minerals. The first zeolite was described in 1756 by Cronstedt, a Swedish mineralogist who coined the name from two Greek words meaning 'boiling stones', referring to the evolution of steam when the rock is heated. About fifty different natural zeolites are now known and more than one hundred and fifty have been synthesized for specific applications such as industrial catalysis or as detergent builders.

Clinoptilolite is a naturally-occurring zeolite, formed by the devitrification (ie the conversion of glassy material to crystalline material) of volcanic ash in lake and marine waters millions of years ago. It is the most researched of all zeolites and is widely regarded as the most useful. In common with other zeolites, clinoptilolite has a cage-like structure consisting of SiO4 and AlO4 tetrahedra joined by shared oxygen atoms. The negative charges of the AlO4 units are balanced by the presence of exchangeable cations - notably calcium, magnesium, sodium, potassium and iron. These ions can be readily displaced by other substances, for example heavy metals (mercury, lead, cadmium, etc..) and ammonium ions. This phenomenon is known as cationic exchange, and it is the very high cationic exchange capacity of clinoptilolite which provides many of its useful properties. Being a naturally occurring mineral, the precise composition of clinoptilolite is subject to a degree of variation. However, an approximate empirical formula is $(Na,K,Ca)_{2\text{-}3}Al_3(Al,Si)_2Si_{13}O_{36}{\cdot}12H_2O$. The Chemical Abstracts Service (CAS) Number for clinoptilolite is **12173-10-3**.

Clinoptilolite is currently used in diverse applications such as drinking water purification, air filtration, plant fertilizer and as an animal feed additive. Many studies have shown that clinoptilolite absorbs toxins created by molds in animal feeds, as well as enhancing nutrient absorption by cattle, pigs, lambs and other animals. Clinoptilolite of volcanic origin has been approved by the EU for use in the category of "Binders, anti-caking agents and coagulants" in feeding stuffs for pigs, rabbits and poultry at levels of up to 20,000 mg/kg. In the United States, clinoptilolite falls under the category of sodium aluminosilicate and has ***GRAS*** (Generally Recognized as Safe) status used primarily as an anti-caking agent (Code of Federal Regulations, Title 21, Section 182.2727).

Clinoptilolite forms the basis of the anti-diarrhea drug 'Enterex', which was approved by the Cuban Drug Control Agency in 1995. The large majority of toxicology studies on zeolites have been performed on clinoptilolite because of its widespread use. No fatal case arising from the oral uptake of this zeolite has been identified.



Framework structure of clinoptilolite

SOURCE OF CLINOPTILOLITE

Deposits of clinoptilolite exist in many countries around the world, including the USA, Cuba, Italy, Turkey, Greece, Ukraine and Japan. Navan Global currently imports clinoptilolite from a single mine in the Southeast, USA. This deposit is a very high purity clinoptilolite and, unlike many deposits, contains no radioactive materials and very low levels of heavy metals. In the event of alternative source(s) being utilized in the future, the mineral will of course be subjected to the same rigorous quality control procedures.

How does it work?

Clinoptilolite has a cage-like structure, with pores and channels running through the crystal. The cage carries a net negative charge, making it one of the few negatively-charged minerals found in nature. Because of its cage-like structure and negative charge, clinoptilolite has the ability to draw to itself and trap within itself positively charged heavy metals and other toxic substances.

The zeolite in the Daily Detox *Plus* (DDP) attracts and traps small, highly-charged particles that fit into the pores and channels of the zeolite cage.
The SiO_4 units are electrically neutral, but each AlO_4 unit carries a negative charge, creating fixed,

negatively charged sites throughout the crystal structure. The negative charges of the AlO_4 units are balanced by the presence of exchangeable, positively charged metals known as *cations* (pronounced "CAT- ions"). These cations usually consist of calcium, magnesium, sodium, potassium and iron. These ions are only loosely held and can be readily displaced by other substances, such as toxic heavy metals.

This phenomenon is known as "cationic exchange", and it is the very high cationic exchange capacity of zeolites which provides for many of their useful properties. In their chemical makeup, zeolites are a lot like clay, in that they are both made up of aluminum, silica and oxygen. However, there is an important difference in their structure.

Many types of clay have a layered crystalline structure (similar to a deck of cards) and are subject to shrinking and swelling as water is absorbed and removed between the layers. In contrast, zeolites have a rigid, 3-dimensional crystalline structure (similar to a honeycomb) consisting of a network of interconnected tunnels and cages. Water moves freely in and out of these pores but the zeolite's framework remains rigid. Another special aspect of this structure is that the pore and channel sizes are nearly uniform, allowing the crystal to act as a molecular sieve.

Whereas most chelating agents used for detoxification are non-specific, only relying on charge for binding potential, the clinoptilolite seems to be highly specific for the toxic heavy metals. Research has shown that the smaller the diameter of the metal and the higher the charge of the metal, the greater the affinity it has for the activated liquid zeolite. Higher charges simply increase the strength of binding with higher binding characteristics. The small size allows for deeper access into the zeolite pores with more points of coordination (attachment).

Larger atoms do not fit into the zeolite cage as well and so are more easily exchanged for higher-affinity metals. As an example of this phenomenon, arsenic has a charge of +3 and an atomic radius of approximately 1.8 angstroms, while potassium has a charge of only +1 and an atomic radius of approximately 2.8 angstroms.
The arsenic binds with very high affinity for the zeolite while the potassium has no affinity whatsoever. It just so happens that the most toxic metals are those with a small radius and high ionic charges. The healthy minerals and electrolytes tend to have larger size with smaller ionic charges.

The clinoptilolite binds a variety of toxins. This includes heavy metals (Lead, Cadmium, Mercury, etc..), nitrosamines and others. Cationic exchange is an entirely passive process – when the zeolite is in close proximity to these high-affinity compounds, they will be drawn to the zeolite and either absorbed into the cage or adsorbed onto the surface of the zeolite. There is no chemical activity in this process.

The zeolite will not be drawn to compounds in an effort to 'rip' metals away from them. In other words, the zeolite will not pull metals that are sequestered inside tissue or bone. If, on the other hand, the tissue has already released free metals into the system, the zeolite will have the ability to trap and remove it.

HISTORY OF USE IN ANIMALS

Review of Literature

There are extensive reports in the chemical engineering, crystallographic and synthetic chemistry literature regarding the use of zeolites, including clinoptilolite (CLN), as molecular sieves and filtration agents. Nitrosamines, heavy metals, dichlorobenzene and mycotoxins, such as aflatoxin B-1 have been shown to coordinate with the structure of, or adsorb into the structure of, zeolites.

In addition, the structure of this naturally occurring mineral is well documented and crystal structures have been grown which demonstrate coordination of CLN with many other compounds, natural and synthetic. The role of CLN as a chemical adsorbent is without question. For the purpose of this report, that literature will not be discussed except as references.

The first studies conducted in a complete toxicology profile usually consist of exposing cells in culture to the agents in question. This has been done with CLN and a summary of this *in vitro* data will be presented. However, this data is more useful in measuring comparative toxicities and is generally not considered to be as relevant as indicators of *in vivo* toxicity.
The evaluation of dietary CLN supplementation through agricultural/animal science research makes

up the bulk of the safety data used in this report. Reports of use in humans do exist in the medical literature and those data will also be outlined herein.

Cell Culture Data

CLN has been shown in the chemical engineering literature to be an effective adsorbent for metal ions that serve as serum electrolytes, like sodium, potassium, calcium, magnesium, as well as toxic heavy metals and environmental poisons. In cell culture experiments, CLN has been shown to cause cell death or a slowing of the growth of the cultured cells. In a culture of human embryonic lung cells, three zeolites were compared: CLN vs mordenite vs erionite[1]. Nikolova and colleagues observed an increasingly toxic effect of these zeolites on the cultures of lung cells, ordered CLN, MOR, and ERI.

Suggestions as to particle size were discussed, however the ionosorbent properties of the individual zeolites, which correlated to their relative toxicities, is ultimately the cause. Cells in culture require calcium and magnesium, some in excess, for successful culture. The in vitro environment is defined and is limited in the amount of these electrolytes that are available. Loss of those, as well as other serum components, was ultimately the cause of the cell death. In other studies, the effect of CLN has been measured against tumor cells and mechanisms of antitumor activity proposed [2,3,4] including alteration of cell cycle genes like p21cip1/waf1 and p27kip1.

In these cell culture studies, the authors unsuccessfully argue specific influence of CLN on genes and growth regulation pathways. In all cases, the influence of CLN on cultured cells appears to be an artifact of sequestration of necessary nutrients, growth factors and serum components. The position that particle size played a role in toxicity would not come into consideration since the product in question contains micronized zeolite. The sheet-like structure of CLN also differs from more toxic species of zeolite, such as asbestos. Asbestos is described macroscopically as rod-like or needle-shaped. As such, these other minerals could be mechanically cytotoxic.

Use as a feed supplement in agriculture

Clinoptilolite (CLN) has been evaluated as a food additive in cows, pigs, rats, mice, dogs, sheep and hens and as a potential candidate for the experimental-induction of carcinogenesis agent in rats.[5]

Cattle

Cattle awaiting parturition underwent long-term feed supplementation with CLN and were evaluated for changes in serum electrolyte levels (Ca, Mg, K, Na, PO4)5 and on serum beta-carotene, Vitamin A and Vitamin K levels[6]. In both studies, no changes in serum levels were detected with CLN feed supplementation. In addition, the cows were evaluated for the development of parturient paresis, also known as “milk fever”, a post-partum condition characterized by low serum calcium.

Supplementation with CLN reduced the instance of this condition indicating it does not bind and sequester serum calcium.

Katsoulos et. al. also evaluated the effect of long-term feed supplementation on the serum concentration of certain trace metals (Fe, Zn, and Cu)[7]. At a level of 1.25% of feed, CLN had no effect on these serum metals while 2.5% resulted in minimally detectable differences which held no clinical relevance. Other work demonstrates the ability of CLN feed-supplementation to reduce the transfer of radioactive cesium from lactating dairy cattle to the milk.[8]

No literature exists describing any adverse clinical events associated with feed supplementation in cattle. Rather, the published clinical experience associated with this species has described benefit and safety.

Swine

CLN has been extensively studied in this model. Animals were fed a diet of 5% CLN and monitored for general health status, blood composition, weight gain, feces production and odor and on the course of gastroenteritis of alimentary origin and diarrhea affecting these animals[9]. This study revealed that feeding swine CLN reduced overwhelming fecal odor, and hastened symptom resolution for animals affected by diarrhea and gastroenteritis. In addition, no hematological affects (reduction in red or white blood cell numbers or morphology) were observed in the test animals.

Moreover, swine fed CLN gained an average of 23% more weight compared to controls. This weight gain is postulated to result not from CLN directly, but from the overall improved health and reduced

incidence of gastrointestinal distress by the test animals compared to control animals.
CLN adsorbs ammonia (as NH4+) from the gastric compartment of these animals.

In another series of experiments, swine were exposed to cadmium with or without 3% CLN feed-supplementation and the effects of Fe-deficiency anemia measured[10]. Adding CLN to the diet of these swine resulted in a reduction in the severity of anemia associated with cadmium poisoning and an overall reduction in the amount of Cd isolated from tissue procured from the poisoned pig, demonstrating the ability of CLN to effectively remove that toxin from the animal's body.

Similar to the cattle study described earlier, the effect of feed supplementation with CLN was evaluated in sows[11]. Vitamins, serum electrolytes and other trace elements were measured in animals with and without pre-treatment with CLN.
The effects on serum and tissue levels were evaluated. Papaioannou found no changes in levels of K, Na, P, Ca, Mg, Zn or Cu, nor in Vitamin A or E, in the serum, liver or kidneys of the sows.

The effect of CLN feed supplementation has been compared to that of other zeolites. Zeolite A, a synthetic version of the mineral, and CLN were fed to growing pigs of varying developmental stages[12]. Weight gains, feed conversion ratios and serum electrolyte levels were measured, as well as the biological value of proteins synthesized (a marker of ammonia removal), plasma ammonia, digestibility of nitrogen, and urinary p-cresol levels were measured. Shurson and colleagues found, in contrast to the other studies, that no effect of weight gain or daily feed intake was observed with either zeolite. CLN supplementation, however, did result in an increased feed conversion ratio. The synthetic zeolite reduced each serum electrolyte measured (Ca, P, Mg, Na, and Fe) linearly with dose but CLN reduced only serum phosphates. Daily fecal nitrogen increased with both zeolites but net protein utilization was reduced in the CLN group. Urinary p-cresol and plasma ammonia were reduced by feeding CLN.

Papaioannou went on to evaluate the effect of combining oral antimicrobial medication with 2% CLN feed supplementation in weaned, growing and finished pigs[13] and in sows and their litters[14]. His group observed no adverse reaction to ingesting CLN. Antimicrobial drugs to prevent diarrhea given simultaneously with CLN did not result in adsorption of the antibiotic. In fact, the co-administration of the drug with the CLN resulted in a shorter clinical course of diarrhea compared to antibiotics alone. In fact, CLN supplementation resulted in an overall reduction in the mortality of weanlings associated with administration of antimicrobial agents.

Overall and average daily weight gains increased as well as the feed-conversion-ratio, the measure of how efficiently the piglets convert food to body weight. Finally, the overall well-being score of all animals improved. Since antibiotic exposure alone carries risk, the major conclusions drawn from this work are the lack of interactive effect of CLN on the systemic availability and efficacy of the antibiotics and the apparent protective effect the CLN provided over the toxicities associated with antibiotic use.

Though one study did show a net reduction in serum phosphates in swine supplemented with CLN, the reduction was described as "clinically insignificant" by the authors. The overall clinical experience with CLN in this species would be described as positive.

Rodents
There are many papers evaluating the effects of CLN in several species of rodent. Rats fed Cd along with CLN give birth to litters of normal size and the pups develop normally[15].

Rats fed CLN after being exposed to 2,2-dichlorovinyl dimethyl phosphate, known commercially as dichlorvos, a neurotoxic pesticide sprayed onto farm animals to eliminate parasites, showed reduced intoxication by the chemical and significantly reduced tissue-level reduction in cholinesterase (a tissue-level effect of dichlorvos poisoning) in all tissues evaluated[16]. Even more remarkable, tissue cholinesterase activity was maintained in rats exposed to the nerve agent, VX, after pre-treatment with CLN[17]. Rats fed CLN alone and in combination with Aflatoxin B-1, a - 8 - carcinogen produced by the fungi, Aspergillus flavus and Aspergillus parasiticus, demonstrated some reduced aflatoxicosis, but an increase in maternal liver lesions, even above aflatoxin B-1 alone[18].
Because both are zeolites, references are made to the similarity between asbestos and CLN. However, they each possess unique structural and chemical properties. Studies have been conducted; questioning the wisdom and safety of zeolite

treatment in general[19], but ultimately proves CLN is safe among zeolites. Diatomaceous earth, quartz, mordenite and CLN were introduced into the respiratory tract of rats by bronchial levage. With all minerals except CLN, this treatment resulted in cytotoxic effects in the tissues, attributed to the rod- or needle-like structure of the other minerals. Carcinogenicity of CLN was evaluated by direct intratracheal administrating of CLN in Wistar rats[20]. The authors found no transformation or carcinogenesis in the rat lung with up to 60 mg of CLN.

Tumor bearing mice were treated with micronized CLN and doxorubicin[21]. The lipid-peroxidation of doxorubicin to 4-hydroxynenal, and thus the cytotoxic effects of the drug, were reduced outside the tumor but left intact within. The combination with CLN also resulted in "a strong reduction of the pulmonary metastasis count, increasing the anticancer effects of Doxorubicin. Mice were injected with melanoma cells and fed micronized CLN for 28 days[22].

The authors reported a significant reduction in melanoma metastasis. In the same study, mice fed CLN for 28 days showed increased lipid-bound sialic acid but, interestingly, a decrease in liver lipid peroxidation. The lymphocytes isolated from these mice provoked a significantly higher graft-versus-host response in control mice.

After intraperitoneal injection of micronized CLN, the number of peritoneal macrophages increased. The authors concluded CLN causes an immunostimulatory effect, as evidenced by the hyperactivated lymphocytes and the increased macrophage count in the peritoneum. Serum chemistry in mice treated with CLN was evaluated along with hematopoetic effects and biochemical indicators of kidney and liver function. The CLN used was either finely or coarsely ground[23]. Ingestion was well tolerated. Animals receiving the zeolite-rich diet were found to have a 20% increased serum potassium level compared to control. Erythrocyte, platelet and hemoglobin levels were also unaffected by the CLN treatment.
The coarse material, however, causes a luekocytosis and concomitant reduction in GM-CFU in the bone marrow. The study demonstrated the absolute necessity of using micronized CLN particles.

Pavelic's group also showed significant antitumor effects of micronized CLN in CBA/HZgr mice with spontaneous mammary carcinoma and in C57BL/6 mice with melanoma tumors and mammary aplastic tumors implanted on the flank3. Interestingly, the antitumor effect was not increased with CLN supplementation prior to tumor induction but was similar to groups treated after tumor implantation. In both cases, growth delay continued until abolishment of the treatment, at which point the tumor grew out. Importantly, this study also evaluated the structure/effect of micronized CLN. Scanning electron microscopy revealed a lack of fibers and instead, a rough, roundish particles in contrast to asbestos, which was very needle like. They also found that asbestos, unlike CLN, catalyzed the production of hydroxyl radicals.

Other animal species
CLN feed supplementation was ineffective against copper poisoning in lambs fed a diet enriched with 20 ppm copper sulfate, but only at the dosing schedule used[24]. Furthermore, Bartko and colleagues showed no effect of CLN therapy on experimentally induced acidosis in sheep[25]. Sheep fed CLN were found to have no deleterious effects after feed supplementation but showed no evidence of health advantage either[26].

Hens fed CLN did benefit from the supplement. In laying hens, supplementation with CLN resulted in significantly lower liver mycotoxin levels after adding CLN and aflatoxin B-1 to the feed[27], but more importantly caused no gross histopathologic changes compared to control. Olver observed no significant effects (body weight, egg weight and age at first egg, rate of amino acid adsorption) of feeding hens up to 50 g/kg CLN[28].

Reviews
Many of the above-mentioned articles were reviewed in a single paper. The first study, an article by Elmore, et. al. is a review of what has been described in use of CLN and other zeolites[29].

Notably mentioned is the determination by the International Agency for Research on Cancer which describes zeolites with a size greater than 5 microns as being carcinogenic to humans. Oral administration of CLN is shown to be non-toxic in animals, but inhalation toxicity is readily demonstrated, especially with particle sizes greater than 5 microns. Along with particle size, fibrousness

presents the greatest toxicity. In the rabbit skin sensitivity model, CLN caused no sensitivity reaction. CLN had no effect on reproductive capacity in rats. The basic conclusion was that CLN was safe, but respiration of the dust should be avoided.

HISTORY OF USE IN HUMANS

There are at least three published trials that can be reviewed for the effect of CLN in humans aside from specific studies conducted on the formulation of DDP. The first paper[30] describes a prospective, open and controlled parallel-group study of 61 immunodeficient patients who received a CLN preparation for 6 to 8 weeks. During this course, there was no change in the primary medical care given to the individuals. The effects of CLN on the cellular immune system were evaluated.

The therapy resulted in CD3+, CD4+, CD9+ and HLA-DR+ lymphocyte counts increasing and CD56+ counts decreasing. The interpretation was an overall stimulation of the immune system, with no adverse reactions to the treatments observed.

The second paper[35] describes the use of CLN in absorbing ethanol in healthy drinkers. The study showed a clear reduction in blood alcohol level that was dose dependent on the amount of CLN ingested. Results were more pronounced in male trial participants.

A third paper[54] outlines a pilot study on the use of CLN in reducing cholesterol in hyperlipidemic patients. The pilot results suggested that oral administration of clinoptilolite may improve lipid profile in individuals with dyslipidemia, which warrants further investigations.

NUCLEAR WASTE & FALLOUT

Nuclear Waste

Early experiments were aimed at concentrating 137Cs and 90Sr from low-level waste streams of nuclear reactors and leaking repositories on clinoptilolite[37-39]. The ''saturated'' zeolite was transformed into concrete, glass, or ceramic bodies and stored indefinitely. Natural zeolites have superior selectivity for certain radionuclides (e.g., 90Sr, 137Cs 60Co, 45Ca, and 51Cr) compared with organoresins and are cheaper and much more resistant to nuclear degradation. Dozens of papers have demonstrated the ability of several natural zeolites to take up these and other radionuclides [40-43].

A mixture of synthetic zeolite A and natural chabazite from Bowie, AZ, was used to take up Sr and Cs, respectively, from contaminated waters at Three Mile Island, PA[44]. Clinoptilolite currently is used to remove Sr and Cs from low-level effluents from a nuclear power plant before they are released to the Irish Sea at Sellafield, U.K.[45], and to capture these isotopes from leaking repository containers at West Valley, NY[46].

Nuclear Fallout

The same selectivities for Cs and Sr by zeolites permit treatment of radioactive fallout from nuclear tests and accidents. The addition of clinoptilolite to soils contaminated with 90Sr markedly reduced the strontium uptake by plants[47], and the presence of clinoptilolite inhibited the uptake of Cs in contaminated Bikini Atoll soils[48].

Several zeolite processes have been developed to counteract the fallout from the 1986 Chernobyl disaster. Shenbar and Johanson[49] found that 137Cs in soils was not taken up by plants after treating the soil with a zeolite, and Forberg *et al.*[50] showed that a zeolite supplement to the diets of Swedish reindeer accelerated the excretion of 137Cs ingested with food contaminated by Chernobyl fallout. Zeolites added to soils reduced the uptake of 137Cs by pasture plants in the vicinity of Chernobyl[51], and dietary zeolite reduced sorption of radiocesium by sheep fed fallout-contaminated rations in Scotland[52]. In Bulgaria, zeolite pills and cookies were prepared for human consumption to counteract Chernobyl fallout[53].

The zeolite apparently exchanges 137Cs and 90Sr in the gastrointestinal tract and is excreted by normal processes, thereby minimizing assimilation into the body.

MICRONIZATION & ACTIVATION

Background

Navan Global's Daily Detox *Plus* (DDP) is the ***original*** **'**liquid' zeolite (colloidal suspension) and the "category creator" for zeolite products used for health and wellness. Over 4 million bottles have been sold worldwide generating thousands of testimonials from satisfied customers. There is no product on the market that helps remove toxins from the body as effectively, or as safely, as DDP.

The reason for the success of the DDP formulation is the proprietary micronization and activation processes used during the manufacturing process. These unique and exclusive processes ensure DDP is a superior, one-of-a-kind product.

Micronization

The first step in the micronization process begins by milling pure clinoptilolite zeolite into ultrafine particles. This milling process reduces the zeolite's particle size to less than one micron. This is important because the smaller the size of the particle, the more readily it can become a colloidal suspension and be absorbed into the bloodstream. This micronization process continually "grounds" the zeolite smaller and smaller until it reaches the consistency of a very fine powder.

Many zeolite products skip this step and simply place raw zeolite or un-micronized zeolite into canisters or capsules (Most commercially available zeolites measure between 2 and 40 microns). Zeolites greater than two microns are primarily beneficial as digestive cleansers as they are far too large to allow for absorption from the digestive tract into the bloodstream. In order to utilize the zeolite as a systemic detoxifier, the crystals need to be reduced in size to less than two (2) microns.

The zeolite in DDP is micronized to a size of approximately 0.39 microns.

(It's important to note, the zeolite cannot be "broken" no matter how small it becomes – it is indestructible. As an example, if a five-carat diamond is broken into five one-carat diamonds, the structure of each carat is exactly like that of the original five-carat diamond, only smaller. And if that one carat diamond were pulverized into dust, each resulting, tiny piece of diamond would have the same structure and properties of the original five-carat diamond. Thus, the structure of the individual "cages," and therefore the ability to sequester heavy metals and other toxins, is unaffected.)

The second step of the micronization process is proprietary milling. During this process, the finely milled zeolite powder is further reduced using specific machinery unique to this process. This ensures that all of the milled zeolite used in DDP is small enough for maximum absorption. Any particles larger than one micron do not pass through the filter and are instead put back through the micronization process. The finely micronized zeolite particles are then utilized in the activation process.

Activation

Another unique aspect of DDP is the proprietary activation process. It is during this process that the micronized zeolite is cleaned and sterilized. This is an important process because zeolites, being formed over millions of years, can absorb harmful elements including metals and toxins. Navan Global's proprietary activation process "cleans out" the cage and ensures a superior and unique product. During the activation process, the micronized zeolite is added to purified water and heated.

A proprietary blend of natural acids are then added and heated at various temperatures during a 48-hour activation process. This activation process cleanses the zeolite – emptying the zeolite cage – ensuring no unwanted substances are present in the final zeolite solution. The water aids in this exchange of compounds and stabilizes the zeolite charge. It is during this process that the product becomes a colloidal suspension, allowing the micronized zeolite particles to be suspended in an ultrapurified water solution.

The solution then goes through a sterilization process of extreme heating and cooling. This process ensures that any bacteria and microbes that may be present are completely eliminated. The solution is heated to extreme temperatures – 180 degrees and higher – which separates the microbes from the material. This layer of unwanted material is removed from the solution.

During this process, the natural acids are continually entering and displacing any microbes and other unwanted substances that may exist in the zeolite – further strengthening the charge of the zeolite solution. This dual activation process of cleansing and sterilization is cycled through over and over again until no unwanted materials exist. The conclusion of this step yields a pristine zeolite in ultra-purified water.

Summary

The Micronization and Activation processes make DDP a unique and superior product. These processes ensure DDP is absorbed quickly into the bloodstream to immediately begin reducing "Body Burden" – the body's overload of environmental toxins.

QUALITY ASSURANCE / PRODUCT ANALYSIS

Each batch of DDP undergoes strict quality assurance processes. This qualitative analysis ensures product (DDP) consistency—bottle-to-bottle, batch-to-batch, year after year.

These quality assurance measures include: ph testing, microbial analysis, trace heavy metal analysis, bulk mineral analysis and much more.

The findings of some of these tests are listed below:

- Inductively coupled plasma optical emission spectroscopy (bulk elemental analysis of inorganic materials) revealed a composition of more than 96% clinoptilolite. *(The remaining percentage was comprised of sodium, aluminum, magnesium and other naturally occurring minerals.)*

- Gas Chromatography-Mass Spectroscopy, Thin Layer Chromatography and High Performance Liquid Chromatography and Elemental Analysis revealed no unexpected organic contaminants traceable to the manufacturing or bottling process.

- Atomic Absorption Spectroscopy revealed no Al, Sb, As, Bi, Cd, Pb, Hg, Ni or Sn and confirmed the presence of Ca, N, K and H20 with the CLN preparation as submitted.

- Particle size analysis revealed over 99% of CLN particles are .5 microns or less in diameter. The smallest particles were 0.39 microns (390 nanometers).

- pH of the solution tested was 4.5 to 5.5 (average of 4.9)

- Addition of Daily Detox *Plus* to a solution of 25% $PbCl_2$ resulted in a spontaneous removal of Pb (at least to a level below 1% by weight), as indicated by the immediate inability of the solution to convert a LeadCheck® swab to a pink color.

CLINICAL TRIALS

Pure Raw Supplies, LLC (as a predicate company) owns the data conducted for six clinical studies in humans.

- DDP therapy in healthy individuals without chronic exposure to heavy metal toxins: A Short-term (7-day) trial in eleven individuals to evaluate changes in urinary excretion of heavy metals. Urinary excretion was measured with Atomic Absorption Spectroscopy (AAS). Participants noted an average fivefold increase in heavy metal excretion.

- DDP therapy in healthy individuals without chronic exposure to heavy metal toxins – An Intermediate-term (30-day) trial in twenty-two individuals to evaluate changes in urinary excretion of heavy metals. Urinary excretion was measure with Atomic Absorption Spectroscopy (AAS). All of the individuals noted an average 5-7 fold increase in heavy metal excretion.

- DDP therapy in otherwise healthy individuals with chronic, employment-related exposure to heavy metal toxins (West Virginia Coal Miners) – A Long-term (84-day) blinded clinical trial in fifty individuals to evaluate changes in urinary excretion of heavy metals and determine longevity of the effect. Urinary excretion was measure with Atomic Absorption Spectroscopy (AAS). Additionally, hair and saliva was collected at the beginning and the end of the trial and measured for heavy metal content. All 40 patients on the DDP noted a 12-15 fold increase in heavy metal excretion with subsequent improvement in general health.

The results of aforementioned studies were combined and published in one document[55].

- Electrolyte levels with the use of DDP – A trial to evaluate changes in vital serum electrolytes in healthy individuals following 30-day DDP therapy.
  There were no changes in serum electrolytes from baseline in these patients.

- Exercise recovery with DDP – A trial to evaluate the effect of DDP therapy on post-workout recovery-time in competitive athletes vs. non-competitive participants. The largest DDP trial to-date included 357

individuals. Approximately 80% of the participants on the DDP noted: less pain during exertion, the ability to workout longer and faster recovery time after physical activity.

- pH balancing with DDP – A trial to evaluate the effect of short- vs long-term DDP therapy on serum and salivary pH in healthy and compromised individuals. All of the patients noted more alkaline pH levels throughout the trial with the use of the DDP.

The following *in-vitro* analyses have been performed to provide rationale for further human trials:

- An *in vitro* analysis was conducted to measure the affinity of DDP for volatile-organic-compounds (VOCs). Sixty compounds were tested to provide information to support a future trial in humans focusing on benzene and dioxin derivatives. The zeolite in the DDP was found to have a high affinity for a variety of different VOCs

- An *in vitro* analysis was conducted to measure the affinity of DDP for uranium. This provides a rationale to study urinary excretion in patients using the DDP that have been exposed to depleted uranium sources. The DDP was found to have a high affinity for U^{6+}.

CLINIPTILOLITE HEALTH BENEFITS

Today, clinoptilolite is being used as a dietary supplement, primarily for human detoxification.

Clinoptilolite has many well-documented benefits:

- **Removes heavy metals:**
  This zeolite has the perfect molecular structure for capturing and removing heavy metals from the body, including; mercury, cadmium, lead, arsenic, aluminum, tin, and excess iron. It also removes radioactive metals like cesium and Strontium-90.[31,32]

- **Reduces absorption of nitrosamines:**
  Nitrosamines (or nitrates) are most commonly found in processed meat, and have been linked to pancreatic, stomach and colon cancer, as well as Type II diabetes. The zeolite captures nitrosamines in the digestive tract before they can be absorbed.[33]

- **Helps to buffer blood sugar:**
  The zeolite may help reduce blood sugar spikes by buffering excess glucose with its negative charge.[34]

- **Helps to buffer body pH to a healthy alkalinity:**
  A slightly alkaline body pH (7.35 - 7.45) is essential for good health and optimal immune function. The zeolite attracts and then buffers excess protons which cause acidity. This can help many conditions from acid reflux to Candida and arthritis.[34]

- **Improves nutrient absorption:**
  In the gastrointestinal tract, the presence of the zeolite increases nutrient absorption and helps promote healthy microorganisms, decreasing the likelihood of stomach flu and infections.[11]

- **Reduces symptoms of allergies:**
  The zeolite captures some of the allergens and antigens that trigger allergies, migraines, and asthma. This can help to reduce symptoms.

- **Stabilizes immune system function:**
  The zeolite does not stimulate the immune system, but allows it to function optimally by removing toxins, viruses, yeasts, bacteria, and fungi which can depress immune function and interfere with hormones. Many people report feeling increased energy, clarity, and vitality.[30]

- **Acts as a powerful antioxidant:**
  The cage-like structure of the zeolite also traps free radical molecules, making it an effective antioxidant (this does not mean that DDP zeolite is a substitute for more conventional antioxidants such as Vitamins C, E and A, lutein and selenium, all of which have other vital roles to play in the body). [21]

- **May help reduce cholesterol levels:**
  One published pilot study suggested that oral administration of clinoptilolite may

improve lipid profile in individuals with dyslipidemia, which warrants further investigations. [54]

- **Completely safe:**
  The zeolite is considered to be completely safe and non-toxic for oral administration in humans and animals. This includes infants, children, pregnant women and nursing mothers. Studies have also been conducted in feed animals and companion animals, including: dogs, cats, horses and birds.

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