

# Heavy Metals, Chinese Herbs & Proposition 65

Mayway has been in operation since 1969 and has been privileged to be a part of the growth and acceptance of traditional Chinese medicine in America today. Through the years we have worked to bring an awareness of the value of traditional Chinese medicine in promoting health and wellness.

Our role is one of leadership. We have participated in solidifying the status of traditional Chinese medicine through the support of trade organizations, research programs, community outreach, and political activism.

Mayway has been at the forefront of raising the standards of quality control within our industry. Over time we have become more vigilant in the sourcing of herbs, as well as the manufacturing and quality control of the goods we import. We have built our own herb processing facility in China to control the quality of herbs from the field to your door. Working with internationally certified GMP\* factories, we have created the Plum Flower® line to ensure that high quality traditional medicines are available in the American marketplace.

Mayway is a responsible supplier that maintains strict Quality Control standards for heavy metals, independent of Proposition 65. These standards as well as Proposition 65 issues are described below.

## Our pledge

Mayway will continue to do the following for all products intended for sale in California:

- We will provide the Proposition 65 warning on all products which do not have test data confirming that all heavy metals are below Proposition 65 "no significant risk" and "no observable effect" levels.
- We will continue to reject batches of Plum Flower® and Min Shan® products if heavy metals exceed Mayway's standards (outlined below) regardless of warnings.
- We will endeavor to look for new sources and new technologies in an effort to further reduce or eliminate the presence of heavy metals in our products.

## Our Quality Control Standards

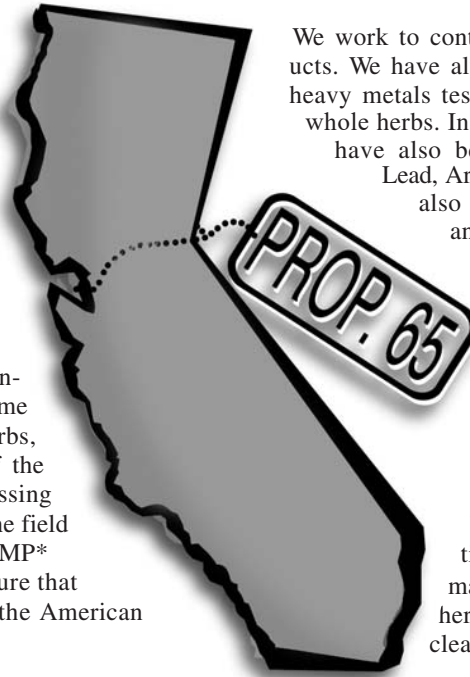
Each and every batch of Plum Flower®, and Min Shan® pills is tested for heavy metals. As there are presently no State or Federal heavy metal guidelines for traditional Chinese medicines, we researched our own. We were guided to the U.S. Pharmacopoeia (USP) to determine safe heavy metal levels for our products. USP levels are Lead 10 ppm\*, Cadmium 3 ppm, Arsenic 3 ppm, and Mercury 3 ppm. However, since the factories we work with have GMP certification granted by the Australian Therapeutic Goods Administration (Australia's FDA equivalent), we also looked at their heavy metal guidelines. We found their levels to be even lower for Lead at 5 ppm, and adopted the Australian standard as our own. Each batch of Plum Flower® and Min Shan® Brand pills is tested to these standards both at the factory and at third party labs for extra quality assurance.

## Our ongoing commitment to improve quality control

We work to continually improve the quality of our products. We have always done microbial, sulfur dioxide, and heavy metals testing on our Plum Flower® unsulfured whole herbs. In addition, since January of 2001, we have also been testing our herbs specifically for Lead, Arsenic, Mercury, and Cadmium. We have also been testing and setting limits for DDT and Benzene Hexachloride, two very toxic and banned pesticides.

Today, due to source improvements, we have further lowered our heavy metal limits for Plum Flower® and Min Shan® formulas to 3 ppm for Lead, 2 ppm for Arsenic, 0.5 ppm for Mercury, and 1 ppm for Cadmium.

We continue to gather data on soil pollution where herbs are grown allowing us to make ever more informed choices regarding herb sourcing as we continue to strive for cleaner, more pure herbs and herbal products.



## What is California's Proposition 65?

Proposition 65 is a statewide initiative passed in 1986 known as The Safe Drinking Water and Toxic Enforcement Act of 1986. This legislation was designed to address public concern about exposure to toxic chemicals. Proposition 65 requires that a list of chemicals which are known to cause cancer or reproductive harm be published by the Governor of California. Proposition 65 imposes certain controls over the listed chemicals, and is intended to allow California's consumers to make informed choices about the products they purchase. This law only applies to products sold within the State of California.

## How does Proposition 65 affect Chinese herbal medicine?

The Governor of California's list contains over 700 naturally occurring and synthetic chemicals. Heavy metals are listed and they are the grounds upon which Proposition 65 is being brought to bear on Chinese herbal medicine. Proposition 65 requires California businesses to provide a "clear and reasonable" warning before exposing anyone to a listed chemical.

The warning reads:

*"WARNING: This product contains chemicals known to the State of California to cause cancer and/or birth defects or other reproductive harm."*

Proposition 65 applies to companies which operate in, or sell products into California. Even if a company has its own standards for heavy metals, as Mayway does, it still must comply with the Proposition 65 warning requirements.

## What are Proposition 65's standards?

Proposition 65 states that a warning must be given unless a business demonstrates that the exposure it causes poses "no significant risk". "Significant risk" is very narrowly defined in Proposition 65. For a chemical listed as a carcinogen (such as lead, arsenic and cadmium) the "no significant risk level" (NSRL\*) is defined as the level which is calculated to result in not more than one excess case of cancer in 100,000 individuals so exposed over a 70-year lifetime. In other words, if you are exposed to the chemical in question at this level every day for 70 years, theoretically it will increase your chances of getting cancer by no more than 1 case in 100,000 individuals so exposed. For chemicals listed as reproductive toxins (such as lead and mercury) the "no significant risk" level is defined as the level of exposure, which even if multiplied by 1,000 will not produce birth defects or other reproductive harm. In other words, the level of exposure is below the "no observable effect level" (NOEL\*) divided by 1,000, or stated another way, 1/1000th of the "no observable effect" level.

## How does Proposition 65 work?

Proposition 65 was designed to provide a market-based incentive for manufacturers to remove listed chemicals from their products. Initially Proposition 65 provided a means for reducing certain exposure that may not have been adequately controlled under existing laws. Despite its successes this initiative has become problematic.

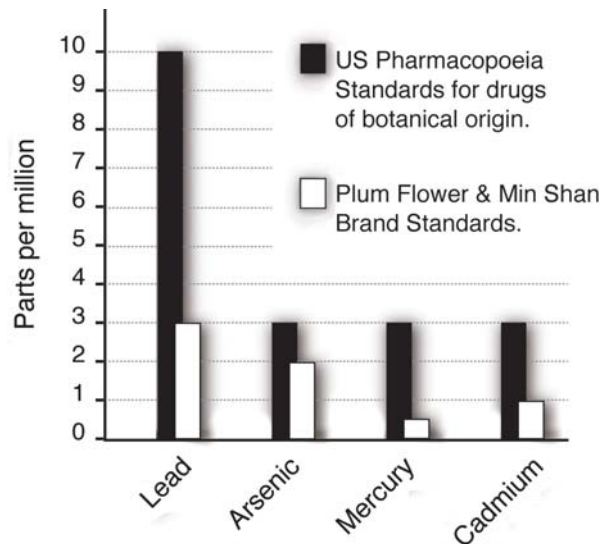
## What are the problems with Proposition 65?

One of the more obvious problems with Proposition 65 is that it does not directly affect the levels of listed chemicals in a product or require products to be safe; it merely requires the product to carry a warning. Additionally, it does not create safety standards for individual industries. Perhaps the most problematic element of Proposition 65 relates to the way by which it is enforced. It allows private individuals and entities to act as enforcers by bringing lawsuits against violators.

Private enforcers and their lawyers collect huge settlement sums through this process. This has encouraged an industry of "enforcers" in California, some with serious concerns for health and environment and others who are little more than vigilante bounty hunters. As a result, many California businesses have had hyper-technical enforcement efforts brought against them that are motivated by profit rather than to seek consumer protection.

## What does a Proposition 65 warning really mean?

It is important to remember that it is not illegal in California to sell products with heavy metals above the Proposition 65 levels, but it is illegal to sell them without a Proposition 65 warning. Proposition 65 does not set new regulations for the manufacturing of products, nor does it require that businesses improve their products. It merely requires that those products not in compliance with its strict standards provide a warning. When a warning is given by a business it means one of two things: 1) The business has evaluated the exposure and has concluded that it exceeds the "no significant risk" level as defined by Proposition 65; or 2) The business has chosen to provide a warning simply based on its knowledge of the presence of a listed chemical without attempting to evaluate the exposure. The exposure in this instance could be below the Proposition 65 levels, could be none at all, or could be exceedingly high. It is also important to note that many industries have succeeded in getting their



own industry wide standards, making them exempt from Proposition 65. Unfortunately the Chinese medicine industry currently has no such protection.

## How does this affect you?

Because Proposition 65 enforcement has been selective, arbitrary, and gradual, there are products on the market that don't yet contain warnings, but may have heavy metal concentrations in excess of the standards of Proposition 65. The company that sells these products just have not been sued, yet. Ironically, this means that it is quite possible that herbal products that carry Proposition 65 warnings (such as ours) could be safer than those that do not.

Initially, looking for products to sell in California that do not carry the warning may seem appealing. This would be acceptable only if the product is within Proposition 65 NSRL levels. Otherwise, the seller is in violation of the law.

Some companies believe that since they employ less than ten people, the law does not apply to them. However, some enforcers have taken the position that both the California Unfair Business Practices Act and the California Sherman Drug Act make it illegal to sell products with dangerous heavy metals without warnings. This exemption certainly does not mean their products do not contain heavy metals and it does not mean these products are safer because they do not bear a Prop 65 warning.

We have placed Proposition 65 warnings on our products since September 1, 2001. We are bringing this issue to you so that you will have the information you need to understand the requirement of California law. Mayway remains committed to providing the highest quality and safest herbal products possible. We face this challenge to our industry with the hope that it will bring an even higher standard to Chinese herbal medicine, and to you, our customers.

We encourage you to contact us with your ideas, thoughts and comments. Call (510) 208 3113 or email [prop65@mayway.com](mailto:prop65@mayway.com).

## How herbs became contaminated with heavy metals.

Metals are a natural part of the earth's make up which exist as concentrated layers of ore in the earth's crust. Naturally occurring erosion and volcanic activity release these layers containing heavy metals from the geological architecture of the earth. The resulting sediments deposit in rivers, streams, lakes, oceans, and soil.

Since the onset of the industrial era, manufacturing has greatly increased the rate at which ores are brought to the surface of the earth. Metals such as lead, mercury, cadmium, nickel, copper, gold, silver, arsenic, manganese and selenium are all used in the manufacturing of every day products. Lead, in particular, was aerosoled into the atmosphere by automotive internal combustion engines during the period in history when lead (tetra-ethyl lead) was a common additive to gasoline. This lead was deposited world-wide as it fell from the sky and contaminated soils in which herbs and food are grown. Lead is used to stabilize plastics and was

formerly used in paint as whitening and drying agent. Mercury and arsenic are the main components of many pesticides, fungicides, and herbicides used in agriculture as well as around the home.

Additionally, factories producing these products discharge toxic smoke into the air and dispose of wastewater contaminated with heavy metals and other toxins into the waterways and surrounding earth. As plants mature they take in components of the soil and water in which they grow. In this way these toxins cycle back into the food chain.



## \* Glossary of Terms

**PPM**- parts per million: a unit of measure equivalent to milligrams per kilogram measured in milligrams (mg) per unit of measure: 5 ppm = 5 mg/Liter and 5 mg/Kg.

**PPB**- parts per billion: a unit of measure equivalent to micrograms per kilogram Measured in micrograms (mcg) per unit of measure: 5 ppb = 5 mcg/Liter and 5 mcg/Kg.

**GMP**- Good Manufacturing Practices. Manufacturing guidelines pertaining to the adherence to certain standards in regards to manufacturing environment and equipment, personnel training, processing, quality control, and record keeping.

**NSRL**- No Significant Risk Level: the level at which it is calculated to result in not more than one excess case of cancer in 100,000 individuals exposed over a 70-year lifetime

**NOEL**- No Observable Effect Level: the highest dose level at which it has not been associated with an observable reproductive harm in humans or test animals.

**Heavy Metals**- metals that exist in the environment or in the body at very low levels and have molecular densities at least five times greater than water.

## Some resources that we found helpful are:

•Office of Environmental Health Hazard Assessment <https://oehha.ca.gov/proposition-65>

•Environmental Law Foundation [www.envirolaw.org](http://www.envirolaw.org)

•ChemicalList [oehha.ca.gov/proposition-65/proposition-65-list/](http://oehha.ca.gov/proposition-65/proposition-65-list/)

•The Ecology Center, Berkeley, CA (510) 548-2220

## Factors Affecting the Absorption of Lead:

- Inhaling lead particles results in a higher absorption rate. Although you absorb only 5-15% of lead you ingest, you absorb about 40% of the lead you inhale.
- Deficiencies of protein, calcium, phosphorous, vitamin E, iron, zinc, and selenium can increase lead absorption in the body.
- Ascorbic acid can decrease lead absorption.
- Iron deficiency is the greatest factor for high lead absorption levels in children.
- Some calcium supplements can be high in lead due to naturally occurring lead in mineral sources.
- A diet rich in carrots and cabbage are reported to increase lead excretion in the urine.
- High protein diets have been shown to reduce lead absorption in the body.

## Tips for lowering exposure to lead and other heavy metals:

- Keep children from playing near high traffic roadways to avoid exposure to exhaust fumes.
- Avoid sanding leaded paint. Repaint surfaces painted before 1978 with lead free paints to "seal in" the leaded paint dust that will result from decay if left uncovered. If leaded paint must be removed, have it professionally done and understand the cleanup process thoroughly. The dust from sand-blasting and sanding will contaminate indoor surfaces and soil around the area you are trying to detoxify, creating a new problem. These processes vaporize lead, which could result in absorption through inhalation.
- Do not smoke, and avoid second hand smoke.
- Run your tap until you feel the temperature change (usually less than a minute) before the first glass of water in the morning or whenever it has sat dormant for a lengthy time.
- Lower your body's absorption of heavy metals by taking an adequate supply of vitamins and minerals.
- Children in particular should have an adequate supply of iron.
- Check with manufacturers for heavy metal levels in your calcium supplements.
- Wash hands well before eating to remove potentially lead-containing dust and soil.
- Eat organic foods to avoid pesticides containing heavy metals.
- Increase carrots, cabbage and protein in the diet.
- Buy herbal products tested for heavy metals. Testing does not mean complete absence of a heavy metal but rather that the level of that heavy metal falls within established guidelines. Know that there are many established guidelines. Determine which one meets your safety standards.
- Recognize that heavy metals exist in our environments in ever greater numbers. Drive less, buy less plastic, eat organically grown foods and filter your water with a high quality filter.

1. *Generations at Risk Physicians for Social Responsibility (Greater SF Bay Area and Los Angeles Chapters) and CalPIRG (CA Public Interest Research Group)*

2. *Environmental Poisons in Our Food, J. Gordon Millichap, M.D. PNB Publishers, Chicago, IL 1993*

## Herbal Products & Prop 65 FAQ's

**Q: With a label that says "This product contains chemicals known to the State of California to cause cancer and/or birth defects or other reproductive harm," how can I believe the product is safe?**

**A:** Mayway has consistently tested its products for the presence of heavy metals for years, specifically lead, arsenic, mercury and cadmium. We have been vigilant in requiring that our products meet the heavy metal standards of the U.S. Pharmacopoeia and the Australian Therapeutic Goods Administration for medicines of botanical origin. However, some products do exceed Prop. 65 notice requirement levels and will therefore need to post the Prop 65 warning when sold in the state of California. Mayway will continue to reject batches of Plum Flower® and Min Shan® Brand products if heavy metals exceed Company standards, regardless of warnings.

**Q: How can I reassure my patients that your products are just as safe or safer than products which do not have the Prop 65 warning?**

**A:** The irony and danger of selective, arbitrary, and gradual enforcement is that there will be products on the market that don't yet contain warnings, even though those products may not only have heavy metal concentrations in excess of Prop 65 standards, but may be in excess of the standards adhered to by Mayway. It is possible and perhaps likely that herbal products which carry the Proposition 65 warning are actually safer than products that don't. As such, it is important that you are aware of the standards of individual companies and brands.

**Q: If I consumed a typical herbal formula for a long period of time, even several years, would that increase my risk of cancer?**

**A:** No. As an example, our maximum allowable limit for lead is 3 ppm. Most of our products have a much lower lead content, usually less than 1 ppm. Even at 3 ppm, the total amount of daily exposure to lead would be 13.32 micrograms (based on the average daily dosage of 8 pills 3 times per day.) The "No Significant Risk Level" (NSRL) for lead is 18 micrograms per day. Again, this means that even at 18 micrograms per day, taking the formula every day for 70 years would increase your chances of getting cancer by no more than 0.00001%. Also note that the average adult only absorbs 5-15% of the heavy metals they ingest, so the term daily exposure means just that, exposure, and not absorption. However, it is important to remember that our company standards are for our products, and that there are no established standards for our industry. As such, it would be advisable that you check with individual companies for their standards and whether each batch is tested.

**Q: Are there heavy metal differences between teapills, extract powders granules, tablets, capsules, and raw herbs?**

**A:** Yes, but not particularly due to the form of the product. Heavy metal content in the same product can vary from batch to batch due to a variety of factors including the type of herb, the part

used, the environment and condition of the soil and water in which it was grown, the individual harvest, and the cleanliness of the herb (e.g. soil residues contain heavy metals.) Although concentrating an herb tends to concentrate the amount of heavy metals just as it concentrates the active ingredients, the resulting levels of heavy metals in a finished product depends almost entirely on the condition and quality of the raw herbs that are used.

**Q: If it was originally passed in 1986, why did it take until 2001 for Mayway to label its products with the Prop 65 warning?**

**A:** Although the statute was passed in 1986, there was no proactive enforcement or action on the part of the government to inform businesses of their legal requirements in regards to Proposition 65. The proposition has relied on selective and gradual enforcement by independent entities with an economic incentive to proceed with legal action. Because there are no state or federal guidelines for heavy metal levels in traditional Chinese medicines, Mayway believed that it was being proactive and responsible by adopting and adhering to the standards of the U.S. Pharmacopoeia and Australian Therapeutic Goods Administration. It was not until 2001, subsequent to a consent decree, that Mayway was compelled to label its products sold in California with a Prop 65 Warning. While we believe that all sellers should be treated equally and that the Prop 65 levels may be too low when applied to botanical products, we recognize that Prop 65 is the law. We also support the idea that practitioners and patients/ consumers have the right to be informed about what they prescribe and ingest, and so we will provide the Prop 65 warning on all of our products for which we do not have test data confirming that lead, arsenic, and mercury levels are below Prop 65 notice requirement levels.

**Q: Can't Mayway just filter out the heavy metals?**

**A:** Heavy metals are absorbed by plants as they grow and become incorporated into the plant's cells, but tend to leach out of the plant during the cooking process. Individual heavy metals can be removed using processes similar to those that are used to filter drinking water, but due to the size of the particles, active components in the extracted liquid would most likely be removed along with the heavy metals. In the end, the filtered liquid may not be much more than filtered water.

**Q: What is Mayway doing to test their products and ensure the highest quality standards?**

**A:** Each batch of Plum Flower® and Min Shan® pills are tested both at the factory and at third party government labs for quality assurance, and recently we have further lowered the heavy metal limits for new production batches. We will continue to reject batches of pills that exceed company standards, even though the Prop 65 warning would enable us to sell those batches without legal ramifications. We will continue to test our raw herbs and endeavor to look for new sources and new technologies in an effort to further reduce or eliminate the presence of heavy metals in our products.

*For further questions about our products and Prop 65, please call us at (510) 208-3113, or email [prop65@mayway.com](mailto:prop65@mayway.com).*