Purity Promise

Quality Assurance programs and policies not only ensure that products meet certain thresholds of acceptability, but they also improve an organization's efficiency and environmental responsibility by reducing waste. One of the main principles of Quality Assurance is "fit for purpose" – meaning a product or service meets its intended purpose. This principle applies to every Redd Remedies product from the beginning of the formulation process to the finished product testing program. This idea may seem like common sense. Of course, we want our formulas and products to do what they are designed to do. That is why we are intentional about the ingredients we use in each product. Our formulas are not designed around marketing; the hottest trends; the newest, flashiest ingredients or which ingredients sell the most. Our formulas are designed to work. We want that same level of intention and careful thought woven into our testing protocols. We want our testing protocols to be "fit for purpose".

The federal regulations for Good Manufacturing Practices (GMPs) of dietary supplements require dietary supplements "consistently meet the established specifications for identity, purity, strength and composition, and limits on contaminants..."[1] Put simply, dietary supplements must meet label claims. If the label says 50 mg of magnesium, the product must contain 50 mg – not 20 mg or 100 mg. If the label says *Origanum vulgare*, the product must contain oregano – not strawberry leaves. And we must have limits on contaminants – the turmeric root we use cannot contain excessive amounts of lead. These regulations are not optional. All supplement companies must verify the identity of every raw material, the purity of those raw materials and the finished products, the strength and composition of raw materials and finished products and we must have established limits on contaminants for raw materials and finished products. (While all dietary supplement companies must follow these regulations, not **all** of them do.) While the attributes that must be met are consistent, "how" those attributes are verified is not consistent. There is no guidance regarding which specific tests must be

[1] Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements, 21 C.F.R. §111.70 (2007).

performed; which testing methods must be used; or what frequency should be followed. This is where dietary supplement companies will vary.

Some companies will do the minimum required; some will go above and beyond; some will conduct needless, unnecessary tests; and some will use inappropriate methods and tests to further their marketing campaigns. Bottom line – every company's testing protocols will be different, because every company's specifications for testing are different. There is no "one-size fits all" when it comes to testing protocols. There isn't one package deal that will work for all dietary supplements. Even within a single brand, the analytical nuances and the testing requirements for each product will be different. Unless a brand is selling only one type of product, they **should** be different.

At Redd Remedies, most of our products are formulas. They are complex blends of botanicals, vitamins, amino acids and minerals. Some formulas contain fatty ingredients, such as phosphatidylcholine; some formulas are 100% botanical based; some formulas are a mix of vitamins and botanicals; and some contain enzymes and probiotics. We have tablets and capsules, liquids and chewables. All of these different ingredients and all of the formula matrices require different types of tests and testing methods.

Some tests will be constant, regardless of the product. These tests include microbiological tests and heavy metals. Other contaminant testing is based on risk. For example, does it make sense to test eggshell calcium for glyphosate residues? Eggs aren't sprayed with glyphosate. (Yes, the hens may eat feed with glyphosate residues, but those residues don't show up in eggshells. They show up in the animal itself – in its tissues and within the yolk and the albumin - albeit in very, very low levels – if at all.) But, you know what can show up in eggshells? Bacteria. With this knowledge we do not waste resources testing for glyphosate in our Bone Health products or Joint Health Original Capsules because it would likely not be found.

In this report, we will describe the various testing protocols used to verify the identity, safety and purity of Redd Remedies products.

Identity

A variety of ingredients requires a variety of testing methods to verify the identity, strength, and composition of ingredients. These methods include but are not limited to:

- High Performance Liquid Chromatography (HPLC)
    - This method is used to identify botanicals, their natural constituents and vitamins- such as vitamin K_2. HPLC is also used to detect some types of botanical adulterants.
- Thin-Layer Chromatography (TLC)
    - TLC is used to identify some botanicals
- Inductively Coupled Plasma-Mass Spectometry (ICP-MS)
    - ICP-MS is used to verify mineral ingredients.
- Other methods that can be used to verify identity and composition include gas chromatography-mass spectrometry (GC-MS).

Safety

Microbiological Assays

Redd Remedies conducts a wide variety of microbiological assays to determine the safety and quality of ingredients and finished products. Bacteria can enter the supply chain, the manufacturing event and the packaging event through many different channels, which is the reason for testing throughout a product's life cycle – from the very beginning to the very end of a product's life at expiration.

Some microbiological assays, such as Total Plate Count (TPC), total coliforms and yeast and mold, are indicators of overall quality and hygienic practices of ingredient suppliers and manufacturers.

High levels of any of these particular microbes would be a red flag, as they can indicate poor sanitation procedures and poor hygienic practices.

Specific bacteria are assayed to verify the safety of ingredients and finished products. Assays include *E. coli*, *Salmonella*, and *Staphylococcus*; these bacteria represent some of the most common causes of food-borne illness. These assays must be negative. Positive assays result in the rejection of ingredients and/or finished products.

Mycotoxins

Mycotoxins are toxic compounds produced by certain fungal organisms, particularly molds. Molds that produce mycotoxins grow on many types of food items, including grains, fruits, nuts and spices.[2] Molds can also grow on many botanical ingredients, especially if they are not handled and stored properly.

Several thousands of mycotoxins have been identified. Among the most poisonous mycotoxins are aflatoxins. Aflatoxins are produced by *Aspergillus flavus* and *Aspergillus parasiticus*. Crops frequently contaminated with *Aspergillus spp.* include rice, wheat, soybeans, sunflower seeds, black pepper, turmeric, ginger and tree nuts. The four principle aflatoxins are B_1, B_2, G_1 and G_2. Collectively, these aflatoxins have been shown to cause cancer and liver damage, immune suppression and reproductive issues.[3]

Food Allergens

Currently, Redd Remedies tests finished products for the presence of gluten using the ELISA R5 method for gliadin. (Gliadin is a protein within gluten and is found in cereal grasses.) Results must be less than 10 ppm. As we make a "Gluten Free" claim on all of our dietary supplements, this claim must

[2] World Health Organization. (2018). Aflatoxins. Retrieved from https://www.who.int/foodsafety/FSDigest_Aflatoxins_EN.pdf.
[3] Ibid.

be verified with valid and reliable methods. This is a nice segue to discuss why you don't see other claims such as "soy free" or "corn free".

"Valid" and "Reliable" are important adjectives when it comes to testing methods. When it comes to allergen testing, the methods available are not always appropriate for use in finished dietary supplements. While dietary supplements are a subset of foods under federal regulations, when we look at dietary supplements through a laboratory lens, they aren't really "food" in the general sense. For instance, adding folic acid to broccoli powder doesn't magically turn it into broccoli (or folate from broccoli). It's still folic acid in broccoli powder. (Have you sat down and made yourself a nice plate of spray-dried broccoli powder?) In allergen testing, the methods make a difference. The presence of allergens in foods are usually tested with various kits, which are created and manufactured by some other third-party. Some of these third parties have their own food safety laboratories and some do not. Some companies just manufacture the allergen testing kits that will be used by various laboratories. Let's stay focused on these allergen testing kits. Many of them are "rapid kits", meaning the lab will get the results in a really short time – within minutes. It's a quick way to screen, which makes them quite popular. Each kit comes with very detailed instructions, because if the test isn't performed correctly, it's not valid anymore. There is also other very important information in these instructions, related to how the tests are intended to be used. We have included examples of the language from 2 of the leading suppliers of such test kits. (We have redacted any company-identifying information.)

> *"The…Soy Protein…Kit is intended for use in the food and beverage industry by trained personnel…(Redacted) has not documented the use of this product in industries other than food or beverage. For example, (redacted) has not documented this product for testing*

pharmaceutical, cosmetic, clinical or veterinary samples. The…Soy Protein…Kit has not been evaluated with all possible food products, food processes and testing protocols."[4]

and...

"(Redacted) for Soy Allergen is used for the quantitative analysis of soy residue in food products such as cookies, crackers, granola/power bars, ice cream, salad dressings, cereal, liquid products (e.g., juices and milk) and clean-in-place rinses."[5]

Do you see "dietary supplements" listed? Do you see "botanical extracts" listed? Do you see "blends of vitamins, minerals, botanical extracts, amino acids"? No? Neither do we. Based on what we have been told; based on the recommendations of the creators of the 2 kits, we do not test for soy – because the tests available would not be reliable enough. In certain circumstances, depending on individual product matrices, the tests may not be viable at all. We appreciate the risk that food allergens can pose to millions of people and we take that risk seriously. We will not use a test method that may or may not be reliable for use on our dietary supplements just to make a claim such as "soy free" or "dairy free".

Are you wondering why we didn't use an example from a corn protein test kit? **There is no test for corn allergens.** We want to let that last sentence sink in a minute, so we're going to repeat it. **There is no test for corn allergens!** That test does not exist, and Gliadin R5 (for gluten) is not a substitute for a corn allergen test. Any company making a "corn free" claim based on a Gliadin R5 test for gluten does not have proper substantiation for that claim.

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[4] 3m. (2017). Product Instructions. Retrieved from https://www.multimedia.3m.com/mws/media/162097401/3m-soy-protein-rapid-kit-product-instructions.pdf.

[5] Neogen. (n.d.) Veratox® for Soy. Retrieved from https:// https://www.neogen.com/solutions/allergens/veratox-soy-allergen/#:~:text=Veratox%C2%AE%20for%20Soy%20Allergen,used%20to%20screen%20environmental%20swabs.

If a Redd Remedies product contains one of the Big 8 food allergens, it is listed on the label beneath the Supplement Facts box, with a simple statement: "Contains: Soy". If a Redd Remedies' product is made without any animal products, that will be listed in the "Made Without" statement.

Adulteration

Adulteration is the act of "making something poorer in quality by the addition of another substance".[6] Botanical adulteration is not a new problem; it isn't even a modern problem. Adulteration has been happening since the beginning of commerce, which closely follows the beginnings of human civilization. It is a problem that is thousands of years old. Dioscorides, the Greek physician and botanist, described ways to detect botanical adulteration in his *De Materia Medica*, which he wrote in about 65 AD.[7] At times, adulteration is accidental and caused by botanical misidentification. For example, according to Bejar, Upton and Cardellina, there are 24 different species of *Rhodiola* that could be misclassified as *Rhodiola rosea* by those harvesting the plant.[8] The differences between these species can be subtle and difficult to detect; it takes a well-trained eye to spot the differences. Unfortunately, much of the botanical adulteration in the supply chain is intentional and economically motivated. You may have the most adulterated food in the world in your pantry right now – olive oil. It is well-known and well-established that some olive oil suppliers intentionally blend refined olive oil into extra-virgin olive oil and label it as "100% Extra Virgin Olive Oil" or blend in oils from other plants, like canola oil, and label it as olive oil.[9]

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[6]Adulteration. (2020). In *Lexico.com dictionary*. Retrieved from https://www.lexico.com/en/definition/adulteration.

[7] Foster, S. (2011). A brief history of adulteration of herbs, spices, and botanical drugs. *Herbalgram*, 92, 42-57.

[8] Bejar, E., Upton, R., & Cardellina, J.H. (2017). Adulteration of rhodiola (*Rhodiola rosea*) rhizome and root extracts. *Botanical Adulterants Bulletin*, 1-8. Retrieved from https://www.cms.herbalram.org/BAP/pdf/BAP-BABs-rhodiola-CC-v4-FINAL.pdf.

[9] Johnson, R. (2014). *Food fraud and "economically motivated adulteration" of food and food ingredients* (CRS Report No. R43358). Retrieved from Congressional Research Website: https://www.fas.org/sgp/crs/misc/R43358.pdf.

The same issues arise in the botanical supply chain and sometimes, the consequences can be devastating for people. Turmeric is one of the most popular and best-selling botanicals on the market today. Because turmeric is big business, there have been several instances of economically-motivated adulteration. Some "turmeric extracts" have been found to be "spiked" with synthetic curcuminoids while other turmeric powders have been found to be adulterated with lead chromate, not only a known carcinogen but a source of the neurotoxin, lead.[10] Lead chromate is added to turmeric powders to give them a brighter orange hue, because highly colored turmeric is considered more valuable.[11] This is where identification testing and contamination testing is most important. It is crucial that the American Skullcap we use in Muscle Ease is actually *Scutellaria lateriflora* and not a plant of the Germander species, which is known to cause liver toxicity.[12] This is also where having a Master Herbalist involved in the formulation process is quite valuable, because these individuals are aware of potential adulteration issues. They know that black cohosh (*Actaea racemosa*) is often adulterated with its Chinese counterpart (*Actaea cimicifuga*)[13]; they have been educated to know that *Panax ginseng* roots typically have lower amounts of ginsenosides, while the leaves have up to 12 times more ginsenoside content.[14] A master herbalist would know that a supplier claiming to have a *Panax ginseng* root material with 25% ginsenosides could very well be selling a suspect material. Maybe most importantly is the lab that runs these botanical identification tests. To fully protect the quality and integrity of botanical materials and to detect possible adulterants, the lab must be experts at botanicals. This expertise is not common to

[10] Bejar, E. (2018). Turmeric (*Curcuma longa*) root and rhizome and root and rhizome extracts. *Botanical Adulterants Bulletin*, 1-11. Retrieved from https://www.cms.herbalgram.org/BAP/BAB/TurmericRootandRhizomeandExtracts.html.
[11] Ibid.
[12] Foster, S. (2016). Adulteration of skullcap with American germander. *Herbalgram*, 93, 34-41.
[13] Gafner, S. (2016). Adulteration of black cohosh (*Actaea racemosa*). *Botanical Adulterants Bulletin*, 1-5. Retrieved from https://www.cms.herbalgram.org/BAP/BAB/BlackCohoshBulletin.html.
[14] Foster, S. (2016). Toward an understanding of ginseng adulteration: The tangled web of names, history, trade, and perception. *Herbalgram*, 111, 36-57.

most food safety labs, so we partner with laboratories that have staff trained specifically in botanical identification and use the accepted methods for identification.

Purity

Elemental Contaminants

Elemental contaminants refer to naturally-occurring single elements, many of them heavy metals, such as lead and mercury. Because elements contain only one type of atom, they cannot be destroyed in the environment. They can only change forms, and sometimes, it is the compounds that are formed with oxygen, sulfur and other elements that give rise to toxicity concerns.

Several elements are listed by The Agency for Toxic Substances and Disease Registry, a division of the U.S. Department of Health and Human Services and are considered toxic substances. A handful of these elements also have human nutritive value – elements including chromium. But we must keep in mind that these are *micronutrients*; we require them in very small amounts. In the words of Paracelsus, the father of modern toxicology, "The dose makes the poison".

Using ICP-MS, Redd Remedies tests for the following toxic heavy metals:

Arsenic

Arsenic is widely distributed in the earth's crust. In the environment, arsenic is combined with other elements, such as oxygen, chlorine and sulfur to form inorganic arsenic compounds. Arsenic in animals and plants combines with carbon and hydrogen to form organic arsenic compounds. It is the inorganic arsenic compounds that are highly toxic.[15] Organic arsenic compounds are less toxic.

[15] Agency for Toxic Substances and Disease Registry. (2007). Toxicological profile for arsenic. [PDF]. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp2.pdf.

Inorganic arsenic compounds are used mainly to preserve wood, while organic arsenic compounds are used as pesticides, primarily in cotton fields and orchards.

Inorganic arsenic is a known human carcinogen.[16] There is also evidence to show that long-term exposure to arsenic in children may result in lower IQ scores.[17]

Cadmium

Cadmium is a soft, silver-white metal. It is usually found associated with zinc, lead and copper ores in the earth's crust. Most cadmium used in the U.S. is extracted as a by-product during the production of other metals. It is used in batteries, jewelry, metal coating and craft glazes. It is also found in cigarettes and in emissions from fossil fuels. This heavy metal can accumulate in plants.[18]

Cadmium is classified as a known human carcinogen.[19] Furthermore, long-term, low-level exposure can cause bones to become fragile and weak.[20]

Chromium

There are three main forms of chromium: chromium, chromium III and chromium VI. Small amounts of chromium III are necessary for human health. This metal is widely used in the manufacturing of metal alloys such as stainless steel. It is mainly released into the environment by industries involved in electroplating, leather tanning, and textile production. It can also be released from burning natural gas, oil, or coal. Chromium can change from one form to another in water and soil, depending on the conditions.

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[16] Ibid.
[17] Ibid.
[18] Agency for Toxic Substances and Disease Registry. (2012). Toxicological profile for cadmium. [PDF]. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp5.pdf.
[19] Ibid.
[20] Ibid.

Chromium VI (also referred to as "hexavalent chromium") is a known human carcinogen and can be found in contaminated waterways and ground water, in the air of workplaces and in the soil of contaminated sites.[21]

Lead

Lead is the most prevalent toxic heavy metal. This bluish-gray metal can be found in all parts of the environment – air, water, and soil. Most of it comes from human activities including mining, manufacturing and burning fossil fuels. When lead is in the air, it can travel long distances before falling to the ground, where it can move into groundwater. Most exposure to lead occurs from contaminated drinking water due to lead present in the water supply pipes.[22]

The effects of lead are the same whether it enters the body through breathing or swallowing. It can affect almost every organ and system in the body. The main target for toxicity is the nervous system in both children and adults. Children are more vulnerable to lead poisoning than adults and the damage it causes to the brain and nervous system lasts a lifetime.[23]

Mercury

Mercury is the most toxic of all the heavy metals. This liquid metal combines with other elements such as chlorine, sulfur and oxygen to form inorganic mercury. It also combines with carbon to create organic mercury compounds. The most common organic mercury compound is methylmercury, produced by bacteria in water and soil.

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[21] Agency for Toxic Substances and Disease Registry. (2012). Toxicological profile for chromium. [PDF]. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp7.pdf.
[22] Agency for Toxic Substances and Disease Registry. (2007). Toxicological profile for lead. [PDF]. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp13.pdf.
[23] Ibid.

Inorganic mercury enters the air from mining ore deposits, burning coal and waste and from manufacturing plants; it enters the water through wastewater discharges. Methylmercury builds up in the tissues of fish.

The nervous system is sensitive to all forms of mercury. Methylmercury and metallic mercury vapors are more harmful than other forms because they cross the blood-brain barrier.[24] Exposures to high levels of mercury can cause brain and kidney damage and harm to a developing fetus.[25]

Pesticides

The term "pesticide" is an umbrella term for any active ingredient that prevents, destroys, repels or mitigates a pest or is a plant regulator, defoliant, desiccant or nitrogen stabilizer. Pesticides include herbicides, insecticides, avicides, rodenticides, fungicides, antimicrobials and many others. More than 17,000 pesticide products are on the market currently and in the U.S. alone, about 1 billion pounds of pesticides are applied each year.[26] Worldwide, pesticide usage is approximately 7.7 billion pounds annually.[27] Data shows that pesticide use isn't slowing down. It's actually increasing. For example, since 1990 to the latest available data, pesticide use in Brazil has increased 298%.[28] In the United States, herbicide usage increased from 420 million pounds in 2005 to 564 million pounds in 2012.[29] In 2012, the last year of available data, the top 5 pesticides in agriculture were: glyphosate, atrazine, metolachlor-S, dichloropropene and 2,4 D.[30]

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[24] Agency for Toxic Substances and Disease Registry. (1999). Toxicological profile for mercury. [PDF]. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp46.pdf.
[25] Ibid.
[26] Pesticide Action Network. (n.d.). Pesticides 101. Retrieved from https://www.panna.org/pesticides-big-picture/pesticides 101.
[27] Alavanja, M.C.R. (2009). Pesticides use and exposure extensive worldwide. *Reviews on Environmental Health*, 24(4), 303-309.
[28] Marquez, E. (n.d.) In the U.S. and the world pesticide use is up. Retrieved from https://www.panna.org/blog/us-and-world-pesticide-use.
[29] Ibid.
[30] Ibid.

Redd Remedies tests for 458 pesticide residues, including pesticides banned in the United States, the European Union and elsewhere; the top 5 pesticides used in the United States, European Union, South America, China and India and hundreds of others. These tests are conducted with GC, LC, LC-MS and MS. Most of the pesticides that can occur within the supply chain are covered by these tests. Sometimes, they are used intentionally to impede fungal growth, thus hiding poor storage and handling practices. Sometimes they show up due to uncontrollable factors, such as drift. Because Redd Remedies' botanical supply chain is global, we need to verify and hold our supply partners accountable. So we test for many, many possible pesticide residues. Each of these 458 pesticide residues has its own detection limit and they range from 0.001 ppm to 0.008 ppm.

Most botanical materials do not have EPA-established limits on pesticide residues and there isn't really a federal standard set for pesticide residues in botanical ingredients that end up in dietary supplements. Federal regulations have yet to get up to speed with the growth of the dietary supplement industry. The most common standard that is used is called the USP 561 "Articles of Botanical Origin". This USP method contains limits for 70 pesticide residues. While this is a good start, we felt we needed to go above and beyond 70 pesticide residues. We are sourcing botanical materials from around the world and the data shows that there are more than 70 potential pesticide residues. We feel that using a panel that includes 458 pesticides can give us the greatest assurances that our products are free of harmful pesticide residues.

The most notorious pesticide, glyphosate, must be tested for separate from other pesticides using a different method and different equipment. Glyphosate and its metabolite, AMPA, are detected through HPLC at a limit of 0.01 ppm. These compounds can be difficult to "pull" out of a sample and it is not always possible to find them in finished products. Not being able to find glyphosate and AMPA in a sample is not the same as the glyphosate level being "zero". It doesn't mean they aren't there; it means

there is too much interference for the equipment to locate them....like trying to find a needle in a haystack. More on glyphosate later in this paper...

Major chemical classifications of pesticides include: organochlorines, organophosphates, carbamates, triazines, pyrethroids and neonicotinoids. In this report, we will cover several of these classes of pesticides and some individual pesticides.

Organochlorines

Organochlorine pesticides are hydrocarbons with chlorine molecules attached to them. This class of pesticides is known for their persistence in the environment and painfully slow degradation, bioaccumulation and high toxicity. Although many organochlorine insecticides have been banned in most developed countries, these inexpensive insecticides are among the most widely used in the developing world. The most famous organochlorine pesticide is DDT. While it is banned in the United States, it is still used legally to control malaria-carrying mosquitoes in Africa, Southeast Asia and other parts of the world. In addition to DDT, adlrin, chlordane, hexachorobenzene and endrin are some examples of organochlorines. These toxic chemicals act as endocrine disruptors, neurotoxins, and carcinogens.[31] Exposure to organochlorines has been associated with breast and prostate cancer, ADHD and other neurodevelopmental disorders, type II diabetes, hypertension, Parkinson's disease and many other negative health effects.[32] The CDC's Fourth National Report on Human Exposure to Environmental Chemicals detected breakdown products of DDT in 99% of people tested.[33] DDT was banned in the United States on December 31, 1972. Nearly 50 years later, it can still be found in our bodies.

Organophosphates

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[31] Jayaraj, R., Megha, P., & Sreedev, P. (2017). Organochlorine pesticides, their toxic effects on living organisms and their fate in the environment. *Interdisciplinary Toxicology*, 9(3-4), 90-100. doi.10.1515/intox-2016.0012.
[32] Ibid.
[33] Centers for Disease Control and Prevention. (2017). Dichlorodiphenyltrichloroethane (DDT) fact sheet. Retrieved from https://www.cdc.gov/biomonitoring/DDT_FactSheet.html.

Organophosphates were originally developed in 1940's Germany as nerve-gas agents for chemical warfare. Today, they are used on our foods and until the recent past, in our homes. These highly toxic chemicals include: parathion, chlorpyrifos, diazinon, fenthion and dimefos. Organophosphates work by inhibiting cholinesterase – an enzyme that breaks down a neurotransmitter called acetylcholine that carries signals between the nerves and the muscles. Without that enzyme, acetylcholine accumulates in the nerves and eventually the muscles become paralyzed. Most people who suffer from acute organophosphate poisoning die by suffocation.[34] Early childhood exposure to organophosphates increases the risk of neurological disorders, including ADHD.[35] Chronic exposure affects adults too. Occupational exposure is linked to difficulties in executive functioning, verbal memory, attention, processing speed, coordination and neuropsychological performance.[36]

Carbamates

Carbamate pesticides are derived from a compound called carbamic acid.[37] These pesticides kill insects in a similar way as organophosphates, but their effects are reversible. Carbamates are widely used in homes, gardens and agriculture. The toxicity of carbamates varies from compound to compound. They can range from highly toxic to little toxicity. Carbamates are known endocrine disruptors and several carbamates are classified as probable or possible carcinogens.[38] As with organophosphates, chronic occupational exposure has been linked to cancer, and neurodevelopmental

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[34] Than, K. (2013). Organophosphates: A common but deadly pesticide. Retrieved from https://www.nationalgeographic.com/news/2013/07/130718-organophosphates-pesticides-indian-food-poisoning .

[35] Engel, S.M., Wetmur, J., Chen, J., Zhu, C., Boyd-Barr, D., Canfield, R.L., & Wolff, M.S. (2011). Prenatal exposure to organophosphates, paraoxonase 1, and cognitive development in childhood. *Environmental Health Perspectives*, 119(8), 1182-1188.

[36] Munoz-Quezada, M.T., Lucero, B.A., Iglesias, V.P., Munoz, M.P., Cornejo, C.A., Achu, E., Baumert, B., Hanchey, A., Concha, C., Brito, A.M. & Villalobos, M. (2016). Chronic exposure to organophosphate (OP) pesticides and neuropsychological functioning in farm workers: A review. *International Journal of Occupational & Environmental Health*, 22(1), 68-79. doi: 10.1080/10773525.2015.1123848.

[37] Fishel, F.M. (2017). Pesticide toxicity profile: Carbamate pesticides. Retrieved from https://www.edis.ifas.ufl.edu/pi088.

[38] United States Environmental Protection Agency. (2007). Revised N-methylcarbamate cumulative risk assessment. Retrieved from https://archive.epa.gov/pesticides/reregistration/web/pdf/nmc_revised_cra.pdf.

issues in children.[39] As a whole, carbamates are relatively unstable and breakdown in the environment within weeks or months. However, most carbamates are highly toxic to insects of the *Hymenoptera* order, which includes bees.[40] Some examples of carbamates are carbaryl, propoxur, carbofuran, aldicarb, oxamyl and trimethacarb.

Triazines

This group of pesticides features chemicals with a wide range of uses. Most triazines are used for selective weed control while others have nonselective properties. This classification has some of the oldest herbicides in use. Triazines are used on corn, sugarcane, sorghum, soybeans, cotton, celery, grapes and certain berries. Atrazine, the second-most used herbicide in the United States is used heavily on corn and this accounts for almost all of the atrazine that enters the environment.[41] While atrazine in soil may remain for several days to several months, in water, it is a different story. Water slows the breakdown of atrazine and it will stay there for a long time.[42] Atrazine is commonly found in the water collected from drinking water wells in agricultural regions.[43] Another problem with atrazine is drift. It can be carried through the air on particles, such as dust. When this happens, breakdown of the chemical does not occur. The wind can move this pesticide long distances. For example, atrazine has been found in rainwater more than 180 miles from the nearest application site.[44] Atrazine has been linked to pre-term births.[45] There is inadequate information related to its carcinogenicity and its effects

[39] Morais, S., Dias, E., & de Lourdes-Pereira, M. (2012). Carbamates: Human exposure and health effects. In M. Jokanovid (Ed), *The Impact of Pesticides* (pp. 21-38).
[40] Fishel, F.M. (2017). Pesticide toxicity profile: Carbamate pesticides. Retrieved from https://www.edis.ifas.ufl.edu/pi088.
[41] Agency for Toxic Substances and Disease Registry. (2003). Toxicological profile for atrazine. Retrieved from https://www.atsdr.cdc.gov/toxprofiles.tp153.pdf.
[42] Ibid.
[43] Ibid.
[44] Ibid.
[45] Ibid.

on children.[46] Other examples of triazine pesticides are: dipropetryn, simazine, methometon, prometon, and prometryn.

Pyrethrins and Pyrethroids

Pyrethrum is a naturally-occurring mixture of chemicals found in certain chrysanthemum flowers. Six distinct chemicals have active insecticidal properties in the whole pyrethrum extract and these are known as pyrethrins. Pyrethrins are often used in household insecticides and products to control fleas on pets.[47] These compounds breakdown quickly when exposed to natural sunlight.

Pyrethroids are man-made chemicals that have a similar structure to pyrethrins, but they are often more toxic to insects, as well as mammals, and they last longer in the environment. More than 1,000 synthetic pyrethroids have been developed, but only about 12 are used in the U.S.[48]

Both of these pesticides are sprayed directly on crops because plants do not take up pyrethrins and pyrethroids easily from the soil. Residues can be found on leaves, fruits and vegetables, which accounts for the main route of human exposure – through food.[49] Some pyrethroids are used as lice treatments and as a common treatment for scabies. Most toxicity seen with these pesticides comes with the exposure to very large amounts. However, compounded effects of pesticide exposures in addition to the combination of other ingredients to enhance effects could cause some health issues. Some examples of pyrethrins are: cinerin I and II. Examples of pyrethroids include: bifenthrin, empenthrin, halfenprox, permethrin, and silafloufen.

Neonicotinoids

Neonicotinoids, also known as neonics, are insecticides derived from nicotine. These pesticides, developed in the 1990's, bind to nicotinic acetylcholine receptors in the central nervous system and

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[46] Ibid.
[47] Agency for Toxic Substances and Disease Registry. (2003). Toxicological profile for pyrethrins and pyrethroids. Retrieved from https://www.atsdr.cdc.gov/toxprofiles/tp155.pdf.
[48] Ibid.
[49] Ibid.

cause overstimulation of the nerve cells, which leads to paralysis and death. Neonics are very water soluble. They persist in the environment and they are systemic, which means the pesticide moves into all parts of a treated plant.[50] Their principal use is in agriculture for seed and soil treatments and on plant foliage ; they can also be used in home yards and gardens, golf courses and for flea and tick treatments for dogs and cats. Residues of these pesticides cannot be washed off fruit or vegetables.[51] Some neonics, such as thiacloprid, have endocrine disrupting properties, but these pesticides are best known for their lethality against pollinators, particularly honeybees.[52,53] It is for this reason that the European Union banned neonics for outdoor use. They may still be used inside greenhouses.[54] Twelve neonicotinoids were recently banned in the United States in the spring of 2019; however, 47 neonicotinoids still hold active registrations with the EPA and are allowed for use.[55] Neonicotinoids are used globally; they are used heavily in South America, Asia, Africa, and Australia; and some parts of Canada still allow their use. Because this class of pestcides is so destructive to populations of pollinators, particularly honeybees, we are careful to ensure they are not used on our botanical ingredients.

Glyphosate

Glyphosate is classified as a phosphonoglycine. It was first registered for use as an herbicide in 1974.[56] Today, it is the most widely used herbicide in the United States and more commonly known as

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[50] Cornell University College of Agricultural and Life Sciences. (2019). Neonicotinoids. Retrieved from https://pollinator.cals.cornell.edu/threats-wild-and-managed-bees/pesticides/neonicotinoids.
[51] National Collaborating Centre for Environmental Health. (2018). Neonicotinoid pesticides. Retrieved from www.nccch.ca/environmental-health-in-canada/health-agency-projects/neonicotinoids-pesticides.
[52] Cornell University College of Agricultural and Life Sciences. (2019). Neonicotinoids. Retrieved from https://pollinator.cals.cornell.edu/threats-wild-and-managed-bees/pesticides/neonicotinoids/.
[53] Ibid.
[54] European Food Safety Authority (2018). Neonicotinoids: Risks to bees confirmed. Retrieved from https://www.efsa.europe.eu/enl/press/news/180228.
[55] Bendix, A. (2019, May 30). *The U.S. just banned 12 pesticides that are like nicotine for bees. Here's how dangerous they are*. Business Insider. https://businessinsider.com/epa-banned-pesticides-killing-bees-2019-5.
[56] National Pesticide Information Center. (2015). Glyphosate general fact sheet. Retrieved from https://npic.orst.edu/factsheets/glyphogen.html.

Roundup.[57] Glyphosate is a broad-spectrum herbicide, which means it will kill any unwanted plants. It is heavily used in genetically engineered "Roundup Ready" crops including corn, in addition to sugar beets, cotton, and soybeans. But Roundup is also used by everyday people in their yards and gardens, at businesses, on golf courses, and public parks. Think of a place and Roundup has probably been there. In 2015, the International Agency for Research on Cancer classified glyphosate as a probable human carcinogen.[58] Because glyphosate is sprayed on many crops, including wheat, barley, oats and beans just before harvest, detectable levels of glyphosate are being found in common foods, beloved by moms and children alike.[59] Tests commissioned by the EWG showed that popular cereals, oatmeal, granola and snack bars contained detectable levels of glyphosate, some above the EWG's Health Benchmark of 160 ppb.[60] Of the 61 samples tested (45 conventional/16 organic), 31 conventional products had glyphosate levels above the benchmark, while no organic products were above the benchmark.[61]

Pesticides containing glyphosate are commonly used worldwide to control weeds and to dry crops prior to harvest.[62] Using glyphosate as a "dessicant" (a drying agent) is likely the main way it shows up in our food supply, as proven by the EWG.[63] Let's think a minute about many of the botanicals that we use in our products. You may or may not realize it, but many botanicals of medicinal value are weeds. They are the very plants that glyphosate is designed to kill. Take couch grass or cleavers for example. You've probably killed couch grass in your yard or ripped it out of the ground. It's the really tall grass that grows along your fence line. What's the best herbicide to totally eradicate couch grass? Glyphosate. Cleavers can be a big problem for canola farmers and cereal grass farmers. What are

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[57] Marquez, E. (n.d.) In the U.S. and the world, pesticide use is up. Retrieved from https://www.panna.org/blog/us-and-world-pesticide-use.
[58] EWG's Children's Health Initiative. (2018). Breakfast with a dose of Roundup? Retrieved from https://www.ewg.org/childrenshealthglyphosateincereal/.
[59] Ibid.
[60] Ibid.
[61] Ibid.
[62] The Cornucopia Institute. (2017). Glyphosate use as desiccant double human contamination. Retrieved from https://cornucopia.org/2017/10/glyphosate-use-desiccant-doubles-human-contamination/.
[63] Ibid.

canola farmers recommended to do to control cleavers? "Using a higher rate of glyphosate is the first thing you can do."[64] Stinging nettles in your yard? Glyphosate. English ivy taking over your house? Glyphosate. Dandelions? Glyphosate. All these examples of weeds are ingredients in some of our products. The risk that glyphosate would show up in these extracts or the biomass is really, really low...unless dead plants are being harvested, which would make no sense...because they're dead.

Do we test every Redd Remedies product for glyphosate? No, we don't. It doesn't make sense to test for glyphosate when we know it isn't going to be there. It certainly won't be in mineral materials; it won't be in vitamin materials and it won't show up in cleavers, because the cleavers used in our products are being purposefully cultivated and wildcrafted. We test for glyphosate where it makes sense – in products that contain fruit powders and fruit extracts; ingredients derived from citrus peels; in products that contain root extracts and mushroom extracts. In these instances, testing for glyphosate is "Fit for Purpose" and yes we absolutely do test in order to ensure the products we deliver to you are pure.

Going Beyond the cGMP Requirements for Testing

It is obvious that we live in a toxic world. Hundreds upon hundreds of toxic compounds can enter our water supply and our food supply. Many toxins become part of the plants we consume. They become incorporated into our body tissues. While many of us are focused on the foods we eat as a way to control pesticide exposures and other toxic exposures, we must take inventory of everything we put in our bodies. That includes our dietary supplements. Afterall, many dietary supplements contain minerals, plant extracts or even plant powders, fruits and vegetables. If these toxic chemicals can end up in foods we eat, what would stop them from entering the botanical extracts you take for your heart

[64] Epp, M. (2017 March 13). Controlling cleavers without quinclorac. Grainews. https://grainews.ca/features/controlling-cleavers-without-quinclorac.

or immune health, or for your joints? If we are going to demand purity and toxin-free foods, we should hold our dietary supplement brands to the same standards.

The supply chain for dietary supplements is global. There is no way around that fact. Many botanicals grow only in certain regions of the Earth and cannot be cultivated here in the United States. *Rhodiola rosea* and Schisandra berries are good examples of incredible botanicals that cannot be cultivated, rather only ethically and sustainably wildcrafted in their native habitats. However, as the information presented in the report shows, the U.S. is not immune to environmental toxins. Country of Origin is not always an indicator of purity and quality. At Redd Remedies, we value and work hard to develop strong relationships with each of our supply chain partners, but trust alone will not guarantee the purity of any raw material. While we feel it is essential to work with growers that have generational knowledge on the care and cultivation of traditional herbs, particularly in China and India, the trust we have in them must be verified and it is verified through testing. But testing alone does not make a quality program. It's just the verification part of quality. Furthermore, running an inappropriate test or using an inappropriate method doesn't really verify anything, because those tests would not be considered valid. Just as we carefully choose our ingredients, we must carefully choose our testing and the methods.

Conducting unnecessary and inappropriate tests is not only a drain on human resources, it is a drain on environmental resources. Laboratories use large amounts of water; they use various solvents, some of them toxic, to prep samples and these solvents can end up in our water and in the air. The environmental impact of laboratories is not something that is often considered, much less talked about – but it is an issue of which we should be mindful. As a company we care deeply about our environment. After all, we live here too! And we get the remarkable herbs that we use from it. We want to use all the necessary tests to ensure purity without being wasteful