Myth Busting Essential Oil Safety

FACT VS. FICTION

Defining an Essential Oil

The International Standards Organization (ISO) gives this definition:

An essential oil is a product obtained from natural raw material, either by distillation with water or steam, or from the epicarp of citrus fruits by mechanical processing, or by dry distillation. The essential oil is subsequently separated from the aqueous phase by physical means.

This describes how the essential oil is obtained, but provides no information on its nature.
Defining an Essential Oil

Drs. Franchomme and Pénélol use the terms of photosynthesis to describe an essential oil:

Plant essences, in the physiological meaning of the term are most certainly true life essences, elaborated by the secretory cells of the plants that have tapped the photo-electric-magnetic energy of the sun and have converted it, with the intervention of enzymes, into biochemical energy in the form of highly diversified aromatic molecules.

What Are Essential Oils?

- An essential oil is the distilled, or expressed, product of the volatile components synthesized by various plant tissues of a single plant species.
- The alchemist Paracelsus (1493-1541) coined the term essence, which equated to spirit. In alchemy, the term spirit refers to the personality or extract of something that retains the qualities of the original substance.
- The term essential was applied to these oils because they held the essence or fragrant part of the plant.
Concentration and Potency

- Essential oils are highly concentrated forms of the plant or herb part from which they are derived.
- For perspective, 1 drop of essential oil can equal around 30 cups of herbal tea in terms of concentration.
- Essential oils can be up to 75 or 100 times more concentrated than the fresh herb.
- It takes 30 hand-picked blossoms or 2,000 petals to produce 1 drop of rose (Rosa damascena) essential oil.

Secondary Metabolites

- Are not necessary for the growth and propagation of the plant; however, plants would not survive without them
- Attract pollinators
- Attract beneficial insects to prey on the plant’s predators
- Provide protection by repelling harmful insects and herbivores
- Serve as antibiotics and antimicrobial compounds for plants
- Allelopathy: prevent the growth of competing vegetation
- Antitranspirant: reduce the rate of the loss of water
Where are essential oils found?

- **Flowers:** jasmine, rose, ylang ylang, neroli
- **Leaves:** citronella, lemongrass, petitgrain, peppermint
- **Bark:** cinnamon
- **Inner bark or wood:** sandalwood, cedarwood, rosewood
- **Resin:** myrrh
- **Seed:** fennel
- **Fruit peel:** bergamot, lemon, lime, orange, mandarin
- **Root:** ginger, vetiver, valerian
- **Berries:** juniper

Our Definition of Essential Oil

- **Extracted by various means,** including steam and dry distillation or expressing from the plant material of a single species
- **Secondary plant metabolites** – serving various roles
- **Volatile components of aromatic plants:**
  - Can be flammable
  - Generally less dense than water
  - Generally non-polar and insoluble in water
  - Can be found in many plant parts depending on the species
  - Highly concentrated forms of the plant or herb
The biosynthesis of terpenes, sesquiterpenes, and ultimately cholesterol and carotenoids is often referred to as Mevalonic Acid Pathway.

Isoprene Unit

Isoprene Example

Limonene Example
Functional Group Families Derived From Mevalonic Acid Pathway

- Monoterpenes
- Sequiterpenes
- Monoterpenols
- Sequiterpenols
- Oxides
- Esters
- Aldehydes
- Ketones
- Lactones
- Chemopreventative
- Anti-inflammatory
- Anti-infectious
- Chemopreventative
- Antinociceptive
- Sedative
- Anti-inflammatory
- Wound healing
- Anti-inflammatory

Phenyl Propanoids: Primary Metabolites

Pyruvate $\rightarrow$ Shikimate $\rightarrow$ Chorismate $\rightarrow$ Phenylalanine $\rightarrow$ Tyrosine $\rightarrow$ Tryphophan
Functional Groups Derived From Shikimic Acid Pathway

- **Phenols** - rubefacient, anti-infectious
- **Phenyl methyl ethers** - antispasmodic, anti-nociceptive
- **Coumarins** - antilymphoedemic
- Thymol, Carvacrol
- Eugenol, safrole, methyl chavicol, methyl eugenol
- Furanocoumarins - bergaptene

Fatty Acid Metabolism

Molecules found in essential oils also arise from other biosynthetic pathways, e.g. certain high-impact trace components originate from the fatty acid metabolism.
The 12 Main Classes of Compounds

What is Essential Oil Safety?

SAFETY: “THE CONDITION OF BEING PROTECTED FROM OR UNLIKELY TO CAUSE DANGER, RISK, OR INJURY.”

“SAFETY CAN ALSO BE DEFINED TO BE THE CONTROL OF RECOGNIZED HAZARDS TO ACHIEVE AN ACCEPTABLE LEVEL OF RISK.”
"The Difficult Art of the Therapist"
~Dr. Jean Valnet, MD

“All is poison, nothing is poison.”
~ Paracelsus

Key Areas Around Essential Oil Safety

- Identification of species, origin, chemotype, extraction method, date of production
- General understanding of essential oil constituents, pharmacokinetics, and pharmacodynamics
- Safety guidelines for application methods: Dermal, Inhalation, Oral, and Internal
- Dilution rates, dosage, and duration, especially for children, the elderly, or frail
- Potential drug interactions
- Potentially hazardous essential oils
- Allergies
- Sensitizers
- Recognizing adverse reactions
Pharmacology is the study of the actions and effects of drugs on living organisms.

The World Health Organization defines a drug as ‘any substance or products that is used or intended to be used or modify or explore physiological systems or pathological states.’

This would include essential oils, when used in the context of aromatherapy.
Pharmacodynamics

- Pharmacodynamics – what the drug does to the body
- Focuses on:
  - How drugs bind to targets,
  - Biochemical, physiological and possible adverse effects of drug binding
  - Potency, specificity and efficacy of drugs
  - Drug binding affinity for target site.
- Using these qualities to determine the usefulness of a drug.

Pharmacodynamics of Essential Oils

- Drug molecules work by binding or interacting with target molecules.
- Essential oil molecules are active with several types of target molecules, these include:
  - Cell membranes, neuronal and muscular ion channels, neurotransmitter receptors, G-protein coupled and second messengers, enzymes, even DNA molecules (rarely)
- Binding affinity – how prone a drug molecule is to bind to another molecule, specifically target molecules.
- Agonist – binds to the same receptor and has the same action as the molecules produced by the body.
- Antagonist – binds to the same receptor, but has no effect or the opposite effect.
Selectivity

- Lock and Key Model
- In reality, drugs, including EOs bind to many sites.
- Want some selectivity or drug is not useful.
- Essential Oils generally have low selectivity
- Diverse components of essential oils show potent selective effects. Also, the large number of constituents found in EO allows one 'drug' to address many aspects of one disease. Ex: Nervous anxiety and eczema
- Lavender can reduce anxiety on CNS level and provide topical anti-inflammatory actions

c. Terracina Amanda Lattin 2009

Potency and Efficacy

- Potency – shown by the amount required to achieve the desired action or effect. The lower the dose required, the higher the potency.
- There is a range of potency within EOs
- Efficacy is the extent of the ability of a drug to produce the desired effect. Again, dosage is a determinate factor here.
- Also, choosing the appropriate essential oil, dosage, and delivery mechanism will affect efficacy.

c. Terracina Amanda Lattin 2009
Essential Oils Actions Relevant to Pharmacodynamics and Safety

- **Hypotensive effects** via calcium ion channel interaction.
- **Convulsant effects**, due to interaction with nervous tissue, “neurotoxicity”.
- **Sedative effects**, due to depression action on the CNS.
- Blood clotting interaction due to **anti-platelet activity**.
- **Possible** interaction with the endocrine system due to **possible** estrogenic effects.
- **Irritation** to the integumentary system due to irritation, sensitization, photosensitization.

Potential Drug Interactions
PHARMACOKINETICS – WHAT THE BODY DOES TO A DRUG

ABSORPTION, DISTRIBUTION, METABOLISM, EXCRETION OF DRUGS.

THE EFFECTIVENESS OF A MOLECULE AS A DRUG IS DETERMINATE ON THE RATES OF THESE ACTIONS.

Essential Oil Absorption

- Essential oils can be absorbed into the body via several pathways. However, they all involve the essential oil constituents passing into the bloodstream through a membrane.
- Essential oils can be absorbed via the skin, the lungs, orally through the intestinal tract, rectally, and vaginally.

"Starr 050125-3235 Eucalyptus globulus" by Forest & Kim Starr. Licensed under CC BY 3.0 via Wikimedia Commons.
As soon as an essential oil (or any drug) is in the bloodstream, the body begins to modify it.

The main strategy to take a molecule and break it down into smaller more polar molecules.

This will make it easier for the kidneys to process and eliminated the drug via these new ‘metabolites’ of itself.

Sometimes it is these metabolites that produce the therapeutic or toxic actions of a drug.

Often used to measure the quantity of a drug that is present in the body at a particular time.

Units of measurement are usually: ng or mg of substance per ml of plasma.

May not be an accurate measurement of the quantity of drug in the body.

Plasma concentration curves used to measure proportion of the initial dose absorbed.
Absorption

- Two application methods used (safely) by aromatherapists with no medical training are inhalation and dermal application.
- This delivers doses to either the skin or respiratory membranes.
- Both methods will eventually deliver EO doses to the circulatory system – at different speeds and in different amounts.

Absorption via the Skin

- Essential oils are applied dermally either neat or diluted in carrier oil.
- Carrier oil reduces or slows evaporation of essential oil constituents and may help their penetration of the skin.
- The blend is left on the skin for several hours – this enables a slow extended absorption – compared to the rapid absorption via the lungs.
- The concentration of essential oil present on an area of skin can change the effect produced.
Absorption via the Skin

- The constituents of essential oils have different binding affinities for the plasma lipoproteins and tissues of the body – this will decide their plasma concentration and if they have multiple phases.
- Essential oil constituents are very likely to be compartmentalized into the high lipid areas of the body such as the adipose tissue layers and the brain.
- Terpenoid constituents readily move into the sebaceous layer that cover the skin because they are highly lipophilic.
- Different constituents absorb at different rates.
- Again, molecular size, polarity and solubility are factors.

- Terpenoid constituents can dry the skin by absorbing the sebaceous layer.
- Terpenoids may also affect the lipids between the cells of the stratum corneum thus allowing larger drug molecules to pass.
- However, the keratinised cells found in the stratum corneum limit the rate of absorption more than the thin epithelium found in the lungs.
- Where the stratum corneum is thinnest is where the higher rates of absorption occur. Face, scalp
Final Aspect of Skin Absorption

- Once the molecules have passed through the Stratum Corneum, they pass into the epidermis and the dermis.
- Although the absorption rates from dermal applications directly into the adipose layers (without entering the blood stream) have not been researched – they do exhibit anti-inflammatory and analgesic effects on muscle and joints.
- Sesquiterpenoids are absorbed in the skin, but not rapidly cleared into the blood stream.

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Monoterpenes and Sesquiterpenes in Sheep’s Blood and Milk

- A mixture of the following terpenes was applied to sheep's skin on their back for a period of 18 days. α-pinene, limonene, and β-caryophyllene.
- Blood and milk samples were taken throughout the administration period.
- Limonene and α-pinene were found in all blood and milk samples after a lag-phase of 2 days.
- B-caryophyllene was detected in all milk samples, but only a few blood samples.
Absorption via the Respiratory System

- Lungs – large absorption area. Thin epithelial layer and lipophilic surface.
- High blood flow – will increase the rate of absorption in the blood stream.
- Monoterpenes absorb faster than sesquiterpenes due to smaller size.
- Other determinate factors include: molecular size, polarity, and solubility.

Half - Life

- The half life of a drug is the time it takes for its plasma concentration to decrease by half of its initial measurement.
- If the EO has high lipophilicity, then there can be bi- and tri-phased distribution. Each phase has a different half life.
- Half life can be modified by changes in the function of metabolic and excretory organs – i.e. the liver and kidneys. Also, by delivery mechanism.
Pharmacodynamics of D-Limonene

- Used “30-40 oz of Mediterranean-style lemonade with a light breakfast”.
- This lemonade used the whole lemon. These large quantities delivered 596mg and 447 mg of D-limonene.
- Showed max level of perillic acid in plasma in one hour.
- Was undetectable in plasma in 24 hours.
- Other work has shown that it can take several days for limonene to completely metabolize out of the body.

Essential Oils in Cow’s Milk

- Due to the research into including essential oils or essential oil bearing plants into animal feed for their antibiotic properties, a 2013 study investigated the effects of essential oil administration on the content of cow’s milk.
- Caraway and oregano essential oils were used.
- The cows were given either a dose of essential oil diluted in sesame oil directly into the duodenum or an inhalation of essential oil.
- Milk was tested immediately before and after essential oil exposure.
- Unaltered essential oil constituents were found in the milk immediately after essential oil exposure.
- But were not found in the milk the following morning.
- **Caraway**: limonene, carvone, and carvacrol **Oregano**: carvacrol, p-cymene
- “Terpene content for treatment milk samples was characterized by the same terpenes found in the treatment essential oil used for that animal, regardless of pathway of exposure.”
Daily Inhalation of Alpha-Pinene in Mice

- Mice were given inhalations of alpha-pinene 90 min. a day for 1 day, 3 days, or 5 days.
- Mice were given a plus maze stress test for 10 minutes after the inhalation.
- Analysis showed that there was a “significant anxiolytic” effect for the 5 days.
- Analysis also showed accumulation of alpha-pinene in the brain and liver.
- Accumulation peaked on the third day.
- Researchers felt this occurred due to the response to the introduced stress in the new environment, and helped keep the anxiolytic effect constant.

Phase I – P450 or CYP

- Different people metabolize via P450 and its related isozymes at different rates. This is genetic trait.
- That is why some people need more or less of a drug than other to achieve the therapy or toxicity.
- In the near future, there will be technology that will allow each of us to find out if we are a slow or fast metabolizer.
- EO constituents that are metabolized via the P450 path in the liver can affect pharmaceutical drug levels in the body.
- This can be beneficial or detrimental. However, the aromatherapist needs to be aware of client’s medications for this reason.
Phase I Liver Metabolism

Here ephedrine is metabolized in two different ways to create new more polar or more polar and smaller molecules for excretion.

Phase II Liver Metabolism

- Instead of breaking molecules down into smaller more polar molecules, Phase II adds specific polar groups to a molecule to make it more polar.
- Usually, the result of these reactions is creating molecules that resemble polar plant glycosides, which dissolve easily in cells.
- Many plant molecules, especially ones with phenolic hydroxyl groups, exist as glycosides, meaning in combination with sugar molecules, to be polar and H2O soluble.
- When they encounter the stomach they usually lose their sugar group and become non-polar.
- Phase II gives them back a polar group.
Effects of Some Essential Oils on Mouse Liver Enzymes

- Essential oils of cardamom, celery seed, cumin seed, coriander, ginger, nutmeg, and zanthoxylum EOs were given by gavage, 10 microliters/day for 14 days.
- Nutmeg and zanthoxylum induced P450 significantly.
- Cardamom caused reduction in P450 activity.
- Aryl hydrocarbon hydroxylase activity increased with ginger. Nutmeg oil decreased it.
- “Glutathione S-transferase activity was significantly elevated in all experimental groups”

Detoxification of Xenobiotics

A COMPLEX SYSTEM OF CYTOCHROME P-450 ENZYMES HAS EVOLVED TO REMOVE NON-NUTRIENT SECONDARY METABOLITES FROM THE ORGANISM.
PRACTICALLY ALL EO COMPONENTS STIMULATE THIS SYSTEM IN ONE WAY OR ANOTHER AND INDUCE THE REMOVAL (BIOTRANSFORMATION) OF TOXINS FROM THE BODY.
Essential Oil Administration

- Administration should reflect desired action.
- Applying essential oils to the affected area or system gives the best results.
- For psychological, emotional, or spiritual work, olfactory stimulation is a must, but can also be incorporated into other applications such as massage or other forms of dermal application.
- This gives the benefit of all aspects of EO actions.
- Inhalation for respiratory problems, infections, or for quick entrance to blood stream.

Safety Guidelines for Dermal Application

- Photosensitization
- Sensitization
- Sensitivity / allergic responses
- Dilution rates
- Ways to increase absorption
- Removal of irritating essential oil
- Skin patch testing
- Increased absorption of drugs
- Broken or damaged skin
- Cautions and contraindications

Phototoxicity and Photosensitization

- Certain essential oils cause photosensitization to the skin while they are present.
- Meaning sensitivity to ultraviolet light, including sun-light and artificial UV light as found in a tanning bed.
- This can range from a mild burn to a deep weeping burn. NAHA (2015)
- To read and see a first hand photosensitivity experience by a lay essential oil user visit: http://thehomespunlife.com/photo-sensitive-essential-oils/
- *Please note, I am not endorsing this website or any of the advice given there.

Photosensitizing or Phototoxic Essential Oils

- Bergamot, *Citrus aurantium* var. *bergamia*
- Lemon, *Citrus limon*
- Lime, *Citrus aurantifolia*
- Angelica root, *Angelica archangelica*
- Bitter orange, *Citrus aurantium*
- Rue, *Ruta graveolens*
- Grapefruit, *Citrus paradise*
- Cumin, *Cuminum cyminum*

Safety Guidelines for Aromatherapy Baths

- The heat from the warm bath water increases circulation in the skin. This also increases the amount of essential oil that can be absorbed during the bath.
- Also, during a bath, the individual is receiving the essential oil via pathways: via inhalation/olfaction and skin absorption.
- For these reasons, it is important to limit the amount of essential oil added to the bath.
- Also, certain oils are irritating to the skin and mucus membranes and should also be avoided in a bath.

Some Mucus Membrane Irritant and Dermal Irritant Essential Oils

- Oregano
- Thyme
- Cinnamon (bark and leaf)
- Cassia
- Garlic
- Onion
- Clove (bud, leaf, stem)
- Fir needle
- Oxidized essential oils
- High phenol, aldehyde, sesquiterpene lactone content
Sensitivity and Allergic Reactions

- Essential oil constituents can be allergens.
- There is information circulating that essential oil constituents can not be allergens because they contain no proteins.
- This however, is incorrect information.
- Essential oils do not contain the proteins and amino acids that usually trigger an allergic response in the body.
- They do however, contain haptens and pre-haptens.
- These small molecules can bind to proteins once in the body.
- This protein and hapten combination can elicit an allergic response.

Sensitization

- Sensitization is a reaction involving the immune system.
- “A state in which the body is sensitized to particular stimuli, e.g. (1) certain individuals exposed to some antigens by a particular route elicit an immune response which may be antibody-mediated, particularly IgE, or cell-mediated, which sensitizes them such that subsequent exposure to the same antigen elicits an allergic response; said especially of such exposure resulting in a hypersensitivity reaction.”

Saunders Comprehensive Veterinary Dictionary, 3 ed. © 2007 Elsevier, Inc. All rights reserved
Sensitization

1. A state or condition in which the response to a second or later stimulus (e.g., a drug) is greater than the response to the original stimulus (e.g., first administration of the drug). 2. The process in which exposure to an antigen results in the development of hypersensitivity.


A sensitization reaction can occur after applying the same essential oil or essential oil blend every day or frequently over longer periods of time.

The reaction produces a red, itchy, sometimes painful skin rash that is persistent until the allergen is removed. Often, once this happens, the person remains sensitized to this essential oil for many years or for life.

Some Sensitizing Essential Oils

Strong

- Cinnamon
- Garlic
- Cassia
- Oakmoss
- Fig leaf
- Backhousia Backhousia citriodora
- Turpentine oil Pinus spp.
- Verbena absolute Lippia citriodora
- Peru balsa Myroxylon pereirae
- Tea absolute, Camellia sinensis
- Inula, Inula graveolens
- Oxidized essential oils, especially needle tree or citrus oils.
Some Sensitizing Essential Oils

Weak or Potential Sensitizers

- Star Anise and anise
- Ylang ylang
- Lemongrass
- Pine (dwarf and Scotch)
- Melissa
- May chang (Litsea cubeba)

Pay attention to essential oils with high aldehyde and phenol content.

Skin Patch Testing

- Skin patch testing is one of the most important safety precautions in aromatherapy.
- Skin Patch tests are easy to perform.
- Can check of both sensitivity and sensitization.
- A sensitivity test is checked over 24 hours.
- A sensitization check over 48 hours, with two applications.
Skin Patch Testing

- To perform a skin patch test, use the crook of the arm, with clean skin.
- For diluted oils, place enough of the blend to cover the inside of the elbow.
- Cover and leave on for 24 hours.
- For undiluted oils, place one drop on the inside of the elbow. Close arm for several minutes.
- Check for sign of sensitivity for 24 hours.
- If burning or irritation occurs, apply base oil or milk, then wash with soap and water.

Skin Patch Testing

- To perform a test for sensitization, begin the same as a test for sensitivity.
- After 24 hours, reapply the essential oil in the same dilution as the first application.
- Leave on for another 24 hours.
- Usually sensitization will begin to show within 48 hours.
Safety Guidelines for Aromatherapy

Inhalations

- Inhalation is generally a safe method of essential oil administration.
- Remember inhalation occurs anytime around essential oils.
- Work in a well ventilated area. Take fresh air breaks.
- Avoid high level exposure for longer than an hour.
- Steam inhalations require only a few drops of essential oils, and few minutes of inhalation.
- Some oils irritate the eyes and mucus membranes.

Safety Guidelines for Internal Use

- Know the intention for the internal or oral use of the essential oil(s)
- Know the RDD for the essential oil(s) and follow it.
- Know the duration guideline for the essential oil(s).
- Use an appropriate delivery method.
- Seek advice from a trained aromatherapist, herbalist or other health care practitioner with training in using essential oils internally.
Safety Guidelines for Internal Use

- Many internal use protocols use around 1 to 3 drops of essential oil.
- Often gel capsules are used.
- Honey, sugar cubes, and charcoal have also been used as a delivery tool.
- Using essential oils in water often coats the mouth, esophagus, and stomach with the essential oil.
- Oral ingestion will deliver 100% of the essential oil to the system.

Signs of Toxicity

- Two types: Chronic toxicity and acute toxicity
  - Acute toxicity would arise from one large dose of the essential oil.
  - Chronic toxicity would arise from repeated use of the essential oil.
- Acute toxicity would be considered poisoning.
- A poison damages or inhibits the system, as opposed to a lethal substance, which kills the system.
Signs of Toxicity

- Signs of acute toxicity with ingested essential oils: nausea, vomiting, diarrhea, confusion, ataxia, and coma.
- Most recorded cases of acute toxicity or poisoning from essential oils have come from ingestion of large amounts of essential oils.
- However, these large amounts of essential oils are readily available, 5ml, 15ml.

Signs of Toxicity

- Repeated, continued use of the same essential oil(s) without break can lead to signs of chronic toxicity (or sensitization).
- This can include: headache, fatigue, cough, kidney and liver irritation, upset stomach, diarrhea, urinary disturbance/changes.
- The best way to check for a correlation between essential oil use and these signs, is to remove the essential oil and note changes.
Oral Use: Delivery Method Makes a Difference

- Encapsulated vs. unencapsulated
- Microencapsulation vs. enteric
- Whole herb
- Half life and bioavailability changes

Case Study: Internal Use of Essential Oils

- W.T. is a female in her mid thirties complaining of abdominal discomfort, occasional constipation, indigestion, and bloating.
- She has been evaluated by two NDs and undergone several courses of herbal support plans, with some improvement.
- She has seen a gastroenterologist who diagnosed gallstones and some inflammation of the small intestine.
- W.T. underwent treatment with her ND for the gallstones and the intestinal inflammation.
- This process took place over 2 years. A.S. has seen improvement in her symptoms but not resolution.
- W.T. continues to struggle with discomfort and sees a colon hydrotherapist. Hydrotherapist advises there is evidence of yeast and/or parasites in the stool.
Case Study: Internal Use of Essential Oils

- W.T. researches on her own and finds a testimonial about a woman who had similar issues, and used a Vitamin A and oregano essential oil protocol with good results.
- I advise against this, as it may be irritating. But, W.T. feels strongly she wants to try it.
- Solution of 25% oregano *Origanum minutiflorum* essential oil and 75% olive oil. With Vitamin A palmitate, 10.1mcg per drop of solution.

- W.T. takes 10 drops of sol. 3 x daily = 7 drops of oregano essential oil. For two weeks.
- Break for 5 weeks.
- Then 2 drops cinnamon essential oil in olive oil 3 x daily for one week.
- Then oregano oil regimen for three weeks.
- Then cinnamon for 10 days, then five days oregano.
Case Study: Internal Use of Essential Oils

- W.T. developed rash on her chest and abdomen in the first few days of taking the essential oils. It persisted for 2.5 months before resolving.
- W.T. developed a head cold a few weeks into the essential oil regimen.
- W.T. developed flu-like symptoms about 5 weeks into the regimen.
- W.T. experienced her first HSV-2 outbreak during the regimen. Estimated to be dormant for 8-9 years.
- W.T. developed a UTI infection toward the end of the regimen, and ended the regimen after an 11 day UTI.
- Her digestive symptoms persisted throughout.
- W.T. tested negative for SIBO after this protocol. W.T. tested low normal for liver metabolism and pancreatic enzymes. W.T. tested with overgrowth of two normal bacteria in her stool sample. Indicating inflammation.

Meaning of GRAS Status

Federal Food, Drug, and Cosmetic Act

- Many essential oils have been given GRAS status by the FDA.
- This status is often used to denote the safety of taking these essential oils internally.
- But, what does GRAS status mean?
- Does GRAS status provide guidelines for how much of these essential oils is safe to consume?
- Does GRAS status include consuming undiluted, pure essential oils?
Meaning of GRAS Status
Federal Food, Drug, and Cosmetic Act

- The Federal Food, Drug, and Cosmetic Act GRAS list is a list of substances that are Generally Recognized As Safe for their intended use – IN FOOD.
- The GRAS list is found in the Act Title 21, Volume 3, Chapter 1, the Subchapter B titled Food for Human Consumption (Continued), Subpart A, section 182. CITE: 21CFR1812
- “It is impracticable to list all substances that are generally recognized as safe for their intended use. However, by way of illustration, the Commissioner regards such common food ingredients as salt, pepper, vinegar, baking powder, and monosodium glutamate as safe for their intended use.”
- “This part includes additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commissioner as generally recognized as safe for such uses.”

Meaning of GRAS Status
Federal Food, Drug, and Cosmetic Act

- “For the purposes of this section, good manufacturing practice shall be defined to include the following restrictions:
  1. The quantity of a substance added to food does not exceed the amount reasonably required to accomplish its intended physical, nutritional, or other technical effect in food; and”
  2. The quantity of a substance that becomes a component of food as a result of its use in the manufacturing, processing, or packaging of food, and which is not intended to accomplish any physical or other technical effect in the food itself, shall be reduced to the extent reasonably possible.”
- Code of Federal Regulations Title 21, Volume 3, Chapter 1, the Subchapter B titled Food for Human Consumption (Continued), Subpart A, section 182. CITE: 21CFR1812
Meaning of GRAS Status
Federal Food, Drug, and Cosmetic Act

- What does “intended physical, nutritional, or other technical effect in food” mean in terms of essential oils?

- Essential oils are not used to provide physical attributes to food, i.e., texture, viscosity, etc.

- Essential oils are not used to provide any nutritional value to food. They do not contain any primary nutrients such as vitamins, minerals, proteins, etc.

- What is left? Technical effect.

- What does this mean in terms of essential oils?

Meaning of GRAS Status
Federal Food, Drug, and Cosmetic Act

- Essential oils primary intended use in food falls under the technical effect:

  "(12) Flavoring agents and adjuvants: Substances added to impart or help impart a taste or aroma in food."


- Title 21, Chapter 1, Subchapter B, Part 170, Subpart A, Sec. 170.3
Meaning of GRAS Status
Federal Food, Drug, and Cosmetic Act

- Essential oils are being researched for these intended uses (**FOR THE FOOD, NOT THE HUMAN CONSUMING THE FOOD**):

- “(3) Antioxidants: Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.”

- (2) Antimicrobial agents: Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under “preservatives.”


- Title 21, Chapter1, Subchapter B, Part 170, Subpart A, Sec. 170.3

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Meaning of GRAS Status
Federal Food, Drug, and Cosmetic Act

Sec. 409. [21 USC §348] Unsafe Food Additives

- (B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

- (4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

- (A) **shall not** fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

- (B) **shall not** establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.
References

References


References


References