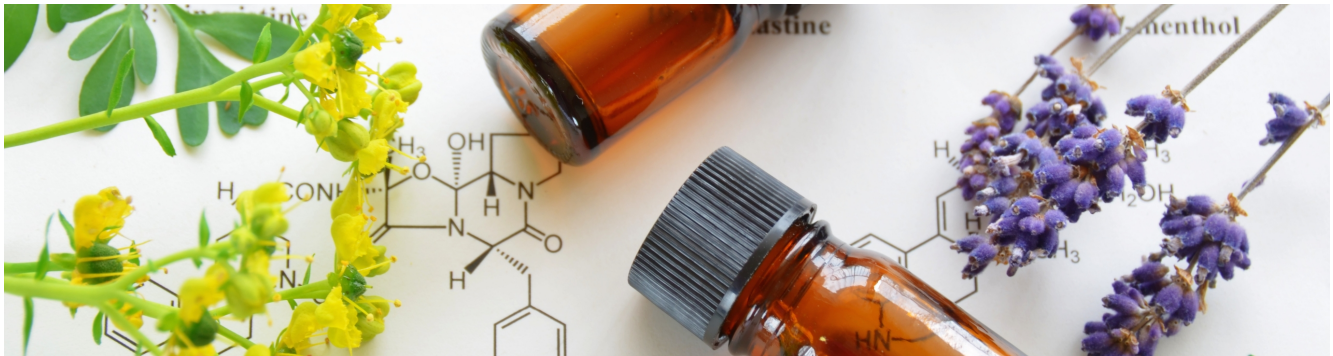

Can Lavender Oil Cause Breast Growth in Children?

Robert Tisserand



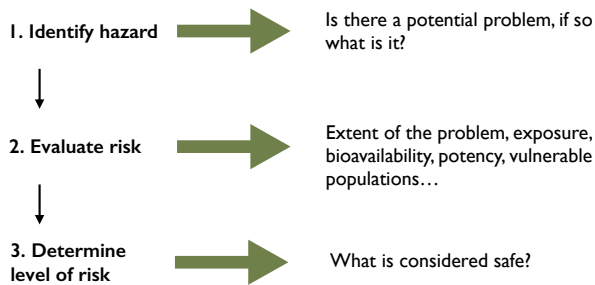
Presentation handout

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Definitions



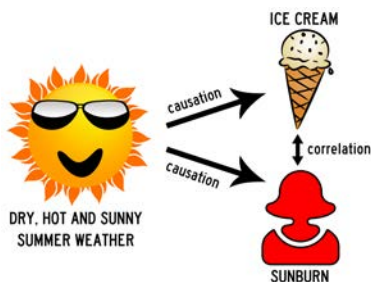
Risk assessment (toxicology)



Correlation & causation

Most cases of gynecomastia resolve spontaneously.

Therefore, resolution of the problem after stopping use of a product is not proof of causation.



Endocrine disrupting compounds

WHO / EU criteria for endocrine disrupting compounds

1. Shows an adverse effect
2. Has an endocrine mode of action
3. The adverse effect is a consequence of the endocrine mode of action

Breast growth

In males

It's called gynecomastia

In females

It's called thelarche

Most cases of prepubertal gynecomastia and premature thelarche are considered to be idiopathic (of unknown cause) and resolve spontaneously

Breast growth during puberty is normal in females, and some occurs in about 70% of males

Pre-clinical evidence



In vitro evidence of estrogenic activity

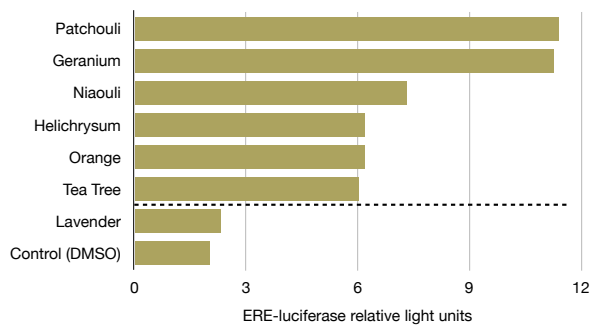
Essential oil	Henley 2007	Simoes 2018	Ramsey 2019
Lavender	Yes	No *	Yes
Tea tree	Yes	Yes	Yes
Geranium	Not tested	Yes	Not tested
Patchouli	Not tested	Yes	Not tested

All used MCF-7 cells

* Least potent of 11 EOs tested



Simões et al 2018



Lavender oil not estrogenic in rats

Uterotrophic assay

Female rats
4% in corn oil
20% in corn oil
in dermal patches
No increase in uterine weight

Five thousand and 1 million times greater exposure than experienced by the "Henley et al" boys

Politano et al 2013



Lavender oil not estrogenic in women

Ten essential oils were tested for effects on salivary estrogen in 15 women aged 43 or 44.

Geranium and rose oils did show an effect, but Lavender oil did not.

Shinohara et al 2016



In a double-blind, crossover clinical trial of Lavender oil capsules in 24 women, there was no interaction with oral contraception

Heger-Mahn et al 2014

Henley et al 2007



Henley et al 2007

Prepubertal Gynecomastia Linked to Lavender and Tea Tree Oils

Derek V. Henley, Ph.D., Natasha Lipson, M.D., Kenneth S. Korach, Ph.D., and Clifford A. Bloch, M.D.

3 cases are reported

Case 1

Male, 4 y 5 m

Healing balm containing lavender oil

Case 2

Male, 10 y 1 m

Hair gel and shampoo containing lavender and tea tree oils

Case 3

Male, 7 y 10 m

Lavender-scented soap and skin lotions

2008 rebuttal

Products not identified
Product ingredients not listed
No evidence that any of the products contained Lavender oil
Even if they did, we don't know how much
No causal relationship established

Transdermal absorption

Product type	Amount applied	Fragrance percent	Retention factor	Fragrance residue	Fragrance absorbed
Toilet water	0.75 g	8.0%	1	60 mg	6 mg
Bath product	17 g	2.0%	0.001	0.34 mg	0.34 mg
Body lotion	8 g	0.4%	1	32 mg	3.2 mg
Shampoo	8 g	0.5%	0.01	0.4 mg	0.04 mg
Hair gel	8 g	0.2%	0.1	1.6 mg	0.16 mg

Cadby et al 2002

Letter to the editor 2014



Letter to the Editor

Lack of evidence that essential oils affect puberty

Dear Sir,

The review by Fisher and Engster [1] due to be published in Reproductive Toxicology repeats the putative link between the essential oils of lavender and tea tree and breast development stating:

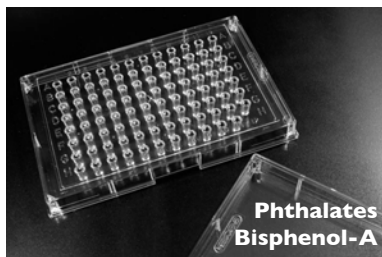
Case reports are a very useful means of identifying possible links between product exposure and detrimental biological effects. However, they are not definitive in their own right. The co-occurrence of all exposure and endocrine disruption, manifested as breast development, has not been demonstrated to be causal. The cause of the pre-pubertal gynaecomastia has not been identified and tea tree and lavender oils have not been definitively identified as endocrine disrupting compounds. Both tea tree (*Melaleuca alternifolia*) and lavender (*Lavandula angustifolia*) oils have a long history of use.

Christine Carson
Robert Tisserand
Tony Larkman

The plastic used in testing contains estrogenic compounds

Polystyrene trays

1. Phthalates and bisphenol A are known endocrine disrupting chemicals



2. Essential oils leach these substances out of plastic

3. This could explain why some in vitro tests show endocrine disrupting effects

Violet waters



Endocrine News article

“In some U.S. Hispanic communities, liberal use of a certain scent, called *agua de violetas*, to perfume babies is common....

When prepubertal gynecomastia began occurring with relative frequency in these communities, a link was established to the lavender oil—containing *agua de violetas*.”

Endocrine News, February 2020

Diaz et al 2016

Alejandro Diaz*, Laura Luque, Zain Badar, Steve Kornic and Marco Danon

Prepubertal gynecomastia and chronic lavender exposure: report of three cases

3 cases are reported

Case 1

Male, 9 y 7 m

Shampoo with lavender oil on ingredients list

Case 2

Male, 9 y 9 m

Agua de Violetas cologne

Case 3

Male, 9 y 4 m

Agua de Violetas cologne

(c) Tisserand Institute 2021

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Diaz et al 2016



Agua de Violetas

"The cologne was purple in color and had a characteristic lavender smell."

HPLC analysis

"UV chromatograms of the agua de violetas cologne concentrated at 210 and 220 nm, matching the UV chromatograms of L. angustifolia."

Conclusion

"These results, combined with the physical appearance and color of the cologne, established that lavender was the main component of this product."

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HPLC analysis

"UV chromatograms of the agua de violetas cologne concentrated at 210 and 220 nm, matching the UV chromatograms of L. angustifolia."

The fact of finding two peaks at these points does not mean you must be seeing linalool and linalyl acetate.

There is simply no evidence here - no chromatogram is shown, either for Lavender oil or for the cologne.

HPLC is a very unusual method to use for analyzing volatiles.

(c) Tisserand Institute 2021

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Color of Lavender oil

ISO 3515:2002

Oil of lavender
(*Lavandula angustifolia* Mill.)

4.2 Colour: Pale yellow



Agua de Violetas



Color of these colognes



Agua de Violetas

"My family is Cuban, and we have a tradition where we douse ourselves and our babies in violetas, a type of cologne that smells like violets."

Eva Mendes
Redbook Magazine, 2015

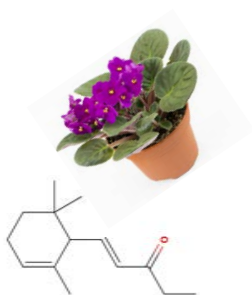


Ionones!

Ionones recreate the scent of Parma violets almost perfectly.

"The discovery of these synthetics – by two German chemists, Tiemann and Krüger – was a breakthrough moment, changing the face of modern perfumery."

<https://perfumesociety.org/ingredients-post/ionone/>



alpha-methyl ionone

Lavender oil constituents

ISO standards

Source	Linalool %	Linalyl acetate %
Australia	25-38	25-45
Bulgaria	22-34	30-42
French Maillette	30-45	33-46
Ukraine	20-35	29-44
Min / Max	20-45	25-46

Also !! other minor constituents, e.g. lavandulol, lavandulyl acetate.

Analysis



Coming up...



Analyses of 5 products from Alexis St-Gelais of Laboratoire Phytochimie in Canada.

These measured not only % of volatiles, but also quantification in mg/L.

Shown are major constituents, plus linalool and linalyl acetate down to 0.01%.

Also, the % of total volatiles in each product.

Laboratoire
PhytoChemia

P.M.B.

Ingredients list

Alcohol denat, Aqua, Parfum, Citronellol, Methyl-2-Octynoate, Benzophenone-I, CI 60730 (EXT D&C Violet no. 2)

% Volatiles	Substance (total 59)
65.82	Dipropylene glycols
14.31	Ionone isomers
6.88	Benzyl acetate
3.09	2,4-Dihydroxybenzophenone
1.76	Citronellol
1.10	Methyl 2-octynoate
0.00	Linalool
0.00	Linalyl acetate

0.73% volatiles
in product



Violetas Francesas

Ingredients list

SD Alcohol 40, Distilled Water, Fragrance, FD&C Red no. 3, FD&C No. 1.

% Volatiles	Substance (total 46)
39.37	Ionone isomers
21.96	Dipropylene glycols
8.03	Benzyl acetate
6.34	Phenylethyl alcohol
4.35	p-Anisaldehyde
3.66	Citronellol
0.23	Linalool
0.00	Linalyl acetate

1.64% volatiles
in product



Ramsey et al 2019

4 cases are reported

Lavender Products Associated With Premature Thelarche and Prepubertal Gynecomastia: Case Reports and Endocrine-Disrupting Chemical Activities

J. Tyler Ramsey,^{1,2} Yin Li,¹ Yukitomo Arai,¹ Ajanta Naidu,³ Laurel A. Coons,¹ Alejandro Diaz,⁴ and Kenneth S. Korach¹

"The continuous use of lavender oil fragrance products was common across these clinical cases and in all cases breast tissue regressed when oils were discontinued."

Case 1 - Mi Tesoro



Female, 7 y 6 m

"On further questioning the family noted frequent exposure to lavender oil in the form of a cologne named 'Mi Tesoro Agua de Violetas' since early childhood."

Breast development resolved 6 months after discontinuing use of the cologne."

Case 1 - Mi Tesoro

Ingredients list

Alcohol, Distilled Water, Fragrance.
D&C Red no.33, FD&C Blue no.1

% Volatiles	Substance (total 69)
42.13	Ionone isomers
7.22	Galaxolide isomers
6.83	Benzyl acetate
4.79	Phenylethanol
4.61	Citronellol
4.22	Benzyl alcohol
3.38	Heliotropin
0.00	Linalool
0.00	Linalyl acetate

0.48% volatiles
in product



Case 2 - Baby Magic



Female, 3 y 11 m

"Her mother reported that she had been bathed with a soap containing lavender oil named "Baby Magic Calming Baby Bath Lavender and Chamomile" since infancy.

Total resolution of her breast tissue was noted 6 months after discontinuation of the soap containing lavender oil."

Case 2 - Baby Magic

Ingredients list

Matricaria recutita flower extract
Lavandula angustifolia flower extract
Parfum

% Volatiles	Substance (total 42)
69.59	Phenoxyethanol
10.28	Unknown compound
8.53	Lauric acid
2.05	Bis(2-ethylhexyl) ether?
0.92	Linalool
0.00	Linalyl acetate

0.98% volatiles
in product



Case 3 - Lavender diffuser

Limonene	
Mouse irritation threshold	32 ppm
8 hour occupational exposure limit in 5 European countries	5-25 ppm
Diffuse 15 drops Orange oil in 64 m3 (4x4x4 m), 2,260 ft3	1 ppm
Detection threshold	0.06 ppm

Female, 7 y 9 m

"Sat near a teacher's table, which had a lavender oil diffuser running all day and was exposed to lavender oil for 1 year before noticing breast development."

"Exposure to lavender oil was discontinued and her breast tissue completely regressed upon evaluation 3 months later."

Case 4



Male, 7 y 11 m

Since infancy, he was exposed daily to lavender oil named "Crusellas Violet Water Cologne."

Resolution of his breast tissue was noted 6 months after discontinuation of the cologne.

Case 4

Ingredients list

Sda Alcohol 408, Water, Fragrance,
FDC Violet No.2, FDC Red No.40

% Volatiles	Substance (total 118)
14.93	Benzyl acetate
13.47	cis- & trans-Woody acetate
12.72	Ionone isomers
10.06	Limonene
6.62	Benzyl benzoate
6.36	Geraniol
4.96	(Z)- α -Amyl cinnamaldehyde
0.95	Linalool
0.06	Linalyl acetate

1.6% volatiles in product



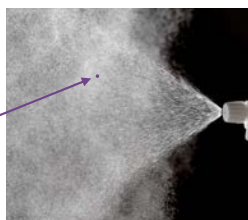
Case 4

% Volatiles	mg/L	% of Product	Substance
14.93	2,433	0.24	Benzyl acetate
13.47	2,194	0.22	<i>cis</i> - & <i>trans</i> -Woody acetate
12.72	2,073	0.21	Ionone isomers
10.06	1,639	0.16	Limonene
6.62	1,077	0.11	Benzyl benzoate
6.36	1,037	0.10	Geraniol
4.96	807	0.081	(Z)- α -Amyl cinnamaldehyde
0.95	155	0.015	Linalool
0.06	9.8	0.00098	Linalyl acetate

If linalyl acetate represents 25% of lavender oil, the product could contain 0.004% Lavender oil = 40 parts per million

Case 4

If linalyl acetate represents 25% of lavender oil, the product could contain 0.004% Lavender oil = 40 parts per million



If 1 g of cologne is sprayed on the skin, this could contain 0.04 mg (40 micrograms) of lavender oil.

If 3.6% of this is transcutaneously absorbed (Lapczynski et al 2008, for linalool), this would equate to 1.4 mcg of lavender oil.

Perspective: 1.4 mcg x 35,000 = 1 drop.

Conclusions



Breast growth summary

Ionone isomers and benzyl acetate were found in significant amounts in all four Violetas products analyzed.

There was no conclusive evidence of lavender oil being present in any of the five products analyzed.

Even if lavender oil was present, its potency would need to be extremely high to cause hormonal changes.



Assumptions

"...most commercial products have minimal ingredient listings. Therefore, we could only assume that the products labelled as containing LO followed ISO regulations and did contain the components that were relevant..."

Ramsey et al 2019

1. Neither of the *Agua de Violetas* products are labelled as containing Lavender oil.
2. No ingredient lists were provided
3. To avoid assumptions, the products could have been GC-MS tested.

Epidemiological study



Prevalence of endocrine disorders among children exposed to Lavender Essential Oil and Tea Tree Essential Oils

Jessie Hawkins, PhD, Christy Hires, MPH, Elizabeth Dunne, MS, RDN, Lindsey Keenan, RDN

In 556 children with a mean age of 6.33, those who were regularly exposed to lavender or tea tree essential oils experienced the same risk of endocrine disorders as those who were not exposed.

No cases of prepubertal gynecomastia were identified in either group, and prevalence of precocious puberty, delayed puberty, growth hormone deficiency, and hypothyroidism were all consistent with population norms.



Jessie Hawkins, PhD

Risk assessment

1. Identify hazard



Estrogenic activity for lavender oil found in two studies, a third found no effect.



2. Evaluate risk



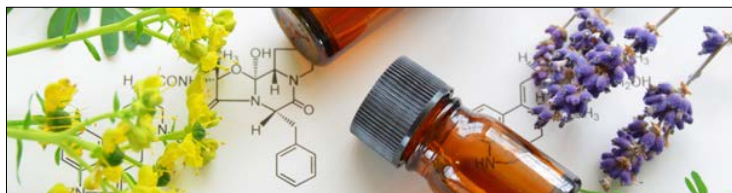
An in vivo study in rats found no estrogenic effect. Lavender is oil not estrogenic in adult females.



3. Determine level of risk

Some cases correlate with the use of lavender oil, but most do not.

Currently, the risk appears negligible.



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