

**Example calculation of margin of safety (MOS) for lavender oil at 0.5% in a women's body moisturiser
In compliance with EU regulation 1223/2009**

1. Composition of lavender oil (Lavandula Angustifolia Oil) from various literature sources

Linalool	30%
Linalyl acetate	33%
Ocimenes	8%
Beta-caryophyllene	5%
Lavandulyl acetate	5%
Terpinen-4-ol	4%

Note: Like much of the research into essential oil composition the numbers are "typical" and don't add up exactly to 100%. In this case we have ignored components present at <3%.

2. NOAEL of linalool

The World Health Organisation has agreed a NOAEL of 50mg/kg/day based on a 90 day oral rat study (Joint FAO/WHO Expert Committee on Food Additives; 1999, WHO food additives series; 42). Higher daily doses cause liver toxicity.

3. Calculated NOAEL for lavender oil

The other main component linalyl acetate has been calculated by the OECD (SIDS profile, 2002) to have a NOAEL of 64mg/kg/day due to the fact that it hydrolyses readily in the body to linalool and the much lower toxicity acetate anion. Put another way the equivalent total linalool content of lavender oil is 56%. So just considering these 2 components the NOAEL of lavender oil is $50\text{mg/kg/day} / 56\% = 89\text{mg/kg/day}$.

Of the other components, ocimenes are structurally very similar to myrcene which has a measured NOAEL of 250mg/kg/day. Terpinen-4-ol has a measured NOAEL value of 400 mg/kg/day with the critical effect being kidney toxicity. Beta-caryophyllene is chemically similar to limonene but has higher molecular weight. The measured NOAEL of limonene is 250mg/kg/day so beta-caryophyllene would be expected to be higher still. Lavandulyl acetate is the ester of an alcohol that has similar chemical structure to other monoterpene alcohols and is expected also to have an NOAEL of >250mg/kg/day. In conclusion, the other components are much lower in toxicity than linalool and will not significantly change the overall toxicity of lavender oil, so the value to use is 89mg/kg/day.

4. Exposure to lavender oil

Amount of body moisturiser used per day = 8g (generally used figure from SCCNFP/0321/02)

Amount of lavender oil applied each day $0.5\% \times 8\text{g} = 0.04\text{g} = 40\text{mg/day}$

The amount of lavender oil actually absorbed through the skin assumed to be 100%

(In practice this is unlikely but various studies show essential oils are absorbed very easily as would be expected from the low molecular weight oil soluble components present. In the absence of definitive data it is normal for toxicologists to assume 100% absorption for these types of substances.)

5. Systemic Exposure Dose (SED)

This is defined as the amount absorbed through the skin divided by body weight

Typical body weight for adult female assumed to be 60kg (this is on the low side of the range to take into account that lower weight consumers will experience higher doses and be more at risk).

$$SED = 40/60 = 0.67\text{mg/kg/day}$$

6. Margin of Safety (MOS)

This is defined as NOAEL/SED

$$MOS = 89/0.67 = 132$$

7. Conclusion

The margin of safety is greater than 100 so lavender oil at 0.5% in this product is considered to be safe. However, if the manufacturer wanted to increase the lavender oil concentration to 1.0% the margin of safety would drop to 66, which would be unacceptable.