

CALCULATION OF FINISHED PRODUCT CONCENTRATION FOR METHYLEUGENOL

NOEL: 1 mg/kg body weight/day (lower end of dose range) – based on the evaluation of the RIFM Working Group of Scientific Experts

Applying a safety factor of 1000 for systemic effects leads to an acceptable dose of 1 µg/kg body weight/day

Taking into account **40% dermal penetration** results in an acceptable dose of **2,5 µg/kg body weight /day** for Methyleugenol
(1 µg/kg body weight/day = 0,4 x 2,5 µg/kg body weight /day)

This corresponds to 150 µg/day Methyleugenol for a typical 60 kg person.

Based on the exposure table as given in the RIFM Criteria Document percentages are assigned to the contributions of certain product categories to the total exposure of a fragrance compound / ingredient per day:

Body lotion:	0.378 mg/kg body weight /day correspond to 14,84% of the total daily exposure of 2,547 mg/kg body weight /day
Face cream	3.14%
EdT	39.26%
(Fine fragrance	39.26%; not used concurrently with EdT)
Fragrancing cream	37.96%
Antiperspirant	3.26%
Shampoo	0.27%
Bath products	0.0785%
Shower gel	0.3926%
Toilet Soap	0.47%
Hair Spray	<u>0.314%</u>
	100%

Using these percentages the daily exposure of 150 µg Methyleugenol for a typical 60 kg person is split up as follows:

Body lotion	22,26 µg/day (= 14.84% of 150 µg/day)
Face cream	4,71
EdT	58,89
(Fine fragrance	58,89)
Fragrancing cream	56,94
Antiperspirant	4,89
Shampoo	0,405
Bath products	0,11775
Shower gel	0,5889
Toilet Soap	0,705
Hair spray	0,471

Conversion via the amounts of products applied to skin per day results in the following maximum concentrations of ME in the finished product (%).

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Explanation: The skin surface residue for body lotion per day is 5.68g/day, the amount of ME per day contributed via the application of a body lotion has been calculated 22,26 µg/day (see above); the percentage therefore is

$$\text{Body Lotion} \quad \frac{22,26 \mu\text{g/day}}{5.68 \text{ g/day} \times 10^6} \times 100\% = 0.00039\%$$

Face cream	0.000294	
EdT	0.00785	rounded: 0.008
Fine fragrance	0.01963	rounded: 0.02
Fragrancing cream	0.00392	rounded: 0.004
Antiperspirant	0.000978	
Shampoo	0.000506	
Bath products	0.002355	
Shower gel	0.0011	
Toilet soap	0.001468	
Hair spray	0.000471	

Body Lotion, face cream, antiperspirant and hair spray are summarized to result in 21.55% of the total exposure as **leave on products** with a limit of **0.0004**.

Rinse off products (shampoo, bath products, shower gel, toilet soap) contribute altogether 1.21% to the total exposure, with a limit of 0.00097 **rounded to 0.001**.

The same limit is applied to all household products (except those defined as non-skin contact products) on the basis that at these levels, incremental exposure from these products would not significantly increase the over-all per capita exposure to Methyleugenol.

CALCULATIONS FOR NON-SKIN CONTACT PRODUCT LEVEL

It is assumed that for non-skin contact products there will only be occasional and accidental (that means little or no) skin contact. The limit is therefore set at the maximum allowed for skin products i.e. 0.02%. To take account of inhalation from some classes of non-skin products (see calculation below for candles) this figure should be applied to the concentration in the fragrance compound.

Exposure calculation for ME from candles:

Limit of 0.02% ME in the fragrance oil used in the candle.

Assume a 5% fragrance load in the candle and a content of 0.02% ME
 $5\% \times 0.0002 = 0.001\% \text{ ME}$

Assume a candle burn rate of 5 grams/hour during 4 hour exposure (per day) and also assume that all of the ME contained enters the atmosphere:

$$5\text{g} \times 0.001\% = 0.00005\text{g ME}$$

$$0.00005\text{g} \times 4 \text{ hours} = 0.0002 \text{ grams ME/day}$$

Assume room size of 2,5 x 2,5 x 3m (18.75 cubic m)

$$0.2 \text{ mg}/18.75 \text{ m}^3 = 0.011 \text{ mg/m}^3 = 11 \mu\text{g/m}^3 = 0.011 \mu\text{g/l ME (per day)}$$

Assume human respiratory volume 1000 litres/hr

$$1000 \text{ litres/hr} \times 4 \text{ hours} = 4000 \text{ litres}$$

$$0.011 \mu\text{g/l} \times 4000 \text{ litres} = 0.044 \text{ mg ME}$$

Assume 10% lung deposition

$$0.044 \text{ mg ME} \times 10\% = 0.0044 \text{ mg ME} / 60\text{kg person} = 0.073 \mu\text{g/kg ME exposure}$$

This would result in a safety factor of around 14000.