**ABSTRACT:**

In the EU, the safety of consumer products like feminine hygiene products is covered by the General Product Safety Directive (GPSD) which provides a framework for the safety of consumer products that are not covered by specific sector legislations. The GPSD is supported by the Risk Assessment Guidelines for Consumer Products which provides a methodology for authorities to assess the risks from consumer products. However, the safety of chemicals, including their presence in absorbent feminine hygiene products which can be regarded as articles under REACH Regulation, is governed by the REACH Regulation.

It is generally recognized in the scientific community that risk assessments shall reflect realistic exposure of a product and shall mimic in-use conditions. When conducting a risk assessment, manufacturers are recommended to estimate the actual exposure to the substance using the available measured data from sound scientific methodologies whenever possible.

A standard set of tools/parameters to calculate the exposure to chemicals and to assess potential risk from the use of absorbent feminine hygiene products (tampons, pads and panty liners) is displayed. We also present an example for exposure-based risk assessment and safety of feminine hygiene products to show how the EBRA principles can be applied.

**INTRODUCTION**

Feminine hygiene products are complex in nature due to their compositional components possibly including impurities which could pose safety concern to consumers. The presence of a substance “X” in products as complex as feminine hygiene ones does not, in itself, provide any information about the safety of said products. Besides biological potency of a substance, exposure resulting from typical product use must be taken into account.

**Product class characteristics:**

- 3-dimensional structures
- Material classes: – materials in direct skin contact
  - materials with non-direct skin contact (requiring a liquid carrier to transport substances to the skin)
  - constructive materials with no skin contact (e.g. release papers), not considered in the EBRA case study

**METHODOLOGY**

**Hazard identification and characterization**

**Selection of key parameters to define the exposure and assess potential risk:**

- Substance availability from product materials using analytical methods mimicking in-use conditions
- Considerations addressing the 3-dimensional design ⇒ different material classes in relation to skin or mucous membrane contact
- Consumer habits and practices data like daily use frequency

**Tiered assessment**

The approach to the exposure based risk assessment is tiered and iterative.

- Tier 1 applies conservative defaults (e.g. 100% dermal or mucosal membrane penetration, direct skin contact with a given chemical constituent etc.), to derive a worst case estimate of exposure
- Tier 2 applies additional refinements such as chemical and product specific information. The outcome of Tier 2 may warrant additional refinements and assessments.

**Exposure calculation**

**KEY EXPOSURE PARAMETERS**

| Amount | = | Amount of ingredient “X” in one product (typically in mg / product) |
| E | = | Extractable / Soluble fraction |
| Rw | = | Re-wet factor (Rewet is a measure of wetness returned to the surface of an AHP) |
| Tr | = | Transfer to skin factor |
| P | = | Dermal penetration factor |
| Freq | = | Daily frequency of product use (number of products used/ day) |
| Bw | = | Female body weight (kg) |

**EXAMPLE OF EXPOSURE CALCULATION**

pantyliner top sheet / direct skin contact

| Amount | Typical range |
| case by case, amount of ingredient “X” in one product (% of “X” in raw material and amount of raw material used in one pantyliner ⇒ mg/ pantyliner) |
| E | From 0 to 1 |
| Rw | 0 - 100% extractable |
| Tr | 0 - 100% rewetting on product surface |
| P | 0.01 - 100% transfer |
| Freq | 0 - 100% systemically bioavailable |
| Bw | average Europe, 66-70 kg |

**Formula for daily exposure calculation:**

\[ \text{Amount} \times (E) \times (Rw) \times (Tr) \times (P) \times (Freq) \times (1/Bw) = \text{mg/kg/day} \]

**MARGIN OF SAFETY (MoS) CALCULATION:**

MoS = Safe Reference Dose / Exposure, ⇒ acceptable MoS level or insufficient MoS level

MoS level depends on the threshold, e.g. Derived No Effect Level (DNEL) which accounts for uncertainty in the assessment.

If the margin of safety is insufficient ⇒ tier 2 approach

---

**REFERENCES**


The authors declare no potential conflicts of interest with respect to the funding, research, authorship, and/or publication of this paper.