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Exposure Based Risk Assessment (EBRA) Principles Applied to Feminine Hygiene Products

Presented by EDANA's Absorbent Hygiene Products Working Group, which consists of manufacturers of baby diapers, feminine hygiene and incontinence products with a combined EMEA market share of over 75%, and for whom consumer safety is of utmost importance.

ABSTRACT:

In the EU, the safety of consumer products like feminine hygiene products is covered by the General Product Safety Directive (GPSD)[1] 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*[2] which provides a methodology for authorities to assess the risks from consumer products. However, the safety of chemicals, including their presence in consumer products (defined as articles under REACH) is governed by the REACH Regulation[3].

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.

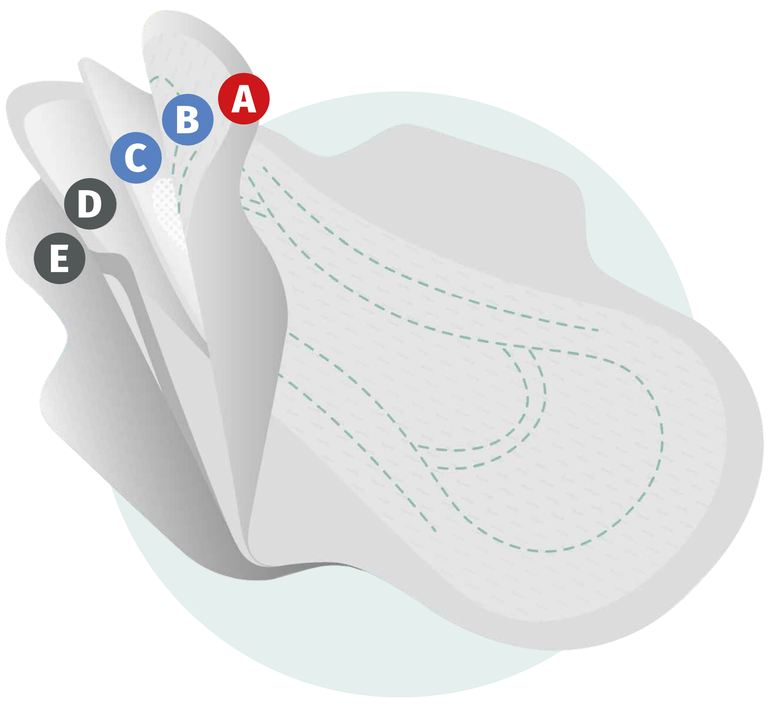
INTRODUCTION

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

A look inside your pad or napkin



A **TOP SHEET**
A soft sheet which is comfortable against the skin

B **ACQUISITION LAYER& CHANNELS**
Draws and directs fluids into the most absorbent areas

C **INNER CORE**
A sheet to absorb moisture or fluid (superabsorbent beads may also be integrated)

D **BACKSHEET**
A waterproof layer to ensure there is no leakage

E **ADHESIVE &RELEASE PAPER**
Glue that sticks the pad to clothing, and a non-stick paper

A **Direct skin contact**

B **C** **Indirect skin contact**

D **E** **Negligible / no exposure**

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 mucus 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

	Typical range	
Amount		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	0 - 100% extractable
Rw	1	0 - 100% rewetting on product surface
Tr	<0.01 to 1	0.01 - 100% transfer
P	From 0 to 1	0 - 100% systemically bioavailable
Freq	< 1-3	average per usage exposure period (day)
Bw	average Europe, 66-70 kg	

Formula for daily exposure calculation:
(Amount) x (E) x (Rw) x (Tr) x (P) x (Freq) x (1/Bw) = x 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

1. Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on General Product Safety | **2.** Commission Decision of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive) (2010/15/EU) | **3.** Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

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