Exposure Based Risk Assessment (EBRA) principles applied to Menstrual Products

EDANA represents the vast majority of suppliers and manufacturers of absorbent hygiene products (AHPs) covering a large market share of branded and private label products in Europe, Middle East and Africa.

ABSTRACT:

In the EU, the General Product Safety Regulation (GPSR)[1] provides a framework for the safety of consumer products (e.g., menstrual products) that are not covered by other specific sector legislations. The GPSR outlines the requirements manufacturers need to fulfil to place products on the market. Central in this regulation is the manufacturer obligation to make sure a product is safe for the user. For chemical risk assessment, Exposure Based Risk Assessment (EBRA) is generally recognized as an appropriate, science-based approach, to determine if health risks are associated with use of consumer products. The EBRA method is widely applied both by authorities and the absorbent hygiene product industry. EBRA is performed in three steps, exposure determination, human reference value (safe limit) identification and a Margin of Safety calculation (MoS). The exposure determination, for using menstrual products, is often performed stepwise. Initial exposure assessment use simplified assumptions on migration of substances from the product to the user and how the product is used. This often result in exaggerated, worst-case exposure and refined exposure estimation must be developed based on deeper understanding of release of substances from the product, use and menstrual product function.

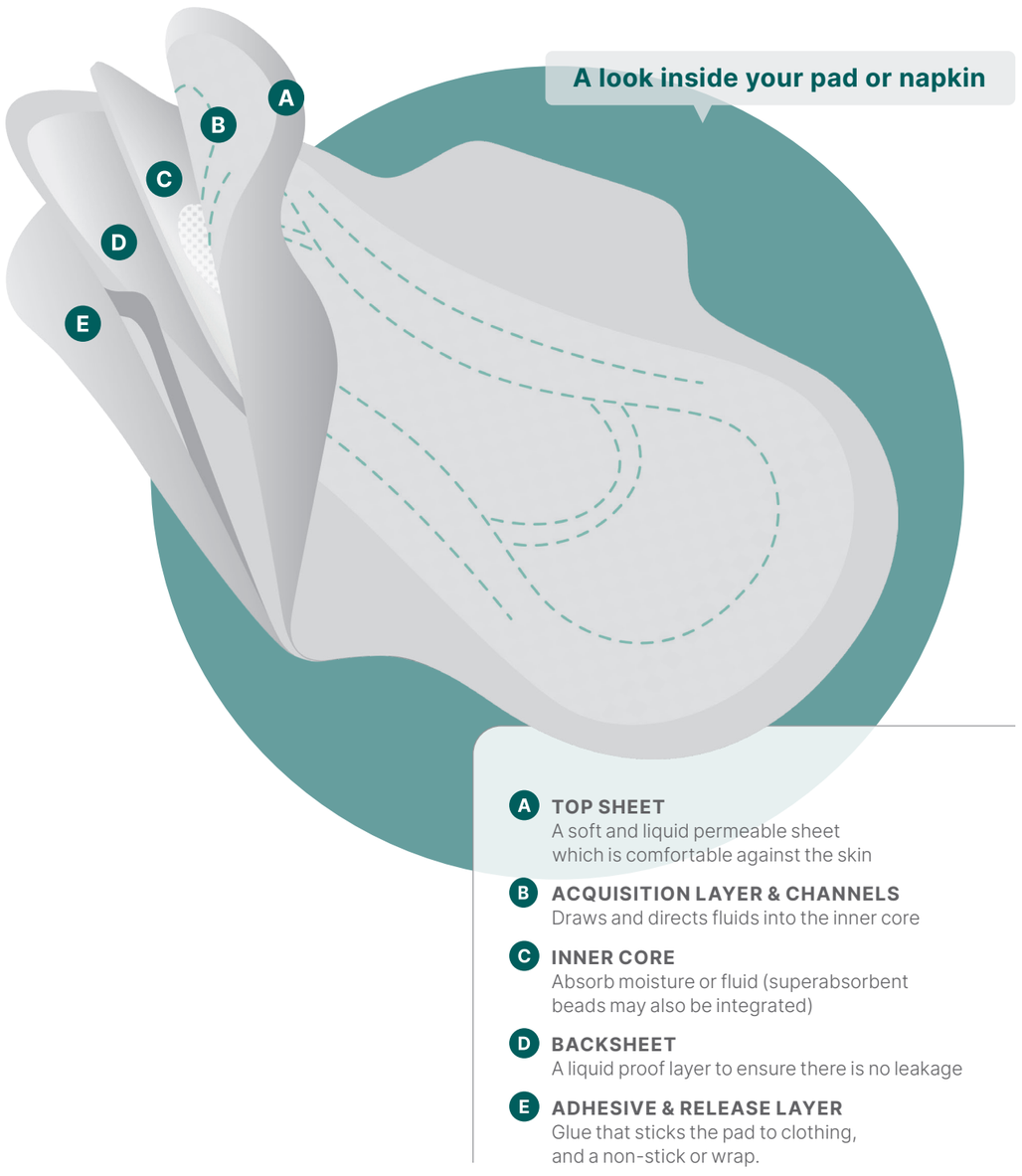
Recently developed EDANA test methods that are a core part of the EDANA Stewardship Program for Absorbent Hygiene Products (AHPs) have been developed to generate use-relevant data on release of substances from menstrual products.

INTRODUCTION:

Menstrual pads and napkins are layered products that are made of several different components. Each component is produced using subcomponents and processing aids to provide the desired functional properties of the component. The supply chain is often complex and there is a risk for impurities being present in the components. Some imputities can be perceived as a safety concern to consumers. However, the mere presence of a substance “X” in a layered product such as a menstrual product does not, in and of itself, mean that the product is unsafe. The exposure resulting from typical product use needs to be taken into account to understand if there is a risk for the user.

Product characteristics:

- 3-dimensional structures
- In relation to body contact, there are :
  – materials with direct skin contact
  – materials with indirect skin contact (requiring a liquid carrier to transport substances to the skin)
  – constructive materials with no skin contact (e.g., release papers)[5]



EBRA METHODOLOGY:

Identification of substances of potential concern in the product e.g.:

- testing products for substances of concern
- suspected impurities
- information from component suppliers

Key parameters to define the exposure:

- degree of substance migration from product-to-product user
- impact of the 3-dimensional structure of the product on migration
- consumer habits and practices like daily use frequency

Tiered assessment of exposure

- Tier 1 applies simplified, conservative assumptions and is often a worst-case estimate (e.g., 100% migration of substace to the user, 100% dermal or mucosal membrane penetration.)
- Tier 2 applies refined parameters for the exposure assessment (e.g. amount of substance migratin from the product to the user, impact of the 3-dimensional structure of the product and dermal/mucosal penetration.)

Additional refinements of the exposure may be necessary (based e.g. on new experimental data on migration or dermal uptake) if safe use of the product is not demonstrated using tier 1 or 2.

If the risk assessment result in “a health risk cannot be excluded”, risk mitigation measures are needed e.g., reducing the substance amount or eliminating the substance.

Exposure calculation

KEY EXPOSURE PARAMETERS:

Physiologically relevant Exposure Parameter	Value Pads/ Liners	Rationale
Amount of trace chemical detected or Amount of trace chemical migrated to user	Weight of substance/ weight of product,(% or ppm). If ppm/10000, to convert to %	Per analytical report (using e.g., CEN CWA 18062 test method[4])
Mass of product	Grams	Weight of the product tested
Frequency of use[I]	X pads/ liners/ day	e.g., Michael J DeVito and Arnold Schecter. 2002
Rewet factor[II]	<5%	e.g., Woeller and Hochwalt. 2015[6]
Transfer factor[II]	10%	
Dermal/ Mucosal absorption	50%[IV]	
	unless specific dermal penetration data or other relevant information is available	
Body weight	50Kg	CDC tables, teenagers included

I. Duration correction is used as part of EBRA considering their use only for specific number of days in a year, so that exposure represents a fraction of a year.
II. A rewet factor accounts for the fluid returning from the absorbent layers to the surface of an AHP under pressure. It can be used to calculate how much of extracted trace chemicals will migrate to the skin.
The transfer factor defines, based on experimental data, how much of chemicals will migrate from materials in direct skin contact. In the case of tampons, there is no differentiation between rewet and transfer.
If there is internal data available on rewet/ transfer, it can be used instead.
III. exposure assessments assume that all components are in direct skin contact and the assumption is 100%, until further data can be established to claim otherwise.
IV. According to SCCS in the absence of experimentally determined dermal absorption. This conservative value may also be used in cases where only inadequate dermal absorption data are available.
V. Very conservative assumption given the lack of scientific data, the nature of the product and the area of exposure

EXAMPLE OF TIER 2 EXPOSURE CALCULATION:

Napkin or Panty liner: *Estimated daily consumer exposure = (Trace element detected or migrated x Mass of product x Frequency of use/day x Rewet factor (or Transfer factor* for direct skin contact) x dermal absorption)/ Body weight*

* not applicable if evaluating data from a milled product

MARGIN OF SAFETY (MOS) CALCULATION:

MoS=HRV/Exposure

*MoS: Is the comparison of the estimated exposure to a limit under which the risk of causing adverse effects is considered to be minimal. These safe limits are developed under different names e.g. RfD (reference dose), an ADI (acceptable daily intake) and they include areas of data extrapolation and uncertainty.
**MoS>1 is typically judged by risk assessors and regulatory bodies to be unlikely to cause harm and provides an assurance of human safety.extrapolation and uncertainty.

REFERENCES

1. https://ec.europa.eu/info/business-economy-euro/product-safety-and-requirements/product-safety/consumer-product-safety_en#the-revision-of-the-general-product-safety-directive
2. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004D0905
3. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
4. Currently a CEN pre-standard:CEN - CEN/WS 118 (cencenelec.eu) | 5. not considered in the EBRA case study
6. K.E. Woeller and A.E.Hochwalt, Safety assessment of sanitary pads with a polymeric foam absorbent core. Regulatory Toxicology and Pharmacology 73 (2015) 419-424).