Exposure-Based-Risk Assessment (EBRA) and the EDANA Stewardship Program

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Abstract

- Disposable absorbent hygiene products (AHPs) (diapers, menstrual products) havemade an important contribution to the quality of life and skin health of millions of people.
- Regulatory classifications and requirements vary across products and countries
- Classical toxicological approach of hazard identification, exposure assessment followed by risk assessment to mitigate any safety concern of intentional as well as unintentional presence of substances is applied.
- Major ingredients, which construct the AHPs, are well characterized from a safety perspective. Possible presence of trace chemicals have led to questions on the safe use of AHPs in the recent years.
- EDANA (European disposables and nonwoven association) volunteered to champion a transparent trust building initiative, The EDANA Stewardship Program CODEX™, to self- regulate trace chemicals possibly present in AHPs and demonstrate that AHPs are safe for consumers.
- The EDANA Stewardship Program includes state-of-the-art scientific and standardized methodologies (CEN Workshop Agreement 18062), a list of guidance values for each substance, which are used as analytical thresholds and are based on regulatory limits as well as national guidelines.
- The CODEX guidance values are connected to the respective test method and the values as such should be decoupled from safety aspects, as they are based on regulatory/standard limits and do not include the aspect of actual human exposure. Exposure-based risk assessment is needed to confirm safety once a trace chemical has been detected via the CODEX testing method (CEN Workshop Agreement 18062.)

INTRODUCTION:

Menstrual products are layered products that contain many components, subcomponents, processing aids, and possibly also impurities, some of which could pose 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

Product characteristics:

- 3-dimensional structures
- In relation to body contact:
  - 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
Key parameters to define the exposure

- Substance migration from product-to-product user determined by analytical methods mimicking in-use condition
- Impact of the 3-dimensional design on migration
- Consumer habits and practices data like daily use frequency

Tiered assessment of exposure

- 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 (dermal absorption data for example)
  Further tiers might be possible.
  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.

KEY EXPOSURE PARAMETERS

Physiologically relevant Exposure Parameter	Value Pads/ Liners	Value Tampons	Rationale
Amount of trace chemical detected	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	X tampons/ day	e.g., Michael J DeVito and Arnold Schecter. 2002
Rewet factor[II]	<5%	100%	e.g., Woeller and Hochwalt. 2015[6]
Transfer factor[II]	10%		
Dermal/ Mucosal absorption	50%[IV]	100%[V]	
	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

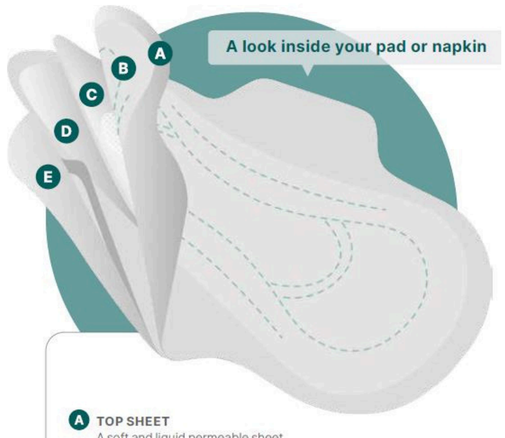
EXAMPLE OF EXPOSURE CALCULATION

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

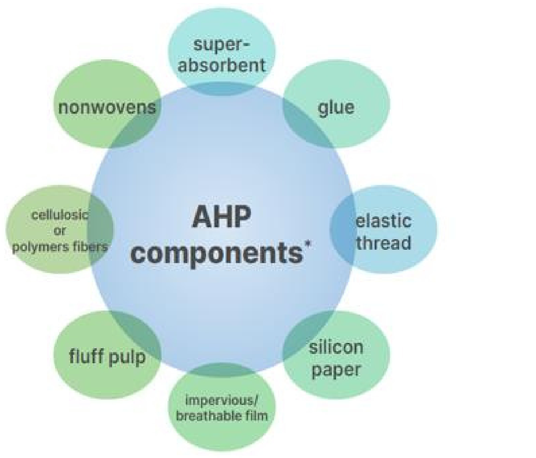
Tampon: *Estimated daily consumer exposure = (Trace element detected x Mass of product x Frequency of use/day x Rewet factor x mucosal absorption)/ Body weight*

* not applicable if evaluating data from a milled product

A look inside your pad or napkin



- **A TOP SHEET** — A soft and liquid permeable sheet which is comfortable against the skin
- **B ACQUISITION LAYER & CHANNELS** — Draws and directs fluids into the inner core
- **C INNER CORE** — Absorb moisture or fluid (superabsorbent beads may also be integrated)
- **D BACKSHEET** — A liquid proof layer to ensure there is no leakage
- **E ADHESIVE & RELEASE LAYER** — Glue that sticks the pad to clothing, and a non-stick or wrap.



*components made from precursors with own production chain

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.

REFERENCES

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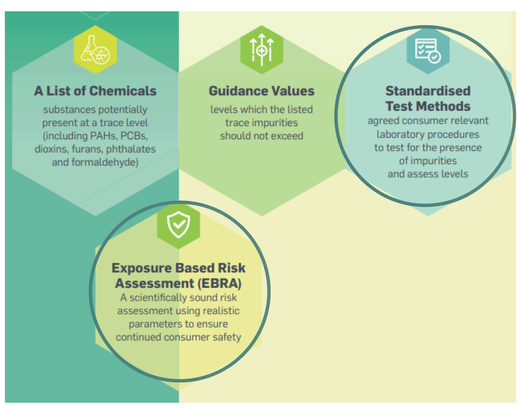
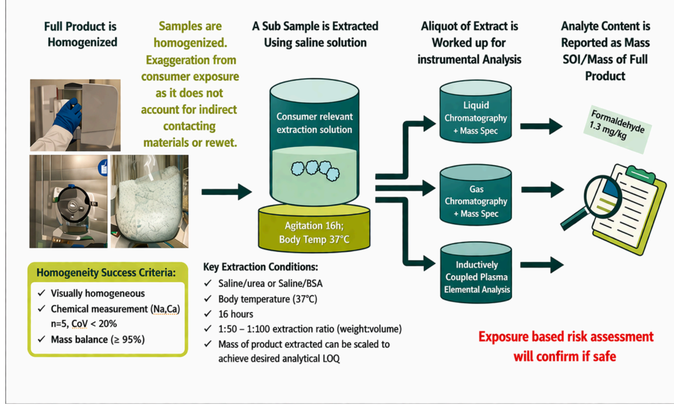
2. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004D0905
3. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
4. Currently a CEN pre-standard:CEN - CEN/WS 118 (cencenelec.eu) | 5. not considered in the EBRA case study
6. K.E. Woeller and A.E.Hochwalt, Safety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

Building Trust: EDANA Stewardship Program for AHPs

- The EDANA Stewardship Programme for AHPs is a voluntary initiative of the nonwovens industry
- The core part of this Program are the minimum voluntary guidance values for trace chemicals, which ensure consumer safety: The EDANA CODEX™
- The Program addresses concerns regarding possible trace chemicals that may be found in AHPs when sensitive analytical methods are applied in specialized laboratories.
- It provides increased transparency and enhanced reassurance for consumers regarding trace levels of impurities found in AHPs.
- Potential trace chemicals are well below existing regulatory limits and pose no risk to consumers and are reassuring consumers that products are safe to use.



Simplified EDANA Test Method Approach: CWA 18062



ORIGIN OF TRACE SUBSTANCES (PPM/PPB):

- anthropogenic pollutants: agriculture/forestry
- industry processes: e.g. catalysts, unreacted monomers, process aids
- naturally present in the environment

Not intentionally added substances (NIAS): NIAS may be present, but not added for technical reasons, have no function in the product:
- Impurities – unintended constituents in a material emanating from production processes
- Contaminants – unintended substances with origin from sources outside the production process, e.g., storage, transportation, ubiquitous in the environment

TRACE SUBSTANCES MANAGEMENT ⇒ SAFE USE OF AHPs

Key aspects

- Raw material control includes working with suppliers to:
  - understand source and nature of raw materials
  - analyze process of manufacture
  - assess likelihood of contamination
  - monitor compositional changes and processes
- Compliance with legislation (e.g., REACH Regulation[2])
- Test of raw materials via state-of-the-art analytical methods (as detailed in the EDANA Supply Chain information Guideline[6] for AHPs)
- Test of finished products (e.g., CEN CWA 18062 test method[5])
- Exposure based risk assessment (EBRA) to assure safe use of products

RISK ASSESSMENT OF TRACE SUBSTANCES

Increasing sensitivity of analytical methods will lead to detection of traces in extremely low concentrations, therefore the need for EBRA (shall reflect realistic exposure to chemicals) to demonstrate acceptable Margin of Safety (MoS).

- Identification and quantification of trace substances use methods simulating extraction/ transport of substances by physiological fluids (salt solutions, synthetic urine etc.) Organic solvents not recommended as they do not reflect real use conditions
- Exposure calculation based on product usage data (e.g., product weight, products used per day and weight of product user)
  - Often performed using generic usage data initially. If needed to refine data, a tiered approach is used → exposure calculation → exposure level (mgtrace substance/kgbodyweight/day)
- Exposure based risk assessment, Margin of Safety (MoS) calculation based on:
  1. Exposure calculation
  2. Relevant available toxicological safe exposure limits
  3. If no data exist → alternative approach: tox. data from structurally related chemicals using read-across approach, SAR (Structure-Activity Relationship) combined with TTC approach (Threshold of Toxicological Concern), endorsed by EFSA/WHO

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3. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX %3A02012R0528-20220415 | 4. https://www.edana.org/how-we-take-action/edana-stewardship-programme-for-absorbent-hygiene-products
5. https://standards.cencenelec.eu/dyn/www/f?p=CEN:110:0::::FSP_PROJECT,FSP_ORG_ID:78414,3235264&cs=12D27C0D8FC7D89DE017D8E491055FACE
6. https://www.edana.org/docs/default-source/product-stewardship/edana-safety-and-regulatory-supply-chain-info-(2022).pdf?sfvrsn=ccc83bef_2