EDANA Test method for user relevant Assessment of Trace Chemicals in Absorbent Hygiene Products (AHPs)

EDANA

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About EDANA, the voice of nonwovens

- International association serving the nonwoven and related industries composed of 300+ member companies
- Founded in 1971 and based in Brussels
- Unique trade association structure, representing the whole supply chain of absorbent hygiene products (baby diapers, incontinence products and feminine hygiene products) from raw materials to finished products
- Long-standing experience and tradition in dialogue and guidance on product safety with many stakeholders (EU, MS, NGO's, customers and consumers)

Introduction

- Following concerns about the chemical safety of AHPs, EDANA developed the Stewardship Programme on AHPs.
- Three elements: list of substances, guidance values and a **test method**.
- A harmonised method is needed as several results have been published, obtained by poorly documented test methods and using harsh extraction methods.
- In the next slides we'll outline the requirements that such a method needs to meet. And provide an overview of the method highlighting the key steps in the development of the method.

Requirements

- *Easy to handle.* Any laboratory with state-of-the-art analytical equipment and well-trained staff can run the method.
- *Validated*. The method is proven to deliver reliable results within the operating parameters of the method.
- *Robust*. The method delivers the same result independent of the operator or the laboratory that is running the test. In effect, the method is repeatable and reproducible.
- *Reflects consumer relevance*. The product is tested under circumstances that reflect aspects of typical consumer usage.

Absorbent Hygiene products are 3-dimensional

- Sanitary towels and nappies are absorbent hygiene products (AHPs) and are 3-dimensional products composed of multilayer materials with specific functionalities. The 3-dimensional construction of sanitary towels and nappies is explained in detail in infographics posted on the EDANA website: https://www.edana.org/discover-nonwovens/products-applications/absorbent-hygiene-products

- They are designed with a primary functionality to capture and 'lock' biological fluids/wetness away from the skin. They achieve this using special materials, which can include particles that absorb and store fluids, that are designed differently from the textiles that are in scope of this restriction proposal.

- The video below demonstrates how liquid is locked away, reducing the exposure of liquid to the skin, via the so-called rewet.

Rewet diaper fluid retention lab demo video

Simplified EDANA Test Method Approach

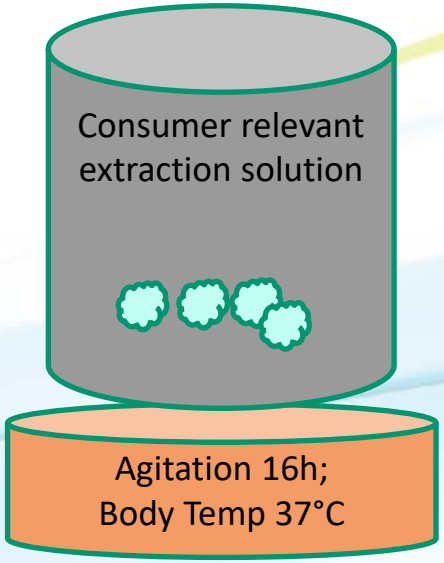
Full Product is Homogenized

Homogeneity Success Criteria:

- ✓ Visually homogeneous
- ✓ Chemical measurement (Na,Ca) n=5, CoV < 20%
- ✓ Mass balance (≥ 95%)

NWSP 360.1.R0(20)

A Sub Sample is Extracted Using Urine Mimic

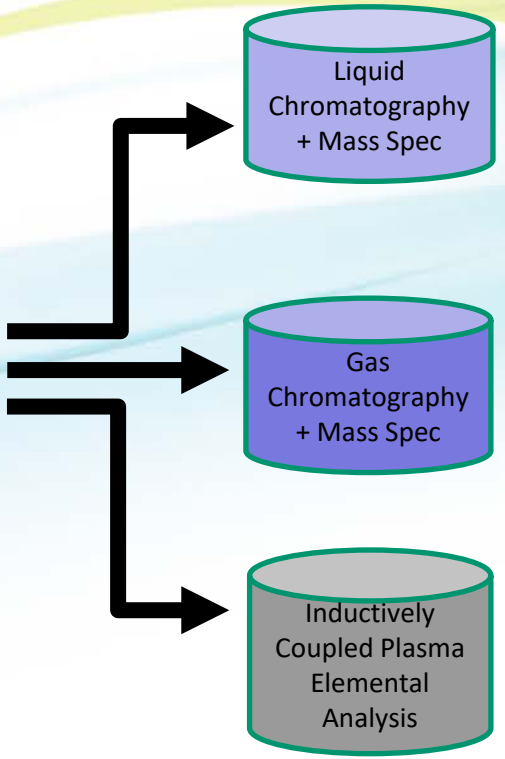


Key Extraction Conditions:

- ✓ Saline/urea or Saline/BSA
- ✓ Body temperature (37°C)
- ✓ 16 hours
- ✓ 1:50 – 1:100 extraction ratio (weight:volume)
- ✓ Mass of product extracted can be scaled to achieve desired analytical LOQ

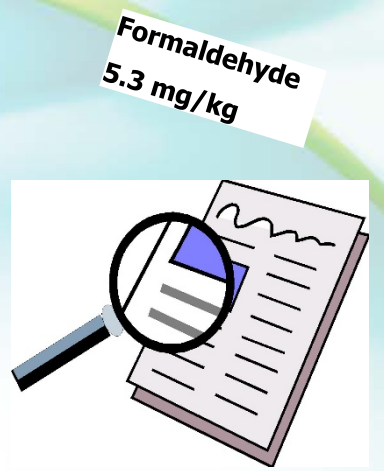
NWSP 360.2.R1(22)

Aliquot of Extract is Worked up for instrumental Analysis



NWSP 360.3.R0(20)

Analyte Content is Reported as Mass SOI/Mass of Full Product



Key steps in the method development

- Decision to **mill** the entire product.
  - Alternatives like squeezing intact product or disassembling have been assessed but rejected.
  - Important to make sure no potential source for a contaminant is missed.
  - Milling offers advantages like homogeneity, optimised surface area, multiple -and identical- retain samples, use of standard equipment.
- Several **extraction** liquids have been considered and tested to find the optimum between consumer relevance and robustness.
  - For Baby and Adult Incontinence products: **saline + urea** (0,9 % NaCl + 0,93 % urea).
  - For menstrual products **saline + BSA** (0,9 % NaCl + 1,0 % BSA).
- Sensitivity analysis has been performed to assess impact of consumer parameters: temp, duration, extraction liquid.
- The laboratories may use any method they have that is validated and appropriate for chemical instrumental analysis of aqueous extracts
- Results can only be reported if the **Method LOQ** doesn't exceed one third to one fifth of the guidance values

Conclusion

- ✓ This method enables testing for the migration of chemicals in a user relevant way.
- ✓ It is easy to re- apply across accredited laboratories and across countries.
- ✓ Results can be used for compliance and risk assessment.

THANK YOU!

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