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Principles for the Risk Assessment of Trace Substances in Absorbent Hygiene Products (AHP)

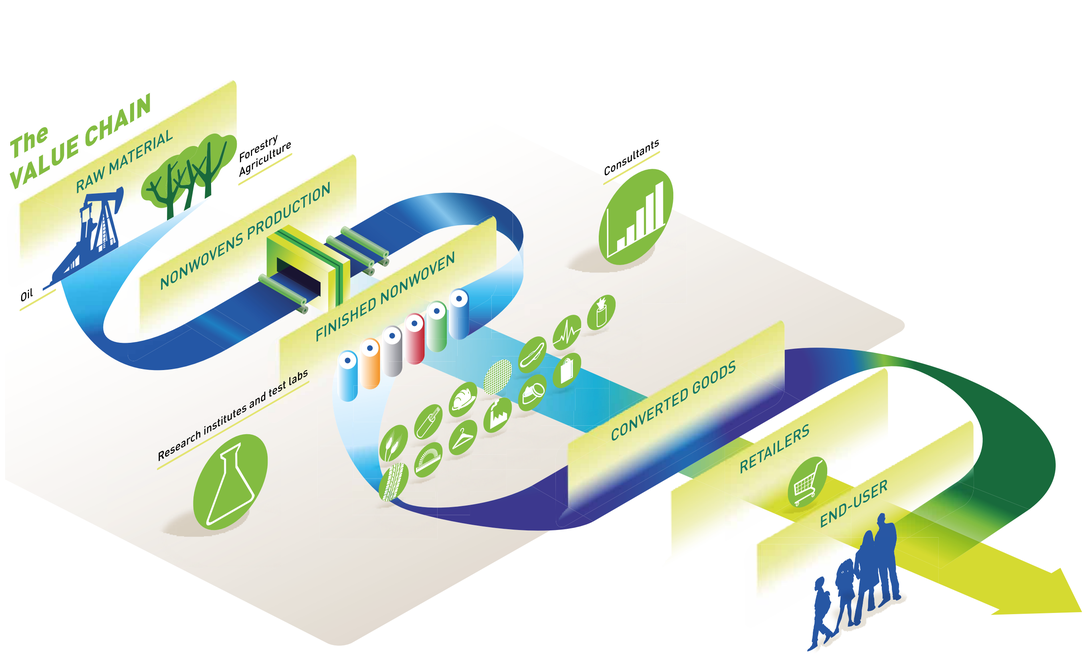
Presented by EDANA's Absorbent Hygiene Products Working Group, which consists of manufacturers of baby diapers, feminine hygiene and incontinence products with a combined EMEA market share of over 75%, and for whom consumer safety is of utmost importance.

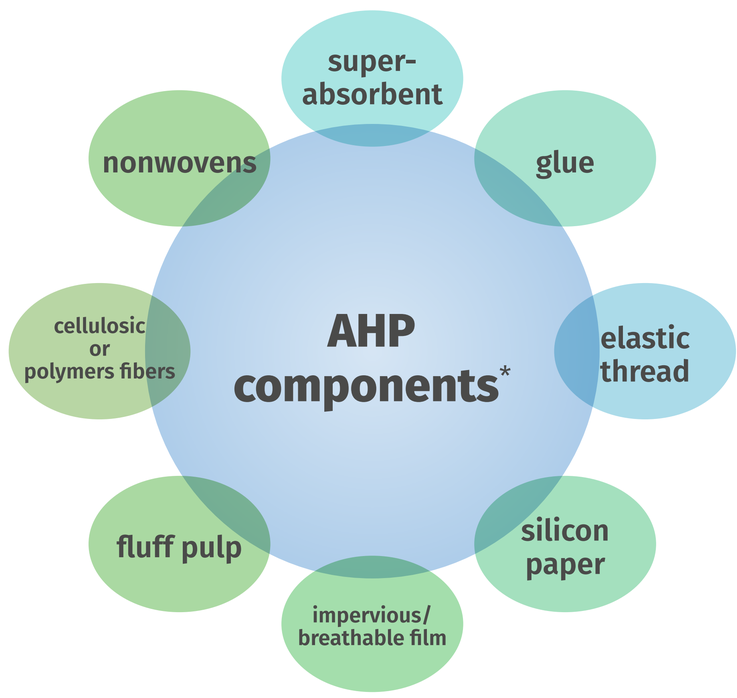
ABSTRACT:

AHP safety requirements are covered by general ('horizontal') EU legislation applicable to multiple consumer goods [1, 2, 3]. Any approach to manage and control traces should be primarily based on safety considerations and on the applicable regulatory requirements.

Traces are usually found at the maximum concentration level range of ppm and can originate from a variety of sources (agriculturally or industry based raw materials). Some trace substances are naturally present in the environment.
Manufacturers are encouraged to apply their developed methods based on the principle of real "in-use" conditions. Thus, for AHP the methods should simulate the extraction and transport of trace substances mediated by physiological fluids. Best In Class (BIC) procedures and state-of-the-art technology are implemented.

Here, we present key requirements for traces management covering the detection and identification of traces as well as the risk assessment linked to maximum acceptable trace exposures and safe limit concentrations.





*components made from precursors with own production chain

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): Present, but not added for technical reasons:

- Impurities - unintended constituents in a material as manufactured, e.g. unwanted side products
- Contaminants - unintended substances with origin from sources outside the chemical pathway/process, e.g. bad storage, ubiquitous in the environment

TRACE SUBSTANCES REQUIRE TRACES MANAGEMENT ⇨ SAFE USE OF AHPs

Key aspects:

- Raw material control incl. working with suppliers:
  – understand source and nature of raw materials
  – analyze process of manufacture
  – assess likelihood of contamination

- Potential test of raw materials / finished products (BIC methods, repeatability/reproducibility)
- Compliance with legislation, risk assessment to assure safe use of products

RISK ASSESSMENT OF TRACE SUBSTANCES

Increasing sensitivity of analytical methods ⇨ detection of traces in extremely low concentrations, questionable physiological/safety relevance ⇨ need for risk assessment

- Identification and detection of trace substances
  – Test environment not simulating in-use conditions (e.g. product shredding/ chemical solvents) not recommended ⇨ Use methods simulating extraction/ transport of substances by physiological fluids (salt solutions, synthetic urine etc.)
- Exposure calculation based on finished product usage
  – Definition of exposure parameters and exposure calculation principles (tiered approach) ⇨ exposure calculation ⇨ exposure level (mg/kg/day)
- Max. acceptable trace exposure/ safe limit concentration based on:
  1. Established safety exposure levels (e.g. regulatory agency, scientific organization) or
  2. Use of available toxicological data and appropriate risk assessment methods or
  3. If no data exist ⇨ alternative approach: tox.data from structurally related chemicals using read-across approach or TTC approach (Threshold of Toxicological Concern), endorsed by EFSA/WHO

REFERENCES

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