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Determination of trace chemicals extracted from absorbent hygiene products (AHPs) using simulated urine/menses

Bestimmung von Spurenchemikalien, die aus absorbierenden Hygieneprodukten (AHPs) extrahiert werden, unter Verwendung von simuliertem Urin/Menstruationsflüssigkeit

Élément introductif — Élément central — Élément complémentaire

CCMC will prepare and attach the official title page.

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Foreword

This CEN Workshop Agreement (CWA XXX:2023) has been developed in accordance with the CEN-CENELEC Guide 29 “CEN/CENELEC Workshop Agreements – A rapid prototyping to standardization” and with the relevant provisions of CEN/CENELEC Internal Regulations - Part 2. It was approved by a Workshop of representatives of interested parties on 2023-11-14, the constitution of which was supported by CEN following the public call for participation made on 2023-01-19. However, this CEN Workshop Agreement does not necessarily include all relevant stakeholders.

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Introduction

There are numerous examples of analytical methods where disposable absorbent hygiene products (AHPs) have been extracted with organic solvents in order to assess the level of trace chemicals in products for consumer usage. However, organic solvents do not reflect the actual product use, where the relevant biological fluids in contact with AHPs are exclusively water based. EDANA has developed a new standard procedure to assess the levels of trace chemicals in AHPs with the aim of producing a method that is easy to handle for laboratories, validated (repeatable and reproducible) and which reflects consumer relevant aspects.

Safety information

This document does not claim to address all of the safety concerns, if any, associated with the use of this method. It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use. It is expected that the person performing this test has been fully trained in all aspects of this procedure.

This procedure uses equipment that creates a high noise level and ear protection may be required.

During the milling process superabsorbent polymer dust can be released (if present) from the AHPs and respiratory protection (dust masks) can be required.

1 Scope

This document specifies a method to identify and quantify trace chemicals potentially present in disposable absorbent hygiene products (AHP). It is applicable for the investigation of disposable baby diapers, disposable menstrual products and disposable adult incontinence products. Table 1 shows the various product categories in scope.

Table 1 — Product categories in scope

Baby diapers	Menstrual products	Adult incontinence products ^a
Diapers (all-in- ones)	Napkins	Pads (inserts)
Pants (pull-on training pants)	Panty liners	All-in-ones
	Tampons	Pants (pull-ups)
		Belted products
NOTE Products that absorb excreta designed for non-infant children and teenagers are in scope as well.		
^a For a list of product types and their names see ISO 22748		

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 187, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of sample*

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 22748, *Absorbent incontinence products for urine and/or faeces — Terminology and classification*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp/>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

absorbent hygiene product

AHP

consumer product designed to absorb human fluids and excreta

Note 1 to entry: An absorbent hygiene product comprises menstrual products (sanitary napkins, panty liners and tampons), baby diapers and incontinence care products.

3.2

product

absorbent hygiene product in a retail packaging

3.3**sample**

homogeneous matrix of milled material derived exclusively from two or more identical products having been milled according to the procedure described in Clause 5

Note 1 to entry: A sample is identifiable and traceable back to the original packaging.

3.4**test specimen**

specific portion of the identified sample upon which an extraction and/or test is performed, and which is identical in composition to the sample

3.5**extraction liquid**

simulant representative for the extraction of certain types of AHPs (see Clause 6)

3.6**blank extract**

specified amount of extraction liquid obtained when the simulant is carried through the entire extraction, filtration and analysis procedures in the absence of a test specimen

Note 1 to entry: The blank extract is generated contemporaneously with any sample extract to which it will be compared.

3.7**sample extract**

specified amount of extraction liquid obtained when the simulant is carried through the entire extraction, filtration and analysis procedures in the presence of a test specimen

3.8**limit of quantitation****LOQ**

minimum amount of analyte that a laboratory has proven capable of quantifying

Note 1 to entry: In the case that this method is used to test against a predefined limit value, the LOQ shall be a factor of at least five lower than that limit value, to assure sufficient quantitative resolution around the limit value.

3.9**limit value**

predefined threshold value for a substance

Note 1 to entry: The method can be run with or without a limit value for any substance.

3.10**reporting limit**

the greater of the LOQ and three times the result calculated from the blank extract

4 Principle

The method is based on the extraction, using specific body-fluid simulants, of potential trace chemicals present in a homogenized sample obtained by milling entire disposable absorbent hygiene products. Sample absorbent hygiene products are milled to a particle size smaller than 2 mm for the purpose of producing homogeneous samples for subsequent extraction and chemical analysis. Milled absorbent hygiene products are extracted using specific body-fluid simulants extraction with under specified

conditions time, temperature and the specimen/extraction fluid ratio. Extracts are then analyzed using any instrumental method that has been validated and is appropriate for trace chemical analysis of aqueous extracts.

5 Milling of AHP

5.1 General

This Clause describes the preparation of samples from absorbent hygiene products, from which test specimens are taken for extraction into respective fluids and chemical analysis of the extraction fluid. The samples are prepared by milling products in suitable milling equipment with the aim of producing homogenous test specimens of defined particle size.

5.2 Materials and apparatus

5.2.1 **Nitrile gloves.**

5.2.2 **Cutting device.**

5.2.3 **Cleaning brush.**

5.2.4 **Cleaning fluid** (ethanol, hexane for organic residues and deionized (DI) water for superabsorbent polymer (SAP)).

5.2.5 **Glass or stainless-steel collection vessel.**

5.2.6 **PE/PP bags**, bottles or lab containers, qualified for trace analysis.

5.2.7 **Cutting mill** (see Annex A for examples). The mills referenced in Annex A (Retsch SM300 with parallel rotor and Retsch SM300 with V-rotor) have been shown to mill products. Both have been demonstrated to produce a homogeneous sample across a range of marketed AHPs. An appropriate mill is any for which a procedure can be developed so as to produce a homogeneous sample with a particle size smaller than 2 mm, provided the criteria specified in the following sections for each product form are met.

5.3 Conditioning

Product shall be delivered as randomly sourced undamaged retail packs in the original packaging, to prevent absorption of atmospheric moisture. Packages are opened and product to be milled is allowed to equilibrate for at least 2 hours in the standard atmosphere of the milling room (Guidance values $(22 \pm 2) ^\circ\text{C}$, $(45 \pm 15) \%$ relative humidity to avoid clumping of the homogenate).

5.4 Product sampling

Products are taken from a single conditioned pack, in order to assure that all products stem from a single production lot. In the event that one retail pack contains insufficient mass, retail packs can be combined with the limitation that the results may not be attributed to a single production lot. The product shall be stored intact in its original packaging prior to milling.

5.5 Sample preparation

5.5.1 Calculate the approximate amount of sample needed for all extractions planned for the product. Additional product is needed for precleaning the cutting mill (50 g), so a realistic estimate of product amount is at least 150 g.

5.5.2 Whilst wearing gloves, open the product packaging and randomly remove the number of products needed for the analysis.

5.5.3 Unpack sufficient product to achieve the required mass. The product shall be removed in a way that represents the status of in-use consumer conditions (e.g. remove any protective foils, applicators, adhesive backing papers). For products that are difficult to handle owing to the presence of sticky surfaces (e.g. menstrual products such as napkins and liners), it is convenient to stick 2 products together (sticky side to sticky side) or fold any areas with adhesive onto the product, so the adhesive does not stick to surfaces of the mill, hindering the feeding and milling process during milling.

5.5.4 It is important that at least two complete product articles are milled so that the homogenate sample is representative.

5.5.5 The remaining product is kept in the original packaging, which is resealed and stored as retained sample for further use.

5.6 Milling absorbent hygiene products

5.6.1 Mill pre-cleaning

If the state of the cleanliness of the mill is unknown, the equipment must be cleaned according to 5.6.3.

The first product article to be milled is sacrificed and discarded to eliminate contamination and cross contamination of subsequent samples.

5.6.2 Milling

- Refer to Annex A for specific guidance on milling;
- Take a sufficient number of products to generate enough material for the subsequent extractions and analyses (at least 150 g). At least two whole product articles must be taken per sample to ensure a representative sample. If this does not yield 150 g of sample more whole product articles must be milled;
- Record the starting mass of the products to be milled;
- Mill the products and record the mass of the milled material generated for the sample collected. Material remaining in the mill is not included as part of the sample collected;
- Store the milled sample in a suitable container (see 5.2.5).

5.6.3 Mill post-cleaning

Once the product has been milled and the sample collected, remove any residual material from the mill and clean using compressed air or vacuum for fine particles. Liquids, for example, water, can be used to remove swollen SAP material and analytical grade hexane/ethanol to remove adhesive materials.

5.6.4 Confirmation of sample homogeneity and mass recovery

5.6.4.1 General

The following success criteria of visual homogeneity, chemical homogeneity, and mass recovery must be met in order for a milling procedure to be deemed successful. It is via demonstration of these success criteria that a laboratory self-qualifies its milling procedure(s) for use in this method. For a particular

AHP category and subcategory, a laboratory may elect not to perform these success criteria verifications for all products milled after demonstrating milling success on that AHP category and subcategory.

5.6.4.2 Visual homogeneity

After milling manually shake the bag/bottle containing the sample to mix and visually inspect to confirm homogeneity. The shaking time is typically one minute or more.

5.6.4.3 Chemical homogeneity

Verify homogeneity by elemental analysis using sodium as a marker for products containing superabsorbent and calcium for others. If neither sodium nor calcium analysis is capable of confirming chemical homogeneity of milled material, another element, known to be present in material most likely to be associated with undesired segregation, is chosen as an elemental marker.

Homogeneity to be determined using at least 3 times 1 g sample. Each sample can be subsampled in smaller portions if the analytical methods require this. Values for each one gram sample (e.g. 5 × 0,2 g) shall be considered as single values for the evaluation of the compliance with the success criterion which is a coefficient of variation to be < 20 %.

Sodium and Calcium are typically determined by element analysis of a digested sample. Any applied method to be specified in the report.

5.6.4.4 Mass recovery

The % mass recovery must be > 90 % and is calculated as follows:

$$\% \text{ mass Recovery} = \frac{\text{mass of material after milling}}{\text{mass of products before milling}} \times 100 \% \quad (1)$$

6 Extraction procedure by artificial simulant

6.1 General

This Clause describes how to extract trace chemicals from a homogeneous specimen of milled absorbent hygiene products using specific body fluid simulants under conditions that increase the likelihood of migration into solution compared to their conditions of use. The simulants for the various AHP types have been chosen to reflect real life usage aspects and to take account of realistic laboratory practices.

6.2 Materials and apparatus

6.2.1 **Deionized Water** for HPLC use – Grade 1 ISO 3696.

6.2.2 **Sodium chloride**, NaCl.

6.2.3 **Urea**, CO(NH₂)₂ (needed for baby diapers and adult incontinence products).

6.2.4 **Lyophilized bovine serum albumin (BSA) powder** with at least 95 % purity (needed for menstrual products). One suitable source of BSA powder is product number A2153 from MilliporeSigma (St. Louis, MO, USA). Another supplier is Carl Roth GmbH.

6.2.5 **Nitrile gloves**.

6.2.6 **Spatulas**.

6.2.7 **Glass weighing vessel**.

6.2.8 Analytical balance accurate to $\pm 0,01$ g for specimen weighing.

6.2.9 General purpose balance accurate to $\pm 0,1$ g for simulant weighing.

6.2.10 Timer.

6.2.11 Glass closable flask 1 or 2 l.

6.2.12 Extraction vessels, e.g. 250 ml and 125 ml wide neck bottles with caps. The material used depends on the analyte and would typically be glass unless the analyte is known to be affected by glass (adsorption, accelerated decomposition, etc.), in which case food grade plastic is recommended.

6.2.13 Incubated orbital shaker large enough to contain the specimen extraction vessels and capable of maintaining a (37 ± 2) °C temperature for 16 hours.

6.2.14 Filter media and supporting funnel of suitable quality for each subsequent analysis.

6.3 Conditioning

Samples shall be delivered in a closed container. Allow the closed container to equilibrate to the laboratory temperature. The preferred test conditions are (22 ± 2) °C and (45 ± 15) % relative humidity. If these conditions are not available, test at ambient conditions and report the temperature and relative humidity.

6.4 Procedure for extraction of specimens for subsequent analyses

Extraction simulant is prepared according to Annex B or Annex C depending on product analyzed. The simulant should be prepared not more than 1 day before the extraction will be performed. The simulant shall be stored in a closed container in a refrigerator and should be allowed to reach laboratory temperature before use.

6.5 Sample extraction

6.5.1 It is critical that at least 1 g of specimen is used for each extraction in order to ensure homogeneity and sensitivity, whilst respecting the specimen/simulant ratio as specified.

For all product categories one gram test specimen is added to 50 g artificial simulant and shaken together for 16 h. In case 1:50 proves to leave insufficient free fluid, a higher ratio is allowed, which must be explicitly reported together with the result.

A blank extraction procedure with no specimen shall be performed in exactly the same way in parallel to the specimen extractions. Here an equal amount of the same simulant preparation is shaken, filtered and analysed alongside the specimen extractions.

6.5.2 Gently shake the sample by hand until it appears to be visually homogeneous before removing a specimen for extraction. The shaking time is typically one minute. If lumps are observed after the shaking, this disqualifies the sample.

6.5.3 Wearing nitrile gloves, transfer a specimen of at least 1 gram, weighed to the nearest 0,01 grams, from the storage container to the extraction vessel.

6.5.4 Record the mass of the specimen (M_{spn}).

6.5.5 Add the required amount of extraction liquid to maintain the specified specimen/simulant ratio.

6.5.6 Record the total mass of the specimen plus the extraction liquid (M_{tot}). Calculate the extracted mass (M_{ext}) by subtracting (M_{spn}) from the total mass (M_{tot}).

6.5.7 Cap the bottle and shake it gently using the orbital shaker for 16 hours at 37 °C. (The BSA-containing simulant used for menstrual products may exhibit a tendency to foam when shaken and may require that the degree of agitation be reduced so as to control any foaming at an acceptable level.)

6.5.8 After 16 hours, remove the extraction vessel from the shaker and allow the solid material to settle for approximately 30 minutes.

6.5.9 Filter the supernatant through a filter medium suitable for the subsequent chemical analysis. This may require more than one filtration if different filter media are required to prevent contamination or loss of analyte.

6.5.10 Transfer portions of the filtrate into suitable vessels for analysis.

NOTE: Internal standards used in analytical instrumental analyses employed in this document [see Clause 7] are not to be added prior to the completion of 6.5.10.

6.6 Calculation or interpretation of results

$$M_{\text{ext}} = M_{\text{tot}} - M_{\text{spn}} \quad (2)$$

7 Analysis of trace chemical in aqueous extracts

7.1 General

This Clause describes a basis to determine the amounts of trace chemicals in the aqueous blank extract and the aqueous sample extracts prepared in Clause 6. Laboratories may use as a starting point any method appropriate for trace chemical analysis of aqueous samples whether an internal written method or externally published method (e.g., ISO, ASTM, EPA). However, each laboratory would need to validate them for this analysis. These extracts may require further processing depending on the methods used. In many cases additional extraction may be required in order to obtain an organic solvent solution to present to the final instrumental detector. For example, liquid-liquid or solid phase extraction. It may also be necessary to include internal or external standards for calibration at this stage. Examples of chemical classes in scope are listed in Table 3 below.

Table 3 — Non-limiting list of exemplary chemical classes

Chemical class	Acronym of classes
Dioxins and furans	PCDD/PCDF
Dioxin like PCBs	dl-PCB
Phthalates	---
Pesticides and herbicides	---
Polycyclic aromatic hydrocarbons	PAH
Phenols	---
Organotin compounds	OTC
Aldehydes	---
Heavy metals	---

7.2 Materials and apparatus

Materials and apparatus are not specified here as each analysis will have specific details defined as part of the laboratory or standard procedure.

7.3 Procedure

7.3.1 General

This procedure is used to determine the amounts of trace chemicals in aqueous blank and sample extracts, see Clause 6.

7.3.2 Analysis of sample extracts

The sample extracts shall be analysed following the appropriate test methods chosen by the laboratory for the analyte classes. The analysis of the sample extracts includes all necessary quality assurance steps of the laboratory for performing the analysis on the obtained extraction filtrate. This will include the use of internal or external standards for calibration, repeat determinations or spiking experiments.

7.3.3 Analysis of blank extracts

Blank extracts shall always be analysed in parallel with the sample extracts by the respective test methods for the analyte classes.

7.4 Calculation and expression of the results

7.4.1 Calculation of analyte concentration in the original product

Calculate the final result M_A in mg of analyte per kg of product, using the following equation for calculation of the extractable trace chemical in the product. In cases where a concentration step is used, V_{out} and V_{in} should be applied.

$$M_A = \frac{V_{out}}{V_{in}} \times \left(\frac{C_A \times V_{ext}}{M_{spn}} \right) \times 1\,000 \quad (3)$$

where

- M_A is concentration of the analyte in the original product [mg/kg];
- C_A is concentration of the analyte in the final sample extract analysed [mg/ml];
- V_{ext} is volume of extraction fluid which is used for the extraction step [ml]
(assume specific gravity of extraction liquid = 1, M_{ext} [g] = V_{ext} [ml])
(see Clause 6);
- M_{spn} mass of specimen which is used for the extraction [g]
(see Clause 6);
- V_{in} volume of aqueous sample extract used for concentration steps [ml];
- V_{out} volume of organic sample extract present after concentration steps [ml].

If M_A is below the LOQ report it as less than the LOQ. No further calculations are required. If M_A exceeds the LOQ proceed to 7.4.2.

7.4.2 Calculation of analyte concentration in blank extract

7.4.2.1 General

If M_A (the concentration of an analyte in the original product) exceeds the target LOQ for a trace chemical, calculate M_B (the concentration of that chemical in an equivalent blank extract) in the same manner that M_A was calculated.

$$M_B = \frac{V_{\text{out}}}{V_{\text{in}}} \left(\frac{C_B \times V_{\text{ext}}}{M_{\text{spn}}} \right) \times 1\,000 \quad (4)$$

where

- M_B is concentration of the analyte in the blank on an original product basis [mg/kg];
- C_B is concentration of the analyte in the final blank extract [mg/ml];
- V_{ext} is volume of extraction fluid which is used for the extraction step [ml]
(assume specific gravity of extraction liquid = 1, $M_{\text{ext}} [\text{g}] = V_{\text{ext}} [\text{ml}]$)
(see Clause 6);
- M_{spn} is mass of specimen which is used for the extraction [g]
(see Clause 6);
- V_{in} is volume of aqueous sample extract used for concentration steps [ml];
- V_{out} is volume of organic sample extract present after concentration steps [ml].

7.4.2.2 Consideration of blank result (M_B) in the case the method is performed with a limit value

If the concentration of analyte in an equivalent blank sample (M_B) is greater than 1/3 of the limit value for that analyte, the M_A result is not reportable, and sample analysis for that method shall not proceed until the cause of the high blank values is remediated.

In the case of PCDD/PCDF/dl-PCBs, where sum values of congeners are reported, and the WHO (2005) PCDD/F-PCB TEQ in an equivalent blank sample is greater than 1/3 of the limit value, the result is not reportable until the cause of the high blank result is remediated.

If the concentration of analyte in M_B is less than 1/3 of the limit value for that analyte, calculate a blank corrected value, M_{Acorr} , for the sample extract as shown in 7.4.3. Report this M_{Acorr} value if it is above the LOQ.

7.4.2.3 Consideration of blank result (M_B) in the case the method is performed without a limit value

It is not unusual at a particular lab for a method LOQ to be established but for some daily fluctuation in blank extracts to be observed. The reporting limit is defined as the greater of the LOQ and three times the concentration in the blank extract (M_B). If the M_A result is less than the reporting limit, the M_A is not reportable.

If M_A result is above the reporting limit, calculate a blank corrected value, M_{Acorr} , for the sample extract as shown in 7.4.3. Report this M_{Acorr} value.

7.4.3 Calculation of blank corrected value for sample extract, M_{Acorr}

$$M_{\text{Acorr}} = M_A - M_B \quad (5)$$

8 Test report

In addition to the test results expressed as mg analyte per kg of product, the test report shall include at least the following information:

- a) reference the test method used;
- b) name and address of testing institution;
- c) date of the testing;
- d) name and model of testing equipment;
- e) mass of specimen(s) and simulant used in the extraction;
- f) all identification details and source information required for the complete identification of the samples and the products from which they were derived (e.g. lot number(s) and method of sampling);
- g) any unusual features (like an already opened pack) noted during the determination or if the reproducibility and/or repeatability criteria were not met;
- h) milling room and laboratory testing conditions;
- i) any deviations from this procedure or any operations regarded as optional (e.g.: different stirring time);
- j) the uncertainty of the test result;
- k) whether or not samples were conditioned prior to testing and, if so, for how long;
- l) anything unusual noted during the testing.

Annex A (informative)

Example milling procedures

A.1 Example using the Retsch SM300 with parallel rotor

A.1.1 Pre-cleaning

Mill the products as indicated in Table A.1, with the cyclone/vacuum pump disconnected.

The RPM may need to be adjusted to achieve best performance.

Table A.1 — Special instructions for milling

Product	Treatment	RPM 6/8 mm Sieve	RPM 2 mm Sieve
Baby diaper	Cut into pieces if needed to fit mill	700	700
Diaper pants	Cut into pieces if needed to fit mill	700	700
Napkins	Cut into pieces if needed to fit mill	700	700
Panty liners	Cut into pieces if needed to fit mill	700	700
Tampons	Mill "as is"	700	700
Adult pads	Cut into pieces if needed to fit mill	800	1 500
Adult pants	Cut into pieces if needed to fit mill	800	1 500
Adult belted articles	Cut into pieces if needed to fit mill	800	1 500

Discard this material.

A.1.2 Milling the product to produce the sample

1. For each trial, mill a sufficient number of products in order to generate material for the subsequent extractions and analyses. At least two whole product articles should be milled to ensure that a representative product sample is obtained.
2. Record the total starting weight of the products to be milled in order to calculate the mass recovery.
3. Mill products as indicated in Table A.1 and collect samples in a clean vessel.
4. Weigh the final milled material and collect in a suitable container.
5. Calculate the mass balance as a proportion of sample as obtained as a percentage of the starting product milled.
6. Clean mill and sieve by vacuuming with the cyclone system to remove all visible particles.

A.2 Example using Retsch SM300 with V-rotor and a single 2 mm sieve option

A.2.1 Pre-cleaning

Mill the products as indicated in Table A.2, with the cyclone/vacuum pump connected.

The RPM may need to be adjusted to achieve best performance.

Table A.2 — Guidance for milling the different products

Product	Special instructions for milling	Mill speed rpm	Feed rate
Baby diaper	Roll diaper into loose ball.	3 000	1 unit at a time
Napkins	Fold in half so that the adhesive portions stick together so that no adhesive is exposed.	3 000	May be introduced 5 units at a time
Panty liners	Fold in half so that the adhesive portions stick together so that no adhesive is exposed.	1 000	May be introduced 5 units at a time
Tampons	Remove from the wrapper and mill whole articles.	3 000 ^a	1 unit at a time ^a
^a Additional conditions not explored. Note that light tampons may partially block the collection vessel adapter neck. If this occurs, turn off the vacuum system and transfer material to a secondary collection vessel before continuing.			

Discard this material.

A.2.2 Milling the product to produce the sample

1. For each trial, mill a sufficient number of whole products in order to generate material for the subsequent extractions and analyses.
2. Record the total starting weight of the products to be milled in order to calculate the mass recovery.
3. Prepare and mill products as specified in Table A.2 using a V-rotor, 2-mm sieve and the cyclone vacuum system set to ON in the low setting.
4. Weigh the final milled material and collect in a suitable container.
5. Calculate the mass balance – the proportion of sample as obtained as a percentage of the starting product milled.
6. Clean mill and sieve by vacuuming with the cyclone system to remove all visible particles.

Annex B **(normative)**

Extraction simulant diaper and adult incontinence products

Transfer 600 ± 1 g of DI water into a 1 l closable flask.

Add $9,00 \pm 0,01$ g of NaCl.

Add $9,30 \pm 0,01$ g of Urea.

Complete the extraction simulant mass to $1\ 000 \pm 1$ g with DI or HPLC grade water.

Shake the solution for at least 30 minutes at room temperature or until all reagents are dissolved.

For larger amounts the preparation can be scaled up as required.

Annex C **(normative)**

Extraction simulant menstrual products

Transfer 600 ± 1 g of DI water into a 1 l closable flask.

Add $9,00 \pm 0,01$ g of NaCl.

Add $10,0 \pm 0,01$ g > 95 % purity lyophilized bovine serum albumin protein (BSA) powder.

Complete the extraction simulant mass to $1\ 000 \pm 1$ g with DI or HPLC grade water.

Swirl and/or gently shake the solution for at least 30 minutes at room temperature or until all reagents are dissolved. (Note that BSA-containing solutions may exhibit a tendency to foam, and so the vigor of shaking may have to be adjusted to as to minimize foaming.)

For larger amounts the preparation can be scaled up as required.

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