02/03/2022

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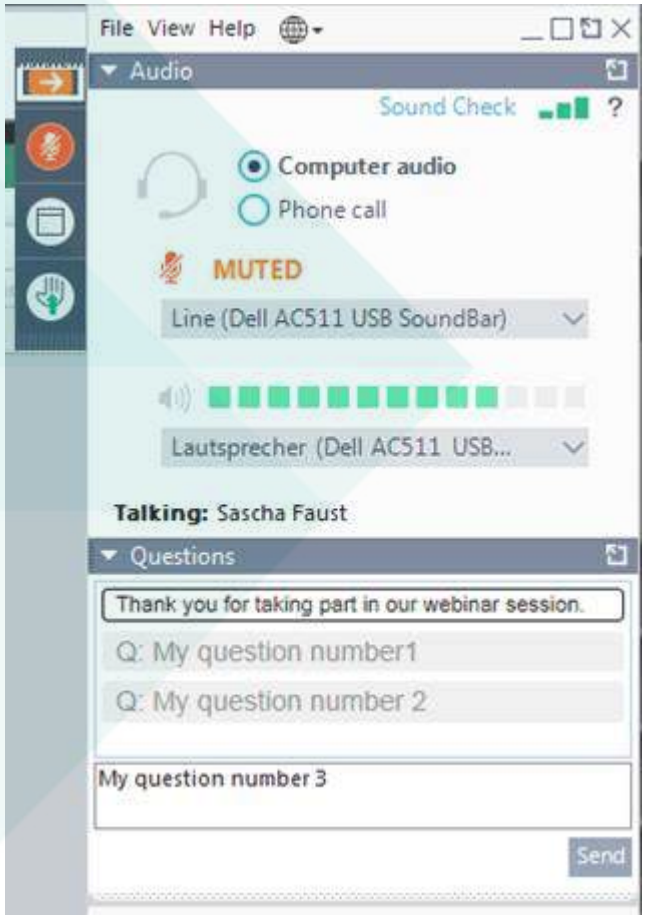
Intimate Care Products: Evaluation of safety and performance in clinical studies.

Our ambition? **Excellence.**

House Keeping

- Approx. 40 minutes speaking time
- Followed by 15 to 20 minutes for a discussion
- You can use the control panel to submit your questions



Agenda

- Regulatory
- Intimate Hygiene
- Grooming
- Sexual Health & Wellbeing
- Menstrual products
- Incontinence
- Post-menopausal Care

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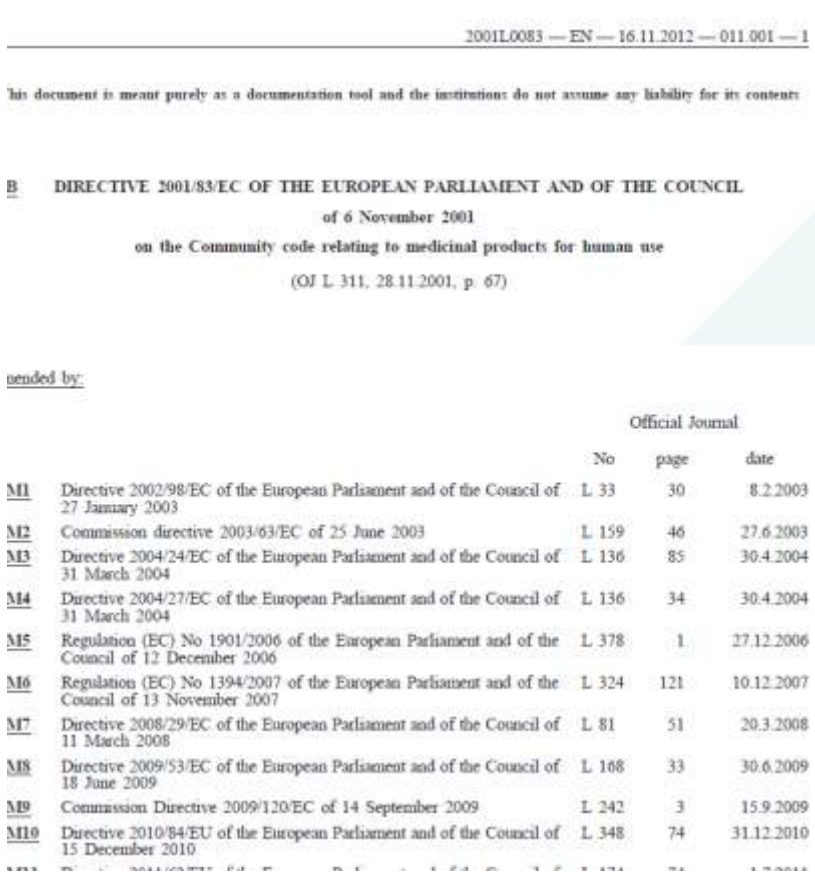
Regulation

§

Medicinal Product Directive 2001/83/EC



2001L0083 — EN — 16.11.2012 — 011.001 — 1

This document is meant purely as a documentation tool and the institutions do not assume any liability for its contents

B DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 November 2001

on the Community code relating to medicinal products for human use

(OJ L 311, 28.11.2001, p. 67)

amended by:

		Official Journal		
		No	page	date
M1	Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003	L 33	30	8.2.2003
M2	Commission directive 2003/63/EC of 25 June 2003	L 159	46	27.6.2003
M3	Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004	L 136	85	30.4.2004
M4	Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004	L 136	34	30.4.2004
M5	Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006	L 378	1	27.12.2006
M6	Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007	L 324	121	10.12.2007
M7	Directive 2008/29/EC of the European Parliament and of the Council of 11 March 2008	L 81	51	20.3.2008
M8	Directive 2009/53/EC of the European Parliament and of the Council of 18 June 2009	L 168	33	30.6.2009
M9	Commission Directive 2009/120/EC of 14 September 2009	L 242	3	15.9.2009
M10	Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010	L 348	74	31.12.2010

Article 1 (2) MPD **Definitions**

- (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medical Device – MDR 2017/745

Official Journal of the European Union

I

(Legislative acts)

REGULATIONS

ULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE

of 5 April 2017

ical devices, amending Directive 2001/83/EC, Regulation (EC) No
lation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and

(Text with EEA relevance)

PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

to the Treaty on the Functioning of the European Union, and in partic
thereof,

Chapter 1, Article 2 - Definitions

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

Cosmetics - CPR: COMMISSION REGULATION (EU) No 1223/2009

EN Official Journal of the European Union

GULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUN

of 30 November 2009

on cosmetic products

(recast)

(Text with EEA relevance)

RLIAMENT AND THE COUNCIL OF THE EURO-

he Treaty establishing the European Commu-
lar Article 95 thereof,

e proposal from the Commission,

the opinion of the European Economic and
),

ce with the procedure laid down in Article 251

(5) The environmental concerns that subst
metic products may raise are considered
cation of Regulation (EC) No 1907/200
Parliament and of the Council of 18 De
cerning the Registration, Evaluation,
Restriction of Chemicals (REACH) and
pean Chemicals Agency (4), which enab
of environmental safety in a cross-secto

(6) This Regulation relates only to cosmeti
to medicinal products, medical devices
ucts. The delimitation follows in pa
detailed definition of cosmetic products
to their areas of application and to the
use.

Chapter 1, Article 2 (1a) - Definition of a cosmetic product

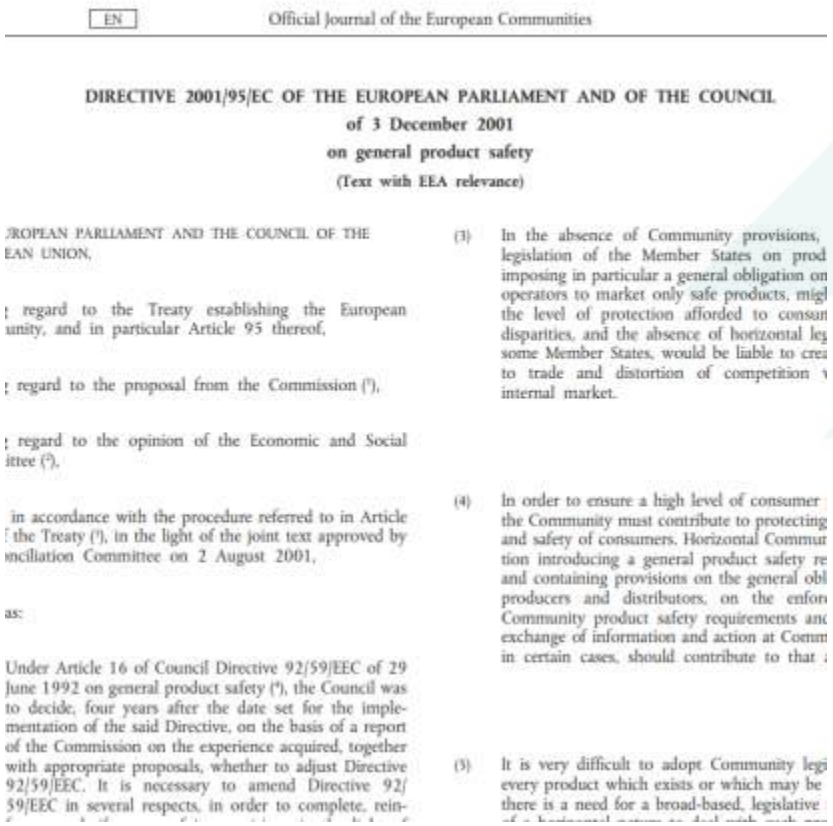
A cosmetic product is a substance intended to be applied to the external parts of the human body:

- epidermis
- hair system
- nails
- lips
- external genital organs
- teeth
- mucous membrane of the oral cavity

And its main purpose is to:

- clean
- perfume
- change appearance
- correct body odor
- protect
- keep in good condition

General Product Safety Directive 2001/95



EN Official Journal of the European Communities

DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 3 December 2001
on general product safety
(Text with EEA relevance)

ROPEAN PARLIAMENT AND THE COUNCIL OF THE
EAN UNION,

regard to the Treaty establishing the European
unity, and in particular Article 95 thereof,

regard to the proposal from the Commission (1),

regard to the opinion of the Economic and Social
ittee (2),

in accordance with the procedure referred to in Article
the Treaty (3), in the light of the joint text approved by
nciliation Committee on 2 August 2001,

as:

Under Article 16 of Council Directive 92/59/EEC of 29 June 1992 on general product safety (4), the Council was to decide, four years after the date set for the implementation of the said Directive, on the basis of a report of the Commission on the experience acquired, together with appropriate proposals, whether to adjust Directive 92/59/EEC. It is necessary to amend Directive 92/59/EEC in several respects, in order to complete, rein-

(3) In the absence of Community provisions, legislation of the Member States on prod imposing in particular a general obligation on operators to market only safe products, migl the level of protection afforded to consur disparities, and the absence of horizontal leg some Member States, would be liable to crea to trade and distortion of competition v internal market.

(4) In order to ensure a high level of consumer the Community must contribute to protecting and safety of consumers. Horizontal Commur tion introducing a general product safety re and containing provisions on the general obl producers and distributors, on the enfor Community product safety requirements and exchange of information and action at Comm in certain cases, should contribute to that

(5) It is very difficult to adopt Community legi every product which exists or which may be there is a need for a broad-based, legislative

Article 2 Definitions

- (a) ‘product’ shall mean any product — including in the context of providing a service — which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

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Hygiene Products

Hygiene

- Soaps, Gels, Wipes
- The global value of the feminine hygiene market is 20 billion dollars
- The top 3 reasons why most women consider using feminine washes & cleansing products are

  (1) to have fresh-feeling after washing

  (2) deodorizing effect

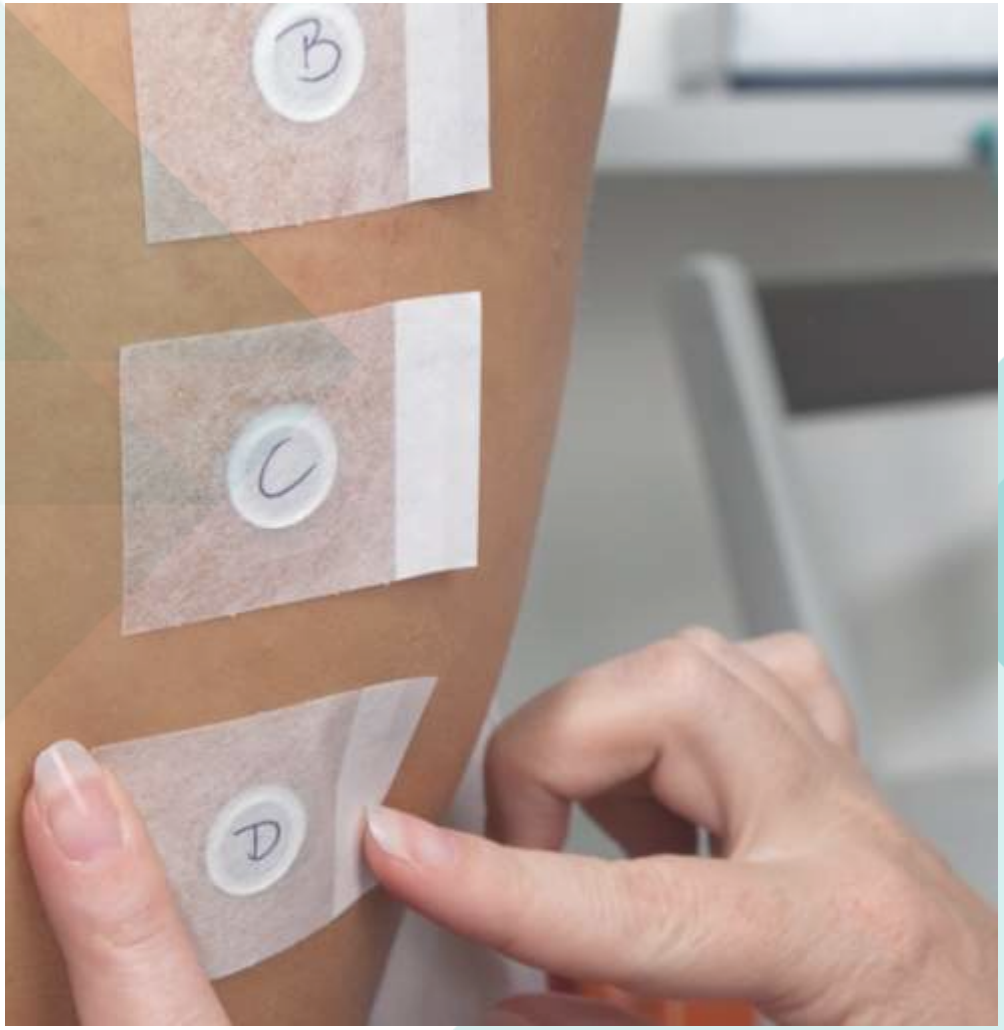
  (3) clean-feeling effect

Hygiene Safety – Standard Tests

- Patch Testing
  - Acute Tolerance
  - Cumulative Irritation
  - Sensitization

- Other Standard Methods
  - Scarification Test
  - Forearm Controlled Application Test

  Endpoints/Measures
  - Visual scoring by expert graders (and/or Dermatologists)
  - Barrier function & dryness (FCAT)



Hygiene Safety – Standard Tests
Example Test Design

Aim control	Determination of the skin tolerability of the test products under dermatological	
Parameters	PI:	Evaluation of primary skin irritation [trained grader]
Test Procedure	Day 1:	Application of test products to the back, under occlusion, for 24 hours
	Day 2:	PI shortly after patch removal
	Day 3:	PI 24 hours after patch removal
	Day 4:	PI 48 hours after patch removal
Panel	50 subjects at least 18 years old	

Hygiene Safety – Standard Tests

- Benefits:
  - Relatively quick & simple
  - Internationally generally accepted standard study designs
  - Maximized exposure conditions to detect specific responses
  - Intraindividual within subject comparison

- Considerations:
  - Does not provide any real insight into in-use exposure

Hygiene Safety – In Use

- In-use Exposure

  Endpoints/Measures
  - Visual examinations
  - Subjective tolerance
  - pH Maintenance / balance
  - Lactobacillus Status
  - Microbiome

  Benefits:
  Better insight into consumer exposure/experience

Hygiene Safety – In Use
Example Test Design

Aim	Determine the skin tolerability of an intimate wash product	
Parameters	P1:	External Examination of Tolerance [Gynaecologist]
	P2:	Subjective Assessment of Tolerance [Subjects]
	P3:	Vaginal pH - Swab [Gynaecologist]
	P4:	Vaginal Microflora Swab [Gynaecologist]
Test Procedure	Day 1:	P1, P2, P3, P4, distribution of products
		Application of products by subjects at home, up to Day 28:
	Day 29:	P1, P2, P3, P4, return of products
Panel	40 subjects per treatment/group, female, at least 18 years old	

Hygiene Safety – In Use

- Microbiome – Recent Advances in Genomic Sequencing

  Long reads
  16S ribosomal RNA Gene Sequencing
  - Provides relative abundance of bacteria taxa

  Whole Genome Shotgun
  Metagenomic Sequencing
  - Taxonomic classification down to species and strain level

  Shallow Shotgun
  Metagenomic Sequencing “light”
  - Only 10% of the Shotgun data

Hygiene Safety – In Use

- Considerations:
  - Panel recruitment can be challenging
  - More complex test site – so data interpretation is more complex
  - Need to consider stage of menstrual cycle, particularly for cross-over designs
  - Concomitant Medications
  - External (Labia Majora) or internal (Mucus Membrane) assessment?
    - Is this a cosmetic product/test, or something else??

Hygiene - Performance Testing

- Cleanliness & Freshness

Designs:
- Controlled or in-use exposures
- Monadic or crossover (with suitable standardization in-between treatments)

Endpoints/Measures:
- Subjective Self-perception

Benefits:
- Actual consumer experience

Considerations:
- Panel demographics
- Avoid bias

Hygiene - Performance Testing

- Odour control

  Designs:
  - Controlled or in-use exposures
  - Monadic or crossover (with suitable standardization between treatments)

  Endpoints/Measures:
  - Self Perception
  - Trained Odor Judges (DIN EN 13725)

Hygiene - Performance Testing
Example Test Design

Aim	Determine the deodorant and subject acceptance of an intimate wash product	
Parameters	P1:	Malodor Intensity Scale [Trained Judge]
	P2:	Self-Assessment Questionnaire (incorporating freshness & odor) [Subject]
Test Procedure	Day -7:	Start of Standardisation (standard unperfumed wash or water only)
	Day 0:	Last wash 8-hours before baseline visit
	Day 1:	Baseline P1, P2, First product use, followed by P1, P2 + 4-hours P1, P2 + 8-hours P1, P2
Panel	30 subjects per treatment/group, female, minimum score for odor at Baseline	

Hygiene - Performance Testing

Benefits:

- Option for more objective measures

Considerations:

- Standardisation of test panel
- Minimise embarrassment for test subjects

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Grooming Products

Grooming

- Growth of the global female depilatory market:
  - Product innovation and line extension by leading brands
  - Consumer emphasis on personal grooming and hygiene
  - Increased demand for do-it-yourself (DIY) hair removal methods
  - More working women leveraging demand for personal grooming

Grooming

- Hair removal:
  Creams
  Razors
  Clippers
  Epilators
  Waxes
  Sugaring
  Intense Pulsed Light (IPL)

- Preparation & After care:
  Exfoliants
  Balms
  Moisturisers

Grooming - Safety Testing

- “Pubic hair removal is a cause of injury — over 50% of women who have removed pubic hair report at least one complication such as lacerations, burns, rashes, and infections,"
  Gynecologist Dr. Jen Gunter - "The Vagina Bible”

Study designs
- Monadic
- Most feature in-use exposures
  - Single use, Repeat use & Exaggerated use

Endpoints can vary, depending on product type
- Erythema/dryness
- Subjective tolerance
- Nicks/cuts, skin stripping
- Ingrown hairs

Grooming - Safety Testing
Example Test Design

Aim	Determine the safety of a new razor concept
Parameters	P1: Tolerance [Gynaecologist/Dermatologist] P2: Nicks/Cuts [Gynaecologist/Dermatologist] P3: Subjective Assessment of Tolerance [Subjects] P4: In-grown hair counts [Gyn/Dermatologist]
Test Procedure	Day -7: Start run-in phase Day 1: First product use, P1, P2, P3 Use of products by subjects at home, Day 22: P1, P2, P3, P4, return of products
Panel	30 subjects per treatment/group, female, experienced with product type

Grooming – Performance Testing

- Study designs
  Focus on in-use exposures
  Can feature within-subject comparisons
  Single use &/or Repeat use

- Endpoints
  Can vary, depending on product type
  - Imaging
  - Expert &/or Automated Image Analysis
    - Hair counts
    - Hair diameter
    - Hair regrowth

Considerations:
Standardisation of test panel/hair growth






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Sexual Health & Wellbeing Products

Sexual Health & Wellbeing

- The sexual wellness market is currently valued at over $30 billion dollars.
  - Condoms
  - Lubricants
  - Adult Toys
  - Vaginal Rejuvination

Sexual Health & Wellbeing - Safety

- Safety Tests
  Can be controlled/supervised use, unsupervised solo use or couples
  Tests should be conducted with a step wise approach, to manage risk
  - Typically acute tolerance followed by in-use situation

- Integrity Trials
  Always focused on the in-use experience (i.e. intended use)
  - Breakage
  - Slippage

Sexual Health & Wellbeing - Safety

- Example Test Design

Aim	Determine the in-use tolerance of a personal lubricant product	
Parameters	P1:	The Vaginal Health Index (VHI) [Gynaecologist]
	P2:	Examination of Tolerance [Gynaecologist]
	P3:	Subjective Assessment of Tolerance [Subjects]
Test Procedure	Day 1:	P1, P2, P3, distribution of products
		Application of products by subjects at home, up to Day 28:
	Day 29:	P1, P2, P3, return of products
Panel	40 subjects per treatment/group, female, at least 18 years old	

Sexual Health & Wellbeing - Performance

- Performance Tests

  Designs:
  - In-use experience, typically requires couples
  - Monadic or crossover (with suitable standardization in-between treatments)

  Endpoints/Measures:
  - Subjective Self-perception

Sexual Health & Wellbeing – Performance

- The Female Sexual Function Index (FSFI)
  Measuring desire, arousal, lubrication, orgasm, satisfaction and pain

- The Female Sexual Distress Scale -Revised (FSDS-R; revised 2005)
  Measuring Sexually Related Personal Distress in Women With Female Sexual Dysfunction (FSD)

- Millheiser Vaginal Laxity Scale
  7-point scale from Very Loose to Very Tight

- Millheiser Sexual Satisfaction Scale
  6-point scale from None to Excellent

Sexual & Sexual Wellbeing - Performance

- Safety, Integrity, Efficacy

Benefits:
- Actual consumer experience

Considerations:
- Panel selection:
  - Sexually active
  - Relationship status?
- Compliance:
  - Willing to use the product – as & when directed
  - What about partners??

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Menstrual Products

Menstrual products

- Pads (Disposable)
- Cloth Pads (Reusable)
- Tampons
- Menstrual Cups
- Panties/Period underwear

How do they compare for the consumer?

	Advantage	Disadvantage
Disposable Pads 	Convenience Affordable	Environment Monthly expense
Reusable Pads/Panties 	No tension of buying monthly supply Environment	Expensive o buy a set Hard to change Difficult to use – wash and reuse
Menstrual Cups 	Using while swimming Environment	Difficult to use for beginners (insertion and emptying) Fear of leakage Risk of Toxic Shock Syndrom
Tampons 	Using while swimming Convenience	Risk of Toxic Shock Syndrom Fear of Loosing Virginity (some cultures)

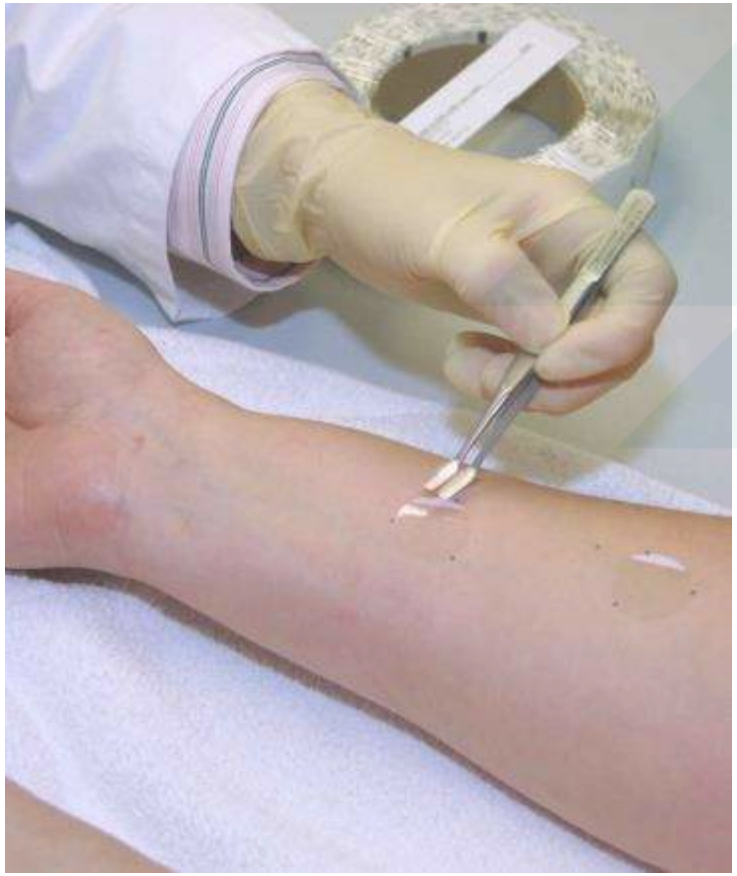
Menstrual product standard

- Physical parameters, packaging and marking of the product
- Performance parameters
- Safety parameters
- Methods of demonstration

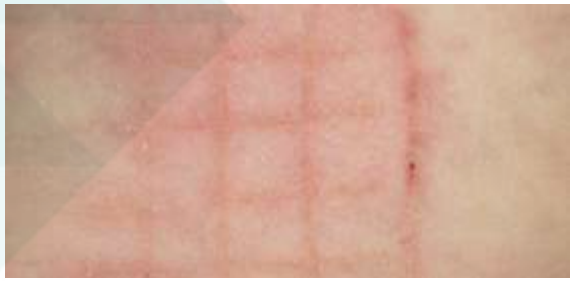
Epicutaneous Patch Test for Tolerability

- Up to 55 subjects
- Application
  Back, negative and positive control
  occlusive/semi-occlusive, wet and dry!
  1 x 24 h or 3 x 24 h
- Products
  Rinse-off, textiles (1 x 24 h)
  Leave-on, skin-care (3 x 24 h)
- Evaluation
  Visual; primary skin irritation
  15 min, 24 h, 48 h after patch removal

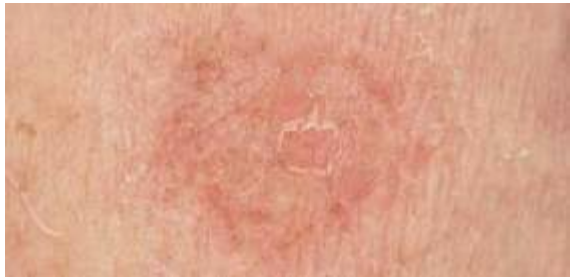
Epicutaneous Patch Test After Skin Challenge or Predamage (Stripping, SDS, Scratching etc.)



No visible skin reaction



Moderate erythema



Strong erythema

EDANA Guidelines for Testing Feminine Hygiene Products

Version 13th December 2018

Edana Code of Practice for tampons placed on the European market

Version 3: September 2020

Tampon manufacturers in Europe have organized themselves within the Absorbent Hygiene Products Working Group of EDANA, the voice of the nonwovens and related industries in order to coordinate the activities of the tampons manufacturing industry in areas of mutual interest. Member companies represent the dominant share of the production of tampons in the European Union.

This code of practice has been coordinated by Edana and has been in use since 1999. It may be used by any producer or distributor of tampons, and is also made available to national authorities. Please note there is a separate code of practice for the UK which can be found at http://www.ahpma.co.uk/tampon_code_of_practice/

Some Things to Consider for User Trials/Performance Tests according to EDANA

- Inclusion of 100 healthy females of menstruating age, good representation of the population relevant to the test market and USERS.
- In case various products are being tested for comparison, the panels should be similar in terms of age profile and they should use products similar in size, brand and type.
- monadic or sequential monadic test design and ensure that the same product is continuously tested during one menstrual period for tampons and sanitary napkins.
- Duration: 3 - 7 days taking typical habits and practices into account along with other relevant parameters, such as country, size/dimension, absorption and type of product (for example day/night use).
- It is recommended that users test only one type of product at a time during the menstrual period. The number of products tested should reflect the user habits on the market in scope of the test.
- Questionnaires used should be based on a mix of statements that will not create any bias for the consumer, with a consistent scale
- Recommendation to keep a diary.

Example Questionnaire

Product questions
Strongly recommended:
1. How would you rate the product overall (excellent-very good-good-fair-poor)?
2. Comments: What did you like about this product? (open question)
3. Comments: What did you not like about this product? (open question)
4. How would you rate the leakage protection of this product (excellent-very good-good-fair-poor)? EXTERNAL
5. How would you rate the absorbency of this product (excellent-very good-good-fair-poor)? INTERNAL
6. How would you rate the product in contact with your skin (excellent-very good-good-fair-poor)?
7. How would you rate overall comfort (excellent-very good-good-fair-poor)?
8. How would you rate the product's ability to help control odours (excellent-very good-good-fair-poor)?
9. Do you have any additional comments about the product?

Other parameters that could be rated, e.g. through follow-up questions, may include:
- Appearance
- Dry feeling
- Softness
- 'Bunching'
- Flexibility
- Information about use
- Day vs night use
- Ability to stay in place
- Ease of application
- Ease of removal
- Size / dimension
- Shape
- Does the adhesive strip leave any residues in garments?
- Packaging
- Disposal

EU Ecolabel criteria for Absorbent Hygiene products

L 320/46 EN Official Journal of the European Union 6.11.2014

COMMISSION DECISION

of 24 October 2014

establishing the ecological criteria for the award of the EU Ecolabel for absorbent hygiene products

(notified under document C(2014) 7735)

(Text with EEA relevance)

(2014/763/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (1), and in particular Article 8(2) thereof,

Characteristics and parameters describing the fitness for use of the product to be tested

Characteristic		Testing practice required (performance threshold)			
		Baby diapers	Feminine care pads	Tampons	Nursing pads
In-use tests	U1. Absorption and leakage protection (*)	Consumer panel test (Leakage occurs in less than 5 % of the product uses)			
	U2. Skin dryness	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)		Not applicable	As for baby diapers
	U3. Fit and comfort	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
	U4. Overall performance	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)			
Technical tests	T1. Absorption and leakage protection	Absorption rate and absorption before leakage		Syngina method	No method recommended
	T2. Skin dryness	TEWL, rewet method or corneometric testing		Not applicable	No method recommended

(*) Panty liners without a core intended to protect the feminine lingerie (light panty liners) are derogated from this requirement.

EU Ecolabel
www.ecolabel.eu

https://ec.europa.eu/environment/ecolabel/products-groups-and-criteria.html

Example Study

Subjects: 30 healthy subjects, User of the product to be tested

Duration: 3-7 days

Area: Genital region

Test Products: Product, reference (option)

Evaluations:

- Questionnaire
  - Skin Dryness, Fit and Comfort
  - Absorption and Leakage Protection
  - Overall Performance

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Incontinence

Example Wear Study

Subjects: 30 female or male volunteers, with >5 urine leakage events/week

Duration: 15 days

Area: Genital area

Test Products: Product, placebo

Evaluations: Days 1 and 15
Recording of underwear wear time
Recording of underwear weight
Daily diary
Visual assessments
TEWL measures
Questionnaire

Example Multicenter Study – Nursery Homes

Subjects: 30 -50 volunteers, aged up to 90 years old, urine incontinent and occasionally double incontinent living in elderly homes

Duration: 4 weeks

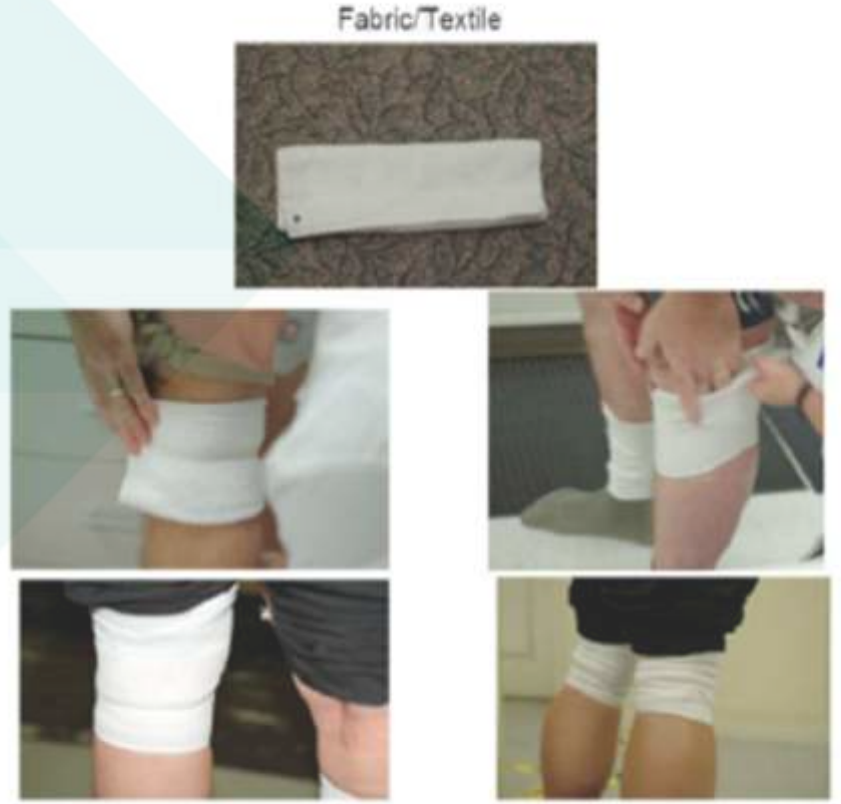
Area: Genital area

Test Products: Product

Evaluations: Skin assessments by nursing staff / doctor / continence nurse
Recording change and of wear time
Questionnaire

ASTM – Standard Behind the Knee Test

Aim	Evaluation of dry products for mechanical and chemical irritation potential in the area behind the knee, under intact skin conditions, after 6 or optional 23.5 hours wear time per day for 4 days.
Parameters	Evaluation of primary skin irritation
Test Product	1 test product and control product
Test Area	Behind the knees
Test Procedure	
Day 1-4:	Application of products under occlusive conditions
	Patch removal by subjects 6 or 23.5 hours after application,
Day 5:	Evaluation 24 hours after last application
Panel	23 subjects, aged 18 years or older



e placed horizontally at the behind-the-knee test site, and held in place by an elastic knee ba

FIG. X6.1 Test Sample Application in the BTK Test (Ref 5)

1 to 5 x 6h Patch Test as an in vivo Model for IAD

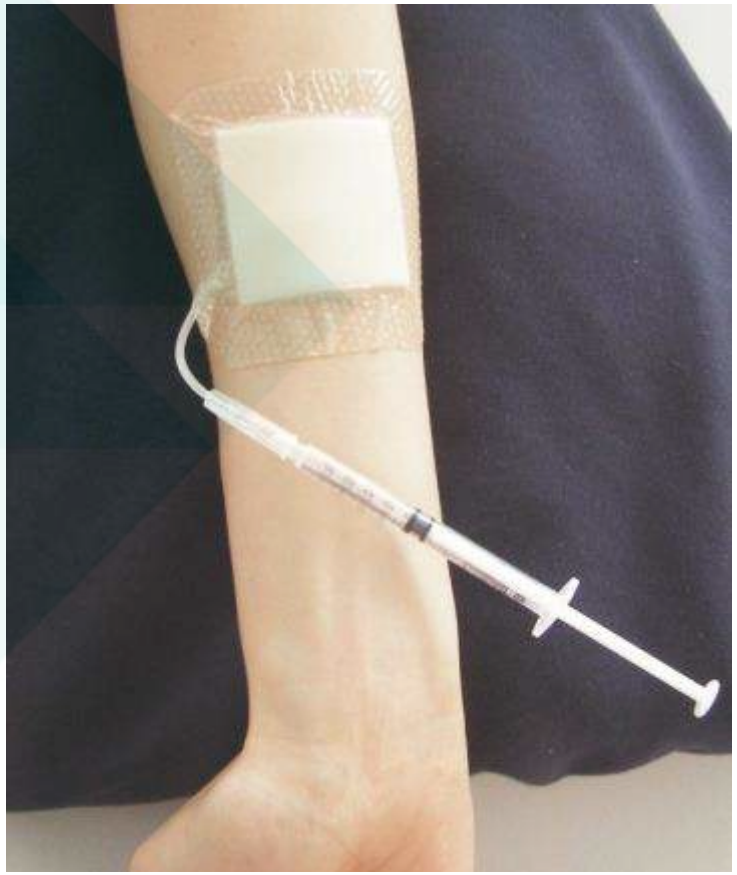
Aim	Lowered irritation potential of incontinence products after occlusive application in with a provocation substance according to the Model by Larner et. al. 2014; 'Development of a cumulative irritation model for incontinence-associated dermatitis'.
Parameters	P1: Dermatological assessment of primary skin irritation P2: Measurement of skin redness[Spectrophotometer] P3: Measurement of skin barrier [Tewameter]
Test Product	Incontinence products and controls (with provocation substance)
Test Area	Forearms; 4 or 6 test areas
Test Procedure	Day 1: Acclimation, P2, P3, application of products with provocation substance and controls over 6h, 1h after patch removal P1, P2, P3 Option Day 2-5: Acclimation, P2, P3, application of products with provocation substance and controls over 6h, 1h after patch removal P1, P2, P3 Day 2/8: Acclimation, P1, P2, P3
Panel	30 subjects, aged between 18 and 70 years (female/male)

Assessment of Skin Dryness or Wetness of Skin

Aim	To determine skin dryness as measured by SSWL (Skin Surface Water Loss) after exposure to an absorbent incontinence product
Parameter	Skin Surface water loss SSWL [g/m²h]
Test Product	up to 5 different incontinence product
Test Areas	Volar Forearms, 2 test areas
Test Procedure	Testing Session 1: Acclimatization for 30 min, baseline SSWL, product application and loading, after defined wearing time SSWL Testing Session 2, 3: same
Panel	25 subjects, aged 18 years or older (f/m)

Maceration Model

- Study over a period of several days on the forearms of subjects
- Application of incontince products or parts and soaking with snthetic urine
- Determination of water loss and measurement of stratum corneum (swelling and skin barrier)



Odor Testing with Expert Odor Judges

- Odor intensity on a scale with 6 sniffers
- For fraganced products malodor intensity and fragance intensity/masking efficacy can be tested in parallel
- Direct sniffing
- Sampling or synthetic urine
- Training according to DIN EN 13725

- Or hedonic evaluation of the odor with 15 panelists

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Postmenopausal Care

Genitourinary syndrome of menopause (GSM)

Table 1. Clinical features of genitourinary syndrome of menopause (adapted from 5–7).

	Genital	Sexual	Urinary
Symptoms	• Vaginal dryness (most common & troublesome) • Itching/burning/irritation • Vaginal/pelvic pain and pressure	• Dyspareunia • Reduced lubrication • Loss of libido/arousal • Post-coital bleeding	• Dysuria • Urgency • Stress/urgency incontinence • Urinary tract infections • Urinary frequency/nocturia
Signs	• Labial atrophy • Decreased moisture • Loss of vaginal rugae • Vaginal pallor • Decreased elasticity • Higher vaginal pH level • Leukorrhea • Introital stenosis • Pelvic organ prolapse • Thinning/greying pubic hair		• Urethral prolapse/caruncle • Ischaemia of vesical trigone • Meatal stenosis

Modern management of genitourinary syndrome of menopause, da Silva et al. Faculty Reviews 2021

Considerations in GSM or VVA Trials depending on the Test Product

- In case of Estrogen
  - Inclusion/exclusion criteria related to potential risk of deep vein thrombosis, such as exclusions for a history of thromboembolic or cardiovascular disease
  - Performing screening mammograms
  - Consideration of an endometrial biopsy or transvaginal ultrasound

- Inclusion/exclusion criteria for BMI and hypertension
- Inclusion/exclusion criteria based on the Vaginal Health Index assessment (% of superficial cells) and vaginal pH
- Inclusion/exclusion criteria based Vaginal Maturation Index (VMI)

- Inclusion/exclusion criteria for severity scores for dyspareunia or urinary incontinence

Example Study with Focus on VVA

Subjects: 30 post-menopausal women with subjective symptoms of "vulvovaginal atrophy“ and additional inclusion criteria such as defined VMI

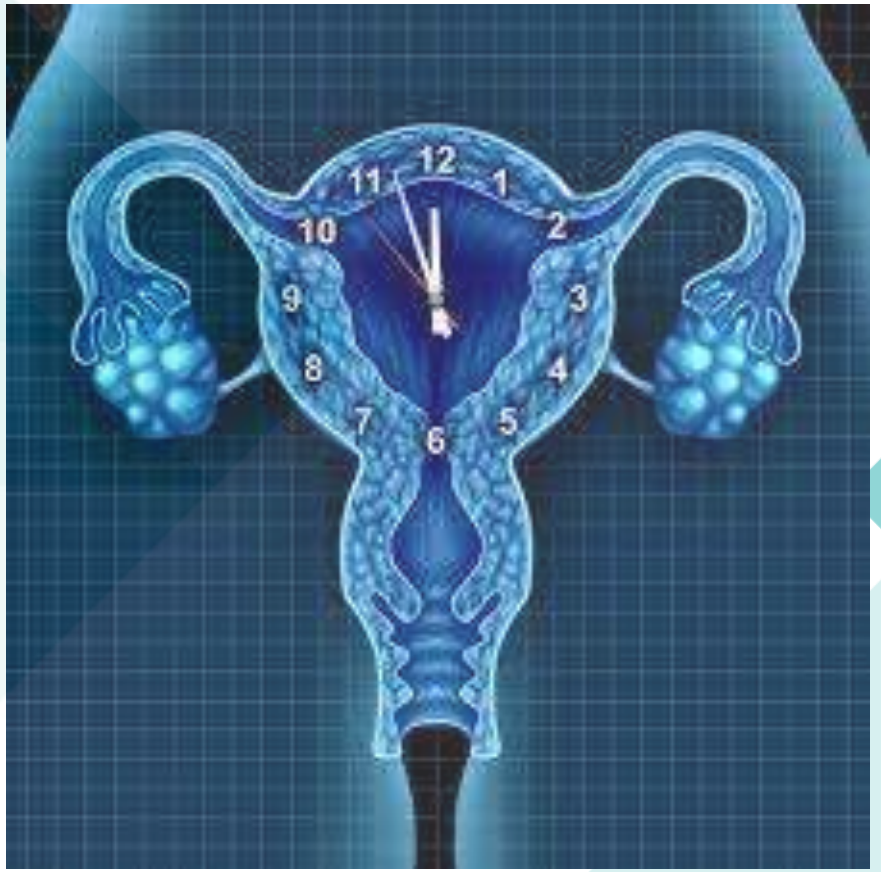
Duration: 29 to 85 days

Area: Vagina

Test Products: Product, placebo

Typical Evaluations:

- Tolerance
- Pelvic exam by OB/GYN
- Vaginal pH
- Microflora such as Lactobacillus
- Vaginal Health Index (VHI)
- Vaginal Laxity and Female Sexual Function Index
- Vulvovaginal symptom questionnaire (VSQ)
- Vaginal Maturation Index (VMI)
- Dyspareunia
- DIVA (Day to Day Impact of Vaginal Aging)
- Digital photography (external treatment area)
- PRO (Patient Reported Outcome)
- QoL



Summary/Conclusion

- In EU feminine hygiene products fall under different regulations:
  - Medicinal Products
  - Medical Devices
  - Cosmetics
  - General Products

- Intimate Hygiene
- Grooming
- Sexual Health & Sexual Wellbeing

- Menstrual products
- Incontinence
- Post-menopausal Care

Thank you for your attention!

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Web: https://www.proderm.de/en/
LinkedIn: https://www.linkedin.com/company/proderm/
Contact: gspringmann@proderm.de
sgrundy@proderm.de