

This is an unofficial translation. Only the German version is binding.

Guidelines for the Evaluation of Personal Sanitary Products¹

Personal sanitary products are commodities in the sense of § 2, Para. 6, No. 6 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch (LFGB)). They include sanitary towels, pant liners, tampons, nappy pants and nappy liners and have the purpose of absorbing bodily excretions.

These commodities must be suitable for their intended purpose and, in compliance with § 30 of the LFGB, must not be manufactured or treated in such a way that their intended or predictable use could be harmful to human health. On the basis of responsible manufacturing practices and the duty of care, manufacturers and those responsible for bringing commodities onto the market take full responsibility for ensuring that they are not harmful to human health.

In compliance with the Commodities Regulation (Bedarfsgegenständeverordnung), azo dyes that through cleavage of one or more azo groups may produce one of the amines listed in Annex 1, No. 7 (§ 3) of this Regulation must not be used.

The BfR has drawn up a list of the materials currently used in the manufacture of personal sanitary products and worked out a number of criteria, which reflect current scientific and technological developments, in the interests of precautionary consumer protection. These criteria can be used to evaluate the corresponding products. However, the components of personal sanitary products have not been individually tested and evaluated by the BfR.

These guidelines are not applicable to pre-moistened personal sanitary products.²

Materials used in the manufacture of personal sanitary products

Sanitary towels and pant liners:

Component	Material
Silicone paper	siliconised paper
Adhesive/hotmelt	thermoplastic rubber, resins, waxes, oils
Cellulose flock	cellulose, lignin
Absorbent	polyacrylate
Protective outer film	polyethylene, polypropylene
non-woven covering	polyethylene, polypropylene, polyester, softening agents/plasticizers, fiber finishing
Tissue layer	cellulose
Other possible components	colorant, binder, perfumed oils

¹ Bundesgesundheitsbl. **39** (1996) 124

² The impregnating liquids used in the manufacture of these products are subject to the Cosmetics Regulation (Kosmetik-Verordnung). The impregnated materials must comply with Recommendation XXXVI "Paper and paper-board (including cardboard) as food-contact materials".

Nappy pants and nappy liners:

Components	Materials
Non-woven	polypropylene, viscose, polyethylene, polyester, softening agents/plasticizers, fiber finishing
Tissue	cellulose, wood pulp
Cellulose flock	cellulose, wood pulp
Absorbent	polyacrylate
Elastic band	cotton, polyurethane, polyethylene, polyester, rubber
Protective outer film	polyethylene
Comfort band	polypropylene, polyethylene
Adhesive	thermoplastic rubber, resins, waxes, oils
Other possible components	colorant

Tampons:

Components	Materials
Absorbent	cotton and/or rayon staple
Removal string	cotton, polyester (water repellent)
Non-woven covering	polyester, polyethylene, polypropylene, viscose staple fibre; if necessary, binder
Other possible components	colorant

Criteria

Cellulose and wood pulp, as well as plastics and colorants, should comply with the corresponding requirements for food-contact commodities.

The content of residual monomeric acrylic acid in the polyacrylate from which the absorbent of sanitary towels, pant liners, nappy pants and nappy liners is made is generally 300 ppm, which corresponds with what is currently technically possible.

Fiber finishing used in the non-woven covering of sanitary towels and pant liners should comply with the requirements of the United States FDA Code of Federal Regulations, Title 21, §§ 176.210, 176.170, 177.2800, 177.1850, 177.1520.³

The following classes of substances are used: ethoxylated castor oil, fatty alcohols, fatty acid polyglycol ester, fatty alcohol polyglycol ether, glycerol and castor oil.

Any perfumed oils that are used should comply with the Code of Practice of the International Fragrance Association (IFRA-Codex).⁴

The manufacturers of menstrual tampons should provide instructions about avoiding toxic shock syndrome.

³ Source: Superintendent of Documents, Attn: New Orders, P.O.Box 371954, Pittsburgh, PA 15250-7954, USA

⁴ Source: Vereinigung Deutscher Riechstoffhersteller e.V., Meckenheimer Allee 87, 53115 Bonn

The rayon staple and cotton used in the manufacture of tampons should comply with the purity requirements of the European Pharmacopoeia for non-sterile sanitary cotton made from cotton and viscose.