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Safety assessment of sanitary pads with a polymeric foam absorbent core

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ABSTRACT

Sanitary pads for menstrual hygiene have a layered design consisting of a fluid permeable surface (topsheet), an absorbent core, and an impermeable backing with adhesive. Most sanitary pads employ cellulose-based cores. This describes the safety evaluation of a menstrual pad with an emollient-treated topsheet and a novel polymeric foam core. A quantitative risk assessment was performed, which included: (1) toxicological evaluation of the raw material components; (2) quantitative exposure assessments of pad constituents, accounting for the fluid handling properties of the product and pertinent conditions of use; and (3) risk characterization for exposure to raw materials (e.g., potential for skin irritation, contact sensitization, or systemic effects, if relevant) and to the physical article itself (potential effects on skin friction, etc.). No significant risk of adverse effects was found. Five years of post-market surveillance substantiates that the product is well-tolerated (1 health complaint reported per 2 million products shipped to market) and surpasses women's expectations for menstrual protection and overall comfort and dryness. This report illustrates how the classical risk assessment paradigm, informed by the impact of product design, functionality and pertinent use conditions, allowed the systematic safety evaluation of a personal hygiene product with a novel, non-cellulosic absorbent foam core technology.

1. Introduction

Millions of women worldwide rely on disposable menstrual pads and panty liners for feminine hygiene protection. Invented in 1896, disposable sanitary pads were first successfully commercialized in the United States in 1921. Most sanitary pads employ the same basic design: a cellulose-based absorbent core placed between a fluid permeable surface (topsheet) and a moisture-impermeable backing (backsheet). Innovation was slow to this product category: the 1970s brought the first substantive improvement, adding a panty-fastening adhesive to the backing to replace traditional pins and belts. Over the next 25 years, significant innovations included apertured film topsheets to keep the surface of the pad cleaner and drier; wrap-around, side panty-shields ("wings") to reduce undergarment soiling; cellulosic cores with superabsorbent gel particles for better protection in substantially thinner pads; and the use of cloth-like perforated topsheets for improved comfort and dryness. This article describes the safety assessment process for our most significant product innovation in the category to date, the introduction of a thin, non-cellulosic, absorbent foam core. The safety assessment process comprised an exposure-based quantitative risk assessment on all product components; analytical testing for residual monomers; and clinical testing on components and/or the final product to confirm skin compatibility. Post-market surveillance of global consumer experience further substantiates product safety in the marketplace. This article illustrates how the risk assessment paradigm enabled the rigorous safety evaluation of a menstrual pad with a novel absorbent material that represents a significant departure from traditional cellulose fiber cores. Other safety evaluations (environmental assessment, worker safety assessment) were followed but not discussed here.

2. Regulatory framework

Regulatory classification of sanitary (menstrual) pads varies globally. Some countries have stringent criteria; others subject this product class to broadly applicable consumer product regulations.

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The United States Food and Drug Administration (FDA) regulates sanitary pads as Class I medical device subject to manufacturing controls and consumer complaint management. In Japan, sanitary pads fall under the purview of the Pharmaceutical and Medical Devices Agency. In the European Union and in Canada, sanitary pads they are considered articles and are regulated as consumer products. Although the specifics may vary among jurisdictions, a human health risk assessment of new products and chemicals is a fundamental expectation in all geographies that have regulatory frameworks (Section 4 below).

3. Sanitary pad composition

The sanitary pad in this investigation has a conventional layered design: a fluid permeable surface (topsheet), an absorbent core, and impermeable backing with adhesive (backsheet). Product component composition is detailed in Table 1. In brief, the topsheet is a polyethylene/polypropylene non-woven fabric bearing an emollient finish; the core comprises a two-layer, low density, open-celled, polyacrylate polymer foam; and the backsheet consists of an impermeable pigmented polyethylene film with a panty-fastening adhesive. Scented versions of the pad contain a small amount of perfume applied between the backsheet and the undersurface of the core.

4. The safety assurance process

Scientific committees (NAS, 1983; SCCS, 2010), regulatory agencies (ECHA, 2013; EPA, 2012; Gaylor et al., 1997) and other authoritative bodies (WHO, 2010) promulgate a tiered risk assessment approach to assessing chemical safety. The exposure-based quantitative risk assessment (QRA) has four components:

- Hazard identification (identifying the nature of potential adverse effects based on the toxicological characteristics of the chemicals or materials in question),
- Exposure characterization (quantifying the exposure to substances of toxicological interest for pertinent routes by determining the magnitude, duration and frequency of exposure under relevant conditions of consumer use),
- Risk characterization (comparing these quantitative estimates to safe benchmarks for which no significant risk of adverse health effects exists, incorporating a margin of safety [uncertainty factor] where needed to extrapolate from experimental conditions to those that occur in use), and
- Risk management (implementing approaches to further mitigate the possibility of adverse effects in the marketplace, e.g., post-market surveillance, product usage instructions, cautionary labels, quality manufacturing expectations, etc.).

This fundamental model has been applied to the human safety assessment of a variety of personal products, including absorbent products such as infant diapers (Kosemund et al., 2009) and sanitary pads (Farage et al., 2004; Farage, 2006) as well as skin care products and fragrances (Api et al., 2015; Bickers et al., 2003). For each of these product categories, the risk assessment approach is iterative, has been refined to account for usage conditions relevant to the product category in question and, when the product is an article, to include toxicological, physical and other relevant additional endpoints associated with exposure to the physical article itself.

As the sanitary pad in this investigation is a physical article, individual product components as well as the finished product were evaluated. An exposure-based QRA was performed on product components; this was supplemented by analytical and clinical testing to confirm the safety of potential residual monomers and skin compatibility of the pad components as well as the finished product itself.

4.1. Hazard identification

The most relevant toxicological end-points for this product category are acute, cumulative and mechanical skin irritation, the induction of delayed contact hypersensitivity (contact sensitization), and the potential for acute or subchronic effects from the raw material components or residual chemicals, should it be possible for toxicologically-significant systemic exposures to occur.

4.2. Exposure assessment

Due to the layered pad design, three degrees of exposure exist to its components: (1) direct skin contact (topsheet and emollient); (2) indirect skin contact (absorbent core and perfume); and (3) negligible skin contact (pigmented backsheet and adhesive) (Fig. 1).

4.2.1. Materials with direct skin contact

The non-woven polymeric topsheet and the emollient continually contact the skin, but only a fraction of the material will transfer during use. In simulation studies, emollient transfer to the skin was found to be <20% (Farage, 2010). This 20% value is adopted as a conservative estimate of the maximum proportion of applied emollient that will transfer to the body. It is also used to conservatively estimate maximum skin transfer of low molecular weight topsheet ingredients or low level residuals that are intended to remain on the pad, but may transfer during use and therefore warrant conservative assessment.

4.2.2. Materials with indirect skin contact

Materials below the topsheet (the absorbent polymeric foam core and the perfume, if pertinent) exhibit indirect skin contact. Transfer of non-polymeric subsurface constituents requires a vehicle (urine, menses). For dermal exposure to occur, low molecular weight constituents of the raw materials must first be solubilized in the vehicle then released from the pad to the skin under

Table 1
Composition of a sanitary pad with emollient-treated topsheet and absorbent foam core.

Component	Function	Raw material composition
Topsheet	Fluid permeable surface cover that is soft to the skin and allows fluid to penetrate	Perforated non-woven fabric of polypropylene/polyethylene fibers
Emollient	Potential comfort and skin moisturizing benefits	Petrolatum based formulation
Absorbent core	Absorb and capture fluids	Polymeric open-celled foam
Perfume	Scent	Fragrance raw materials
Backsheet (printed)	Moisture impermeable barrier	Low density polyethylene film with pigments
Adhesive	Fasten pad to the undergarment	Polyaromatic/polyolefinic block copolymers, hydrocarbon resins, mineral oil