Safety assessment of sanitary pads with a polymeric foam absorbent core

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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 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.

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.
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 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

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

pressure, a phenomenon known as rewet or reflux. Based on laboratory analyses with simulated urine and menses, estimated reflux values are <5% of fluid loadings (proprietary data). This value is used as a highly conservative estimate of exposure to subsurface constituents by assuming their total mass is solubilized in the vehicle.

4.2.3. Materials with negligible skin contact
Constituents of the backsheet and the adhesive have no or negligible skin contact and no exposure through rewet. Data from historical experience, product integrity standards and analytical leachability evaluation support the assumption for no or negligible skin exposure to these materials.

4.2.4. Quantitative exposure assessment
Parameters used in the quantitative exposure assessment are based on the above assumptions and an understanding of menstrual habits and practices (Table 2). Systemic exposures are estimated on a body weight basis; the critical exposure for evaluating skin sensitization risk is the dose per unit area of skin exposed (Robinson et al., 2000). Quantitative exposures are estimated as follows:

Systemic exposure ($\mu kg/kg/d$) = Raw material mass in pad (g) × constituent concentration in the raw material (%) × frequency of use (pads/d) × exposure duration (100%) × transfer to skin (%) × conversion to $\mu g$ ($10^6 \mu g/g$) × dermal absorption (%) / body weight (kg)

Dermal exposure ($\mu g/cm^2/d$) = Raw material mass in pad (g) × constituent concentration in the raw material (%) × frequency of use (pads/d) × exposure duration (100%) × transfer to skin (%) × conversion to $\mu g$ ($10^6 \mu g/g$) × dermal absorption (%) / exposed skin surface area (cm²)

4.3. Risk characterization

4.3.1. Materials with direct skin contact — topsheet and emollient
The polypropylene/polyethylene topsheet is similar to other nonwoven topsheets used in commercial sanitary pads with a long history of safe use. The fabric allows fluid to penetrate and become trapped by the core. Due to its high molecular weight and negligible residuals, no systemic toxicity concerns exist for the topsheet.

The petrolatum-based emollient is composed of highly-refined components approved by various authoritative bodies for leave-on

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**Table 2** Parameters used in the quantitative exposure assessment of sanitary pad components.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values and units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw material mass</td>
<td>– g/pad</td>
</tr>
<tr>
<td>Concentration of a constituent in the raw material</td>
<td>– % (i.e., g constituent/100 g pad)</td>
</tr>
<tr>
<td>Frequency of use</td>
<td>5 pads/day</td>
</tr>
<tr>
<td>Transfer to skin</td>
<td>20% of surface-applied components (estimate for material with direct skin contact)*</td>
</tr>
<tr>
<td>Fluid transfer to skin from internal pad layers (known as rewet or reflux)</td>
<td>5% of absorbed fluid (estimate for materials with indirect skin contact)**</td>
</tr>
<tr>
<td>Dermal absorption</td>
<td>100% (unless dermal penetration data are available)</td>
</tr>
<tr>
<td>Exposure duration</td>
<td>100%</td>
</tr>
<tr>
<td>Body weight (female)</td>
<td>50 kg</td>
</tr>
<tr>
<td>Pad or component surface area</td>
<td>– cm²</td>
</tr>
</tbody>
</table>

* Assumes 100% of residual constituents in topsheet fabric transfer to the same degree (worst-case).

** Assumes 100% residual constituents in inner layers of pad are solubilized in absorbed fluid and transferred to skin through rewet.
skin care products (CFR, 2014a; CIR, 2015; EU, 2004) some of these constituents also are generally recognized as safe for human consumption (CFR, 2014b). The emollient ingredients have been in use at comparable or higher levels in commercial cosmetic and personal care products sold worldwide. A substantial margin of safety exists compared to the established safe benchmarks (No Observable Effect Levels) for emollient constituents (proprietary data). No ingredients have been associated with systemic effects such as mutagenicity, teratogenicity or carcinogenicity. A confirmatory human repeated insult patch test (HRRIPT, Shelanski method, described in Farage et al., 2008; Gerberick et al., 1998; and Marzulli et al., 2004) was performed on sections of topsheet bearing emollient in subjects who perceived their skin to be sensitive. No discernible skin erythema and no evidence for the induction of delayed contact hypersensitivity were observed (Farage et al., 2008).

4.3.2. Materials with indirect skin contact – absorbent foam core and perfume

The absorbent foam core is a stable, high-molecular weight polyacrylate polymer with small amounts of emulsifiers and wetting agents. The polymeric foam itself is biologically inert and non-bioavailable due to its high molecular weight, therefore posing no systemic toxicological concern. Analysis of residual monomers using aggressive extraction solvents (cyclohexane) revealed levels of <200 ppm depending on the monomer in question, but undetectable levels (<4–7 ppm) with solvents that mimic in-use conditions (artificial menses, physiologic saline, and 95% saline/5% ethanol). Based on the QRA, no significant risk of systemic effects exists from worst-case hypothetical exposure to extractable residuals in the foam (unpublished data).

Non-clinical studies for the purpose of regulatory registration requirements were performed to conservatively assess the irritation and sensitization potential of the foam core extracts. Extracts (95% saline/5% ethanol) showed no evidence of cytotoxic effects in L929 cells (all scores 0) and no evidence of vaginal irritation in rabbits (i.e., no difference between naïve, sham, vehicle or treatment groups) (Table 3). No evidence of contact sensitization was observed in the mouse local lymph node assay (LLNA) (Table 3).

Clinical studies on the foam core included a 21-day cumulative irritation patch test as well as an HRRIPT. Study methods (for these and subsequent irritation and sensitization studies) were standard predictive irritation patch tests and Shelanski –type HRRIPT methods, as described in Berger et al. (1982), Levin et al. (2004), Marzulli et al. (2004), and Gerberick et al. (1998). Study methods and results are summarized in Table 4. After 21 consecutive days of exposure, the absorbent foam produced directionally (but not statistically) higher overall mean erythema scores than the non-irritant control (physiologic saline) (1.22 vs. 0.97, respectively, on a 0–4 scale, where a score of 0 denotes no apparent cutaneous involvement and a score of 1 denotes either faint but definite erythema or no erythema but faint dryness) (Farage et al., 2008). In the HRRIPT, the absorbent foam showed no evidence of irritation and no evidence of contact sensitization (all scores zero through induction and challenge phases) (Farage et al., 2008).

The perfume used in scented versions complies with the International Fragrance Association (IFRA) safety standards for usage limits, which are based on risk assessments by expert panels of the Research Institute for Fragrance Materials (RIFM) (Api and Vey, 2008; Api et al., 2015; Bickers et al., 2003). All components of the perfume are present at concentrations below the maximum limits set by IFRA. An exposure-based risk assessment for contact sensitization (Api et al., 2008; Gerberick et al., 2001) from perfume in the sanitary pad concluded that was sufficient margin of safety (1–500) with respect to established sensitization benchmark doses.

4.3.3. Materials with negligible skin contact – backsheet and adhesive

Polyethylene film, a high molecular weight polymer widely used in flexible packaging, is not absorbed dermally. These films and associated pigments (resin-embedded or printed) have been used extensively in personal hygiene products for many decades. The panty-fastening adhesives are composed of high molecular weight, polyaromatic-polyolefin copolymers, hydrocarbon resins, and low levels of antioxidants. Exposures to these components are virtually nil and thus toxicologically insignificant.

4.3.4. Clinical studies on the sanitary pad

Cumulative irritation to the pad itself was assessed in 4-day patch tests in subjects with normal skin (n = 17) or self-declared sensitive skin (n = 15) and found to be comparable to the non-irritant (saline)
control in both populations. No irritation was observed in a 5-day patch test in groups with normal skin. When sanitary pad samples with and without the emollient were evaluated in a 21-day cumulative irritation patch test, mean erythema scores associated with the emollient-treated pad were statistically lower than (and scores with the untreated pad were comparable to) those associated with the non-irritant control (Farage et al., 2008) (Table 4).

The combination of chemical and mechanical (frictional) irritation was examined in a Behind-the-knee (BTK) test (ASTM, 2010; Farage, 2008). In brief, the test pad and a reference commercial pad with a history of safe use each were applied (with the topsheet against the skin) to the popliteal fossa of one leg under an elastic bandage for 6 h per day for 4 consecutive days. Skin irritation and dryness were scored each day before application and 30–60 min after removal of the product. Two studies were performed. The test pad with foam core and emollient-treated topsheet exhibited either comparable or directionally lower scores for erythema and dryness than the reference product (Farage et al., 2008, 2009).

Finally, to further substantiate the absence of contact sensitization risk from the sanitary pad with perfume, an HRIPT was performed on a scented version of the product (Table 4). No evidence of contact sensitization was observed, further confirming the skin compatibility of the scented pad.

5. Post-market surveillance

Manufacturers employ post-market surveillance to monitor consumers’ experience and satisfaction, to further substantiate safe
use in the marketplace, and to be alerted to any unanticipated issues or unusual trends. Consumers provide feedback through a toll-free telephone number printed on the package, by letter, and increasingly, through electronic media such as bulletin boards, social media, and manufacturer’s web sites. Health-related questions and comments are analyzed on a continual basis, with many decades of post-market surveillance serving as a reference for the types and frequencies of comments that can be expected for different product categories.

The sanitary pad in this investigation was first marketed in 2008. Between the fall of that year and spring 2013, over 1.3 billion pads were shipped to the North America market alone. The frequency of health-related comments (typically skin effects) was 1 health complaint per 2 million pads shipped. While no widely-used sanitary pad is devoid of minor irritation or discomfort complaints, the exceedingly low level of complaints is testimony to the rigor of the safety assurance process described herein.

6. Conclusion

This article describes a systematic, tiered approach for evaluating the safety of a new sanitary pad with an emollient-treated topsheet and a novel, non-cellulosic absorbent foam core. An exposure-based QRA was performed on raw material components, supplemented by clinical testing to confirm the skin compatibility of pad components and the product itself. Postmarket surveillance further substantiates that the product is very well-tolerated and surpasses most women’s expectations for menstrual hygiene and comfort. The low incidence of reported health effects further supports that the applied risk assessment approach is both effective and appropriate at assuring that safe feminine hygiene products are introduced into the marketplace. This report illustrates how the classical risk assessment paradigm (ECHA, 2013; NAS, 1983), tailored to the specific product application and conditions of use, enabled the rigorous safety evaluation of a menstrual pad with absorbent foam technology that represents a significant departure from traditional cellulose-based hygiene products.

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References


