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# Exposure Factor considerations for safety evaluation of modern disposable diapers

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ABSTRACT

Modern disposable diapers are complex products and ubiquitous globally. A robust safety assessment for disposable diapers include two important exposure parameters, i) frequency of diaper use & ii) constituent transfer from diaper to skin from direct and indirect skin contact materials. This article uses published information and original studies to quantify the exposure parameters for diapers. Using growth tables for the first three years of diapered life, an average body weight of 10–11 kg can be calculated, with a 10th percentile for females (8.5–8.8 kg). Data from surveys and diary studies were conducted to determine the frequency of use of diapers. The overall mean in the US is 4.7 diapers per day with a 75th, 90th, and 95th percentile of 5.0, 6.0, and 7.0 respectively. Using diaper topsheet-lotion transfer as a model, direct transfer to skin from the topsheet was 3.0–4.3% of the starting amount of lotion. Indirect transfer of diaper core materials as a measure of re-wetting of the skin via urine resurfacing back to the topsheet under pressure was estimated at a range of 0.32–0.66% averaging 0.46%. As described, a thorough data-based understanding of exposure is critical for a robust exposure based safety assessment of disposable diapers.



## 1. Introduction

Disposable baby diapers have improved the lives of consumers in many parts of the world. It is estimated that the total number of disposable diapers used during the first 3 years is 4600–4800. The use of superabsorbent gelling materials has resulted in diapers with the capacity to absorb many times their weight in fluid, and to keep the fluid away from the skin resulting in reduced skin hydration and pH changes, and reductions in the frequency and severity of diaper dermatitis (Odio and Friedlander, 2000). In a recent review by Heimall et al. (Heimall et al., 2012), multiple expert opinion articles were cited recommending the use of super absorbent diapers as a key step in preventing and treating diaper rash.

The major components of the modern disposable diaper are inert polymers with a history of safe use in a number of absorbent consumer products (Dey et al, 2014, 2016). The basic structure and composition of diapers have been previously reviewed (Kosemund et al., 2009). It consists of four functional layers (Fig. 1). The topsheet is the layer in direct contact with the baby's skin, and is composed of soft, porous polypropylene developed to transfer urine and other liquids quickly to the layers beneath. The topsheet may also contain a lotion (emollient) to help protect the skin from over hydration and irritation (Baldwin et al., 2001). The acquisition layer is composed of modified cellulose and polyester, and facilitates the movement of liquid away from the skin to distribute it evenly to the diaper core. The diaper core or absorbent layer consists of superabsorbent polymer gel that may be blended with cellulose and contained within a cellulose or a porous polymer nonwoven layer. Urine is locked and stored within its polymeric structure even under pressure. The backsheet is the water-proof outer layer of the diaper, typically made of soft textured, cloth-like polypropylene laminated with a polyethylene film. Its function is to prevent liquid from leaking out of the diaper. Diapers also contain additional features primarily designed to ensure a good fit,

*Abbreviations:* EBSA, Exposure Based Safety Assessment; QRA, Quantitative Risk Assessment; BW, body weight; PERMID, Prolonged Exposure Rewet Method in Diapers; TWA, time-weighted average; FOU, frequency of use; LOW, length of wear; SABAP, Speed of Acquisition with Balloon Applied Pressure.

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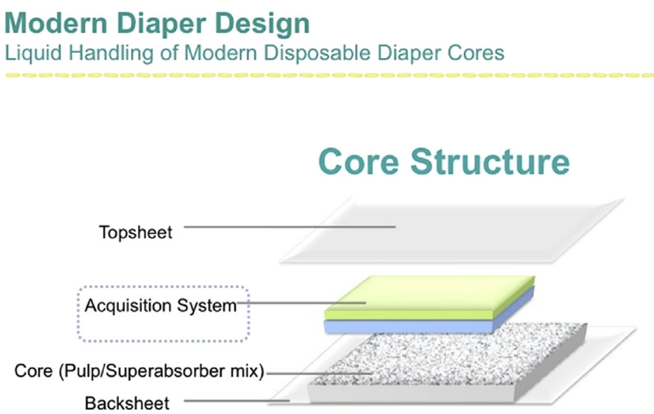


**Fig. 1.** Basic functional layers of a modern disposable diaper.

such as, fastening systems and tapes, and leg cuffs to prevent leakage.

The approach for safety assessment of baby diapers and other absorbent consumer products have been described previously (Kosemund et al., 2009 Rai et al., 2009; Dey et al., 2014), and it follows the same risk assessment process established by the US National Academy of Sciences (National Academy of Science (1983)). It consists of a 4-step process that includes hazard identification, dose-response assessment, exposure assessment, and risk characterization. Hazard assessment and dose-response depend on the potential biological effects of the constituents in the raw materials. Exposure assessment and risk characterization require an understanding of the consumers (children), the conditions under which diapers are used, and a thorough understanding of potential local and systemic exposures. The overall risk assessment approach and consideration for children's product have been recently reviewed where physiological and developmental differences that may result in differential sensitivity associated with early-life exposures have been discussed (Felter et al., 2015).

In addition to the polymeric materials, diapers may also have a small amount of small molecular weight non-polymeric constituents or impurities at very low levels for which a thorough assessment is conducted prior to marketing the product to ensure a high level of consumer safety assurance. This includes evaluation of all relevant toxicological endpoints. Appropriate uncertainty factors are incorporated into the safe threshold levels of individual constituents to account for interspecies and intra-species differences. In addition to a thorough assessment of the systemic endpoints of the diaper constituents, skin irritation and skin sensitization are evaluated for additional safety assurance to ensure absence of local skin effects. This is confirmed via adult skin patch test. Further, clinical in-use studies are conducted to confirm favorable skin compatibility when necessary. Once marketed, consumer health comments are monitored for continued product safety assurance under 'in-use' conditions.

For a robust exposure based safety assessment (EBSA), understanding exposure via accurate consumer habits and practices data and the exposure dynamics of a 3-dimensional product like a disposable diaper is needed. This paper focuses on key parameters used to develop an appropriate diaper exposure assessment. These include diaper user biometric information, including appropriate body weight and surface area for a growing user population (babies) collected from published literature, as well as product related parameters such as frequency of use, length of wear, and constituent transfer to skin (Table 1).

## 2. Diaper user biometric parameters

### 2.1. Body weight (BW)

Diapers are used by babies approximately for 36 months or less (AAP, 2003). During this period, children gain weight rapidly, especially during the first few months of life, as demonstrated by monthly body weight data on international growth standards published by US EPA Exposure Factors Handbook (US EPA, 2011) and the Centers for Disease Control (CDC) (Centers for Disease Control and Prevention, 2010, 2015) (Fig. 2). The US EPA has published recommendations for body weight for exposure assessment of children 0–1, 1–3, 3–6, 6–12 months, and 1–2 and 2–3 years old (US EPA, 2011). It is not practical to assess diaper exposure for multiple age brackets and for a specific point in time, because BWs in the diaper wearing children are transient and rapidly increasing. According to EPA guidance when exposure is likely to occur it is appropriate to sum across time-weighted values for all age periods. This approach is expected to increase the accuracy of risk assessments because it will take into account life stage differences in exposure (US EPA, 2005). A time weighted average (TWA) is used for exposure that is not constant at any one given time, for eg, infant BW changes every day; changing exposure over time. So, consistent with EPA guidance we have chosen to use a TWA BW based on US EPA recommended average BWs for the diapering period of 0–36 months (Table 2). A TWA BW for children 3 months to 2 years was used to determine ingestion of an environmental contaminant by non-dietary hand-to-mouth behaviors and the weighted average BW for 3 months to 2 years was 10.2 kg (US EPA, 2014). This is consistent with the approach taken in this manuscript for estimating TWA BW for the first 3 years to estimate diaper exposure. Human milk and lipid intake distribution was defined using TWA intake for children 0–6 months and 0–12 months for assessing cumulative exposure and risk (Arcus-Arth et al., 2005; US EPA, 2011). Daily inhalation rates for adults and children (10 years, 1 year old and new born babies) were estimated over a specified period of time based on a TWA of inhalation rates associated with physical activities (ICRP, 1981; US EPA, 2011). TWA was also used for health evaluation of exposure to $CO_2$ (NIOSH, 1976). For diaper exposure the TWA BW provides a conservative assumption over the diapering period of 3 years.

Based on US EPA data, the TWA for mean BW for a typical diapering age of 0–36 months for both genders combined is 11.0 kg. The 10th and 95th percentile TWA BW for both genders combined is 9.1 kg and 13.6 kg respectively. The TWA BW from EPA is in reasonable agreement with the TWA BW based on growth data published by the CDC (0–24 months and 24–36 months) (Centers for Disease Control and Prevention, 2010, 2015). Using CDC data the mean, 10th and 95th percentile TWA BW for both genders for children 0–36 months is 10.2 kg, 8.8 kg and 12.4 kg, respectively. The 10th percentile BW for females from this data set is 8.5 kg. For EBSA we use 8 kg BW for the entire diapering period. This is conservative since the TWA BW over 36 months is lower than 8 kg. Although the BW is < 8 kg in the first 6 months of an infant's life, the growth rate is rapid and is 3.5 times faster than between 7 and 36 months (calculation not shown); so the BW during majority of the diapering period is > 8 kg.

### 2.2. Surface area

Appropriate assumption of skin surface area is needed to estimate dermal exposure (mg/cm$^2$/day) to assess skin sensitization based on child specific dose per unit area. In a review of the available human and experimental animal data, Kimber et al. clearly provide evidence that under the majority of exposure