Reviewer's report

Title: Infant skin-cleansing product versus water: A pilot randomized, assessor-blinded controlled trial

Version: 1 Date: 31 January 2011

Reviewer: Maria M Lauriola

Reviewer's report:

- Major Compulsory Revisions

In order to further increase the value of the article, the authors should consider the following points:

- In "Introduction": The sentence "Babies are born with a pH of 6.4 which provides a natural protection against infection [1]; this reduces over three to four days to around 4.9" is not clear. As far as I know the pH of a newborn is close to neutral and, as a result, his skin is more sensitive to infection and irritation than that of an adult. When the pH changes to become more like that of adult skin, which is more acidic, cutaneous defences increase.

- I disagree when the authors say, in the introduction, that "An appropriately formulated cleansing product may avoid these potential problems but would need to be carefully evaluated because it may not be sufficient on its own to achieve appropriate skin care". The intrinsic damaging effects of detergents are well documented, are mainly due to the contained surfactants and consist of: the alkalization, delipidation, skin damage proteins, cell membranes and swelling of collagen fibers, cytotoxicity, irritant and sometimes sensitizing potential (see Effendy I, Maibach HI, Contact Dermatitis 1995, 33, 217-225 and Corazza et al, JEADV 2010, 24, 1-6). I think that an appropriately formulated cleansing product with a simple composition, based on a balanced combination of a few mild surfactants, can at best reduce these harmful effects.

- Concerning the sentence in the introduction: “One structural difference is that the anionic surfactants have the smallest micelles and the non-ionic the largest micelles. Small micelles penetrate easily into the skin barrier leading to skin barrier damage and inflammation. In contrast the large complex surfactant micelles do not penetrate into the skin barrier and as a result do not damage it [24 ]. It is therefore essential when formulating wash products to be used on a baby’s skin to use large micelle mild complexes of surfactants which cause no damage to the skin barrier in normal skin.” I think that this concept is vague and not sufficiently documented by references.

When we argue about aggressiveness of the different classes of surfactants, the critical micelle
concentration (CMC) should be considered. This important characteristic of surfactants is defined as the concentration of surfactants above which micelles are spontaneously formed. Upon reaching CMC, any further addition of surfactants will just increase the number of micelles. The surfactant amount not involved in micelle arrangement is called a monomer. It is the monomer that allows the washing effect. If the CMC value is elevated, there is also a high concentration of monomer that interacts with, and damages, the skin. For this reason, surfactants characterized by elevated CMC value (as lauryl sulphates) have proved to be primary irritants to the skin. CMC is influenced by the charge degree of hydrophilic component; usually, anionic and cationic surfactants have a higher CMC than nonionic agents, and thus become more aggressive (see Corazza et al, JAD 2010, 24, 1-6; Ananthapadmanabhan KP et al, Dermatol Ther 2004, 17, 16–25; Froebe CL et al, Dermatologica 1990, 181, 277–283).

However, although nonionic agents are commonly considered the lowest irritants to skin among the different types of surfactants (see Effendy I, Maibach HI, Contact Dermatitis 1995, 33, 217-225), some authors noticed that nonionic surfactants alter the cutaneous lipid layer more than anionics, because they can solubilize fatty acids and cholesterol in skin (see Ananthapadmanabhan KP et al, Dermatol Ther 2004, 17, 16–25).

- Minor Essential Revisions
  - In "Intervention": the composition of the tested detergent is not declared; in particular, there is not a clear characterization of surfactants in the product.
  - In "assessment of trial outcomes": only the type of instrument for measuring TEWL is specified, not the type of pH meter and corneometer.
  - In "Results" and in the tables: there are no units of measurement of TEWL and hydration.
  - In "Results": no comment on the values of hydration and skin surface pH.
  - In "references": "13. Gemetti C" should be corrected into "Gelmetti C ".
  - The numerical values of the "Table 2" do not seem to be well aligned.

- Discretionary Revisions
  - This is a well-structured article that is easy to read.
  - However, the Introduction is rather long and could be condensed.
  - The Discussion is well balanced and well argues the crucial points of the study.
  - Limitations of the work, consisting essentially in the high incidence of maternal lacking compliance and dropout, are clearly stated. Alternative solutions should be studied to limit this problem in a larger trial (ie. to allow the use of the same cosmetic emollient to all mothers or to compare two different detergents, rather than a detergent vs water).