

Cleansing is Fundamental to Baby Health & Wellbeing

- Mild effective cleansing should gently remove unwanted substances from skin
 - Irritants such as saliva, urine, feces, milk or food residue
 - Environmental substances (dirt, allergens, irritants) especially as babies grow and explore
 - Infectious agents
- Not cleansing can increase risk for skin irritation; can lead to infection
- Can help maintain and protect integrity of skin barrier

Ananthapadmanabhan KP et al. Dermatol Ther. 2004; 17 (suppl 1) 16-25



Cleansing is an ancient ritual performed throughout human history

3000 BCE

Babylonians wrote soap formulations on tablets

500 BCE

Body cleansing prominent in Greece

1,000 AD

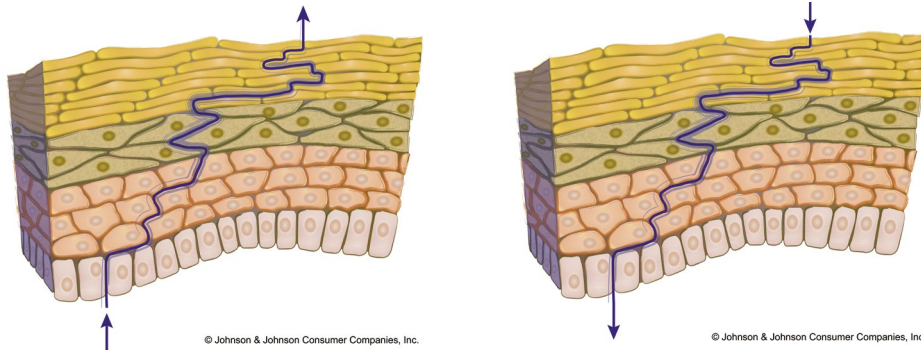
Soap manufacturing emerges in Europe and the Mediterranean

Modern Era

Synthetic detergents and liquid soaps developed

Tyebkhan G Indian J Pediatr. 2002;69:767-769
Walters R et al. J Am Acad Dermatol. 2009;60:AB31
Hunt J. The Pharmaceutical Journal 263;7076:985-989

Cleansing Can Help Maintain and Protect Integrity of the Skin Barrier, However...



- Infant skin is different than adult skin, continues to develop over time, needs special care
- Can lose water 2X as fast
- Smaller cells and thinner skin – shorter pathway outside to inside

Bartels NG et al. *Pediatr Dermatol.* 2010;27:1-8, Blume-Peytavi U. *J Eur Acad Dermatol Venereol.* 2009;23:751-759, Toker E. et al. *Am J Ophthalmol.* 2002;133:746-749, Isenberg SJ et al. *Ophthalmology.* 2003;110:1408-1411, Dahl H, Dahl C. *Acta Ophthalmol (Copenh).* 1985;63:692-694
 Stamatas G, et al. *Pediatr Dermatol.* Mar-Apr 2010;27(2):125-31., Nikolovski J, et al. *J Invest Dermatol.* 2008;128:1728-1735, Mack M, et al. *J Invest Dermatol.* 2009;129(S1):S14

Scientific Evidence Supports Some Cleansers over Others

Mild cleansers should be designed, formulated and tested for infants

- pH neutral or mildly acidic
- Should not disrupt skin barrier, including skin microbiome
- Should not irritate eyes in case of accidental splashes
- Should contain ingredients that are well characterized; assessed appropriate for infants
- Be microbiologically robust, which means many formulations will need appropriate preservative ingredients

	pH	Eye sting	Residue (insoluble)	Skin compatible
Soap	~10	Very high	High	Not usually
Syndet bar	6.5 – 8	High	Lower	More likely to be
Adult cleanser	5 - 6.5	Very high	Low	Not usually
Baby cleanser	5 – 6.5	Low	Lowest	More likely to be

Soaps with high pH can be irritating/drying. Adult cleansers may not be appropriate.

Blume-Peytavi U. *J Euro Acad Dermatol and Venereol.* 2009;23:751-759, Demott K, et al. (2006) *Clinical guidance and evidence review for post natal care: Routine Postnatal care of recently delivered women and their babies.* London: National Collaborating Centre for primary care and Royal College of General Practitioners, Lund C. et al. *Neonatal Skin Care (2nd edition)* 2007 Association of Women's Health, Obstetric and Neonatal Nurses, Bravo L. et al. *Practice recommendations on newborn and infant care.* Presented at: 45th Annual Convention of the Philippine Pediatric Society; April 13-16, 2008; Manila, Philippines Organización Panamericana de la Salud. *Curso de capacitación para agentes comunitarios y parteras: manual de participante: AEIPI neonatal.* Washington, DC; Organización Panamericana de la Salud; 2006., Fernandes J et al. *An Bras Dermatol.* 2011;86:102-110. *Neonatal Infant Skin Evidence-Based Clinical Practice Guidelines, 4th Edition.* Kuehl B et al. *Skin Therapy Letter.* 2003;8; Walters R. *Cosmetics and Toiletries.* 2008;123:53-60 Gfatter et al. *Dermatology.* 1997;195:258-262

Cleansing With Water Alone is Not Ideal and Hard Water Directly Correlated to Atopic Dermatitis

- Water alone may not remove all impurities
- **Contaminants and mineral content may have irritating effect on skin**
- Irritants such as fecal enzymes are better removed with cleansers
- A randomized study assessing bathing of neonates showed that water alone is **not** best for:
 - Preserving skin barrier function
 - Maintaining stratum corneum hydration
 - Can perturb normal skin pH

Study examining water hardness and the prevalence of eczema in 4141 primary school students

Hardness Category	Number of Children	Lifetime Prevalence of Eczema (%)*	1-year Prevalence of Eczema (%)*
1	786	21.2	12.0
2	731	23.4	14.1
3	1115	22.7	14.6
4	1509	25.4	17.3

*Significant trend in odds ratio for prevalence estimates from lowest to highest hardness categories. P = .02, lifetime prevalence; P < .001, 1-year prevalence.

Note - Water hardness was measured as the total concentration (mg/L) of calcium and magnesium salts

Hardness of water is directly correlated to prevalence of atopic dermatitis; with increasing hardness, there were increased rates of atopic dermatitis

Gelmetti C. J Eur Acad Dermatol Venereol. 2001;15(suppl 1):12-15, Tsai TF, Maibach HI. Contact Dermatitis. 1999;41:311-314, McNally NJ et al. Lancet. 1998;352:527-531, Warner R et al. J Invest Dermatol. 1999;113:960-966, Bartels N et al. Pediatric Dermatology. 2010;27:1-8, McNally NJ, et al. Lancet. 1998;352:527-531.

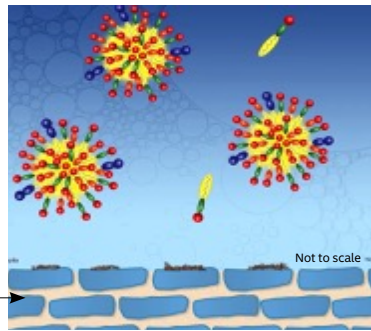
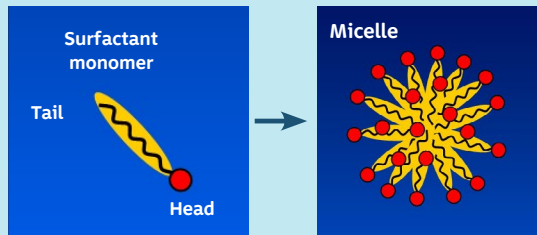
Cleansers for Compromised Skin Such As Atopic Dermatitis Should be Appropriately Formulated

Mild Cleansers Should Use Appropriate Surfactants

Definition

- Surfactants are amphiphilic compounds that aggregate to form micelles
- Contain hydrophobic (tail) and hydrophilic (head) groups; water soluble
- Different types based on electric charge

Walters R, et al. Cosmetics & Toiletries. 2008;123:53-60.



Walters R, et al. Cosmetics & Toiletries. 2008;123:53-60.

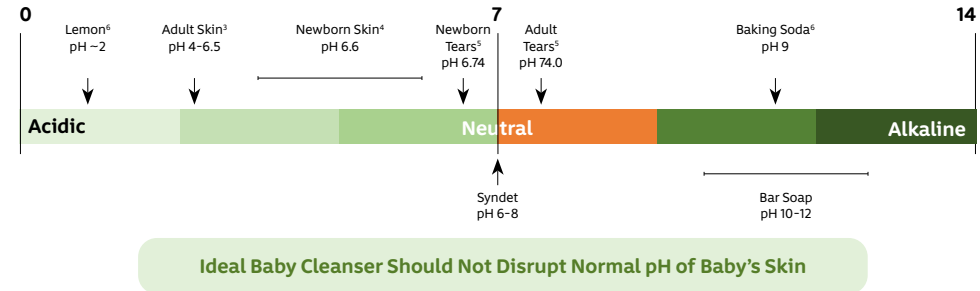
Surfactants (surface-active agents) function as cleansers by reducing surface tension and acting as emulsifying agents

They are a building-block for cleansers, **but can disrupt the complex structure of the skin**

- Aid in cleansing, help separate soils from skin so can be rinsed away
- **Products for babies should use mild surfactant molecules, blended to increase micelle size**
- **Larger micelles have less potential to penetrate and irritate the skin barrier**

Infant Cleansers Should have Appropriate pH

pH Scale: Skin and Cleansing Products^{1,2}

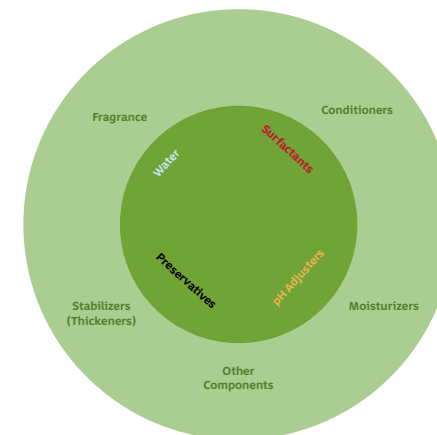


1. Ananthapadmanabhan KP, et al. Dermatol Ther. 2004;17(suppl 1):16-25. 2. Baranda L, et al. Int J Dermatol. 2002;41:494-499. 3. Yosipovitch G, et al. J Invest Dermatol. 1998;110:20-23. 4. Gfatter R, et al. Dermatol. 1997;195:258-262. 5. Abekson M, et al. Arch Ophthalmol. 1981;99:301. 6. Acid Rain Students Site: pH Scale. EPA.

Best Practices in Formulating Mild Cleansers for Infants with Compromised Skin

- Use purposeful, well characterized ingredients
- Use mild surfactants blended to create large micelles
- Neutral to mildly acidic pH
- Appropriate emollients or moisturizers may help prevent dryness and protect skin barrier
- Rigorous and comprehensive assessment for ingredient and formulation safety

Walters R et al. Cosmetics and Toiletries. 2008;123:53-60



Typical Components of An Infant Cleansing Product Should be Appropriate and Well Characterized

Key Takeaways

1. Cleansing hygiene is fundamental to infant's overall health and well-being
2. Infant skin, and its microbiome, is different from adult skin and continues to mature over time which has implications for care
3. An ideal baby cleanser for compromised skin, such as for Atopic Dermatitis, is safe, mild, gentle and effective and should be non-drying and not disrupt, but maintain / protect the infant skin barrier