

## INFANT'S SKIN AND CARE NEEDS WITH SPECIAL CONSIDERATION TO FORMULATION ADDITIVES

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### ABSTRACT

Infancy is the time of adaptation from intrauterine life to the rather dry and cold, environment. Infant skin is more sensitive due to the immature immune system, hence, effortlessly prone to complications. Children from different age groups face diverse skin problems such as cradle cap, infant eczema, diaper rash, prickly heat, and many more. During early infancy, the products such as mild cleansers and lotions are used, and later, massage oils, creams, lotions, soaps, bubble bath, and other products are utilized for another few years, as a part of routine care. The preterm infants are more prone to skin damage and percutaneous toxicity from topically applied products. The ingredients incorporated in infant care products require special attention while choosing a product for them. Topical application of any such product requires thorough screening for potentially harmful ingredients before its exposure to the infant's skin. Products used for infants should be safe and restricted of fragrance, coloring agents, parabens, plant oils, extracts, and other obnoxious ingredients. The literature is flooded with the list of safer excipients that can be utilized for the development of skin care products for infants and children.

**Keywords:** Dermatitis, Formulation additives, Dry skin, Skin structure, Skin barrier.

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### INTRODUCTION

Infant skin is considered most delicate among all skin types [1]. The neonatal period states for the 1<sup>st</sup> month after birth. A newborn baby is born with a protective covering which is wrinkly in nature, called vernix [2]. It naturally peels off during the 1<sup>st</sup> week after birth. The anatomical features such as the presence of thin dermis, decreased cohesion between dermis and epidermis renders it more vulnerable to certain obnoxious stimuli and make it susceptible to certain common skin disorders such as Eczema, cradle cap, heat rash, diaper dermatitis, and other forms of dermatitis [3].

Baby's skin has special skin care needs to protect from common disorders. The formulations chosen for the baby skin require specific consideration [4]. Neonatal skin has peculiar absorption characteristics, with high permeability to topical agents. In the early neonatal period, there is a marked topical drug absorption and high skin water loss because of incomplete development of the stratum corneum [5,6]. On safety, this article discusses the baby skin structural features, the common skin disorders seen in babies, and skin care needs of a baby including the formulation excipients that are commonly recommended and avoided [7].

### SKIN FEATURES OF AN INFANT

Functional and structural skin maturation is a dynamic process, which starts at the moment of delivery and ends in the 1<sup>st</sup> year of life. In full-term newborns, this process begins immediately after birth, while in preterm newborns by 2-3 weeks after birth, the skin is comparable to a full-term newborn's skin [8].

The skin comprises a multi-layered epidermis from ectoderm with an underlying dermis derived from mesoderm [9]. The skin further develops through the embryonic and fetal stage [10]. The epidermis also includes the basal layer and the superficial periderm [11]. Vernix caseosa is a protective hydrophobic layer that guards the fetal skin against intrauterine maceration. It is composed of water (80.5%), proteins, sebum lipids, and antimicrobial peptides with biomechanical and water-binding properties [12].

### DIFFERENCES BETWEEN AN ADULT AND BABY'S SKIN

Infant skin is often regarded as ideal skin, and adults normally seek its features [13]. Higher skin hydration, a lower skin pH, relates to a reduced heat loss after birth. Pre-mature babies have an immature epidermal barrier and lack the protective coating of vernix caseosa; therefore, greater risk of having a lower body temperature [14]. Infant skin has a higher rate of water absorption and desorption compared to adults [15]. Newborns have a large surface area in relation to volume and a high thermal conductance with an increased risk of heat loss. They have less number of melanocytes, which results in less photo-protection of their skin, resulting in abnormal collagen and elastin levels [16]. Sebum levels in the 1<sup>st</sup> week of life are high, which subsequently decrease [17]. The natural moisturizing factor is lower in infants compared to adults, but the level of NMF is reported to be higher in the first 2 weeks of life [18-20].

### COMMON SKIN DISORDERS SEEN IN BABIES

#### Diaper dermatitis

A rash that occurs in the parts within the diaper in infants aged around 9-12 months is usually termed as diaper dermatitis. Around 7-35% of the infant population suffer from diaper dermatitis [21].

Increased wetness in the diaper area results in increased susceptibility of baby's skin to physical, chemical damage, and some enzymatic mechanisms. Excess hydration causes the urease enzyme that is found in the stools to liberate ammonia, a mild irritant, which increases the pH and cause irritation to the skin [21]. Other enzymes such as lipases, proteases come in contact with the skin; they can also break down the skin barrier. The bile salts present in the feces boost the activity of enzymes, adding to the effect [22].

A fungus, *Candida albicans* can also contribute to augment diaper dermatitis. Other microbes have been secluded less often, as they occur as a result of secondary infections [23].

The treatment available in the market does comprise diaper rash creams which contain zinc oxide as their active ingredient as it dries the area,

gives astringent and antiseptic effect. In case of persistent dermatitis, hydrocortisone cream with mild antifungal is recommended [25].

### Eczema

Eczema or atopic eczema is a very common skin disorder among children, which is a form of skin rash that occurs on several parts of the body leaving the diaper area appearing usually before age 5 [26]. Around 20% suffers from itchy eczema [27]. The starting stage of eczema is usually just dry, patchy areas on the skin. If remains untreated, the condition may aggravate into dry, pus-covered inflamed skin. The right reason for the occurrence of atopic eczema is unidentified [28].

Due to frequent bathing of the baby, the natural oils present on the skin sap off, making it dry, leading to eczema [29,30]. Factors contributing include Ecological factors such as high humid temperatures, dust mites in the house, as a reaction to a vaccination, and presence of allergens such as soaps, creams, and detergents and can also be a viral infection [31,32].

Eczema can be treated by moisturizing the baby at regular intervals with thick creams containing emollients with an antiseptic or steroid cream. Emollients are available in various forms such as creams, lotions, ointments, and gels. Ointments with white soft paraffin and liquid paraffin, which are greasy and creams, lotions containing water are used for eczema [33,34].

### Miliaria

Miliaria, also called prickly heat, is a very common disorder. It occurs due to high levels of heat and humidity. It is caused by obstruction of the sweat ducts, causing the eccrine sweat to leak into the epidermis [35].

Miliaria is classified into 3 types according to the level of obstruction of the sweat duct [36] Miliaria crystallina, Miliaria Rubra, and Miliaria profunda [37]. Excessive hydration of stratum corneum leads to transient blockage of sweat ducts because babies have immature eccrine sweat glands [38]. Resident skin bacteria, such as *Staphylococcus epidermidis* and *Staphylococcus aureus*, are thought to play a role in the pathogenesis of miliaria.

Although the prevention of exposure to hot and humid climate is the best measure to protect the infant skin from heat rash, treatment of a heat rash includes powdering the baby with a prickly heat baby powder containing zinc oxide and some natural cooling agents like menthol [39].

### Cradle cap

Cradle cap or seborrheic dermatitis is very common to appear during baby's first 2 months, and it can stay for weeks or months [40]. Cradle cap looks like a bad case of dandruff. It can show up as crusty, greasy, and yellowish inflamed scales on the infant's scalp. Over time, the patches are going to become flaky, and they start rubbing off with bits of baby's hair attached [41].

The one contributing factor of cradle cap is known to be mother's hormones remained on the baby after birth. They stimulate the oil glands to secrete excess oil, which adheres onto the scalp and may take weeks or months to disappear by its own [42]. Another factor may be the presence of fungi, *Malassezia* that grows in the sebum along with bacteria. These fungi can cause infections that show up as severe dandruff [43].

Depending on the cause, the affected area can be treated by massaging it with natural baby oils and rinsing it off gently. For the treatment of fungal infection, antifungal preparations containing ketoconazole can be used [44].

### INFANT'S SKIN CARE NEEDS

An infant's skin is categorized into - dry skin, oily skin, and combination and sensitive skin. Each skin type has special daily care needs specifically considering seasonal variations. It is known that an infant's

**Table 1: The excipients recommended and to be avoided in the formulation of baby oils [72-74,87,88,97,98]**

Excipients		
Category	Recommended	Avoided
Fixed oils	Coconut oil	Mustard oil
	Sesame oil	Clarified butter (ghee)
	Almond oil	Olive oil
	Sunflower oil	Peanut oil
	Castor oil	
	Grape seed oil	
	Safflower seed oil	
	Soybean oil	
	Corn oil	
	Joboba oil	
	Shea	
	Cranberry seed oil	
	Peach kernel	
	Cherry kernel	
	Kiwi seed oil	
	Moringa oil	
	Broccoli seed oil	
Essential Oils	Chamomile oil	Anise/aniseed oil
	Dill oil	Clove bud, leaf, and stem oil
	Lavender oil	Eucalyptus oil
	Tea tree oil	Fennel oil
	Avocado oil	Lemongrass oil
	Calendula oil	Peppermint oil
	Mandarin oil (sweet orange)	Ylang-ylang oil
	Rose Otto (steam distilled rose oil)	Rosemary oil
		Verbena oil
		Wintergreen oil
	Balsam Peru oil	
Mineral oils	Liquid paraffin	

**Table 2: The excipients recommended and to be avoided in the formulation of baby powders [72-74,93-95]**

Excipients		
Category	Recommended	Avoided
Bulking agents	Cornstarch (natural and organic)	Talc
	Tapioca starch	
	Oat starch	
	Sodium bicarbonate	
	Bentonite	
Antibacterial	Kaolin	
	Zinc oxide	
Antioxidant	Tocopheryl Acetate	
Fragrance	None	All
Dyes	None	All

skin is different from adult skin. When it comes to seasonal variations, to protect their skin from various ailments, also in general day-to-day care and product considerations are given utmost importance [45,46].

### Daily skin care

The process of bathing dries out the infant's skin because it saps out the natural. Bathing time should be kept minimal, and the temperature of the water should remain optimum. In general, perfume and detergent-free soap is recommended [47].

To maintain the proper level of moisturization, moisturizing at regular intervals while there is still some moisture left on the skin from the bath helps to lock the water on the skin [48]. Use of emollients can be helpful to restore skin elasticity, sustain skin homeostasis, and control TEWL, while a regular emollient application from birth can be considered an effective approach for atopic dermatitis prevention in neonates [49].

Changing lifestyles cause babies in need of disposable diapers and wipes which are convenient for parents. Airing out the diaper area is very important to prevent moisture accumulation. Constant use of diapers may cause redness, leading to diaper dermatitis in most cases [50]. Baby products contain mild cleansers and protect the natural balance of baby's skin. Skin care products made for babies should have lower levels of chemicals, fragrance, and dyes [51].

#### Summer care

The heat alleviates the perspiration, which leads to skin infections in infants [52]. Sweat contains sodium chloride in it causing rashes and itching [53,54]. Cradle cap can be a sign of fungal infection, and certain antifungal preparations on baby's head can be used. Application of oil is avoided if dermatitis or heat rash is seen along with cradle cap [55]. Heat rash is commonly observed during summer. Prickly heat powders with zinc oxide are widely used [56]. If sweating is heavy and fungal infection is seen, the best way to manage would be using dusting powders [57,58].

#### Winter care

Winter can seem very harsh on infant's sensitive skin. During winter, their skin tends to become dry forming wrinkles [59,60]. Applying any baby massage oil all over the baby's scalp and massaging gently

can remove dandruff from the scalp caused due to winters [61]. Safe, low-dose, and hydrocortisone can be used for heat rashes due to over-clothing [62]. Any signs of eczema, ointments can be used as moisturizers after baths. For good results, oils are massaged at regular intervals, which increases the penetration of oil into the skin [63,64].

#### FORMULATION ESSENTIALS FOR INFANT'S SKIN CARE PRODUCTS

The market is filled with various baby care products such as baby oils, shampoos, soaps, and creams. To choose the right product for your baby skin is a challenge, as they have to meet certain criteria such as being mild and non-toxic. However, not all the ingredients that are present in baby products are harmful. Therefore, the excipients considered harmful should be avoided in baby products. This section discusses the excipients that are usually recommended to use and should be avoided in infant's products.

#### Baby oils

Baby oils are mineral or natural oil or combination of these categories used for applying on baby skin or scalp to moisturize. Massaging baby oils is to strengthen the muscles and relax them. Oil massage of newborns has been practiced for generations. However, oils may vary from potentially beneficial, for example, sunflower seed oil, and to potentially toxic, for example, mustard oil (Table 1). Among all oils,

**Table 3: The excipients recommended and to be avoided in the formulation of baby shampoo [72-74,96]**

Excipients		
Category	Recommended	Avoided
Surfactants	Sodium Trideceth Sulfate	Sodium lauryl sulfate
	Cocamidopropyl betaine	Sodium laureth sulfate
	Disodium cocoamphodiacetate	Ammonium laureth sulfate.
	Coco-glucoside	Carboxylates
	Decyl glucoside	Quaternary ammonium salts
	Lauryl glucoside	Amine oxides
	Sucrose Laurate	Sulfoxides
	Glyceryl oleate	Ethoxylates
	Sodium lauroamphoacetate	Poloxamers
	Betaine	
	Sorbitan Laurate	
	Sodium Cocoyl Isethionate	
	Sodium coco sulfate	
	Conditioning Agent	Polyquaternium-10
Guar Hydroxy- propyl trimonium Chloride		Silicones
Foamer	Butylene Glycol	
	Capryloyl glycine	
Thickener	PCA Glyceryl oleate	
	Disodium oleamide	Sodium chloride
Preservatives	PEG-80	
	Xanthan gum	
	Sodium Benzoate	Parabens: Methyl paraben, propyl paraben etc.
	Glucose oxidase and lactoperoxidase	Formaldehyde donors
Humectant	Phenoxyethanol	
	Potassium sorbate	
	Glycerine	Propylene glycol
Chemical	Calcium gluconate	
	None	Acetaldehyde, Benzophenone, BHA, Benzyl Salicylate, Benzyl Benzoate, Butoxyethanol, Butylphenyl methylpropional, Chloromethane (methyl chloride), Dichloromethane (methylene chloride), DEP, Eugenyl methyl ether (Methyleugenol), Formaldehyde, MEA, DEA, TEA-ethanolamines, Oxybenzone (BP-3), Methanol, Synthetic Musks (Tonalide, Galaxolide, Musk Ketone, Musk Xylene) etc.
Fragrances		FD&C Red No. 6/D&C Green No. 6.
Synthetic Colors		
Other Excipients	Glucose (natural exfoliate)	Isopropyl alcohol (solvent)
	Citric Acid (pH stabilizer)	
	Sodium Hydroxide (relaxer)	
	Allyl caproate (emollient)	
	Triethyl citrate (masking)	

BHA: Butylated hydroxyanisole, DEP: Diethyl phthalate

Table 4: The excipients recommended and to be avoided in the formulation of creams and lotions [72-74,93]

Excipients		
Category	Recommended	Avoided
Emulsifiers	Cetyl palmitate	Propylene glycol (1,2-propanediol, methyl ethyl glycol, 1,2-propylene glycol), 2-bromo- 2 nitropropane-1,3- diol) Triethanolamine Steareth- 20
	Sorbitan Palmitate	
	Ricinus Communis Seed Oil	
	Mineral Oil	
	Capric Triglyceride	
	Sorbitan Olivatate	
	Petrolatum	
	Decyl Oleate	
	Ascorbyl Palmitate	
	Stearic acid	
Humectant	Beeswax	Isopropyl alcohol
	Polysorbate 60	
Alcohols	Glycerine	Ethyl alcohol
	Cetyl Alcohol	
Emollient	Cetearyl Alcohol	Benzyl alcohol Cyclopentasiloxane
	Glyceryl Stearate	
	PEG-40 Stearate	
	Caprylyl Glycol	
	Glyceryl caprylate	
	Caprylyl alcohol	
Preservative	Lecithin	Parabens Formaldehyde donors Phthalates: (Di (2-ethylhexyl) phthalate (DEHP Di (2-ethylhexyl) phthalate (DEHP), dioctyl phthalate (DOP), and bis (2-ethylhexyl) phthalate (BEHP)). Methylisothiazolinone and methylchloroisothiazolinone Diazolidinyl urea and Imidazolidinyl urea Ethylhexylglycerin (conditioning agent)
	Phenoxyethanol	
	Sodium benzoate	
	Sorbic acid	
Other Excipients	Citric acid (pH stabilizing agent )	Potassium lactate (conditioning agent)
	Dimethicone (conditioning agent)	
	Bentonite (emulsion stabilizer)	
	Tocopheryl acetate (skin conditioning)	
	Zinc oxide ( diaper rash)	
Chemical	None	Linalool
Fragrances	None	Hexyl cinnamal
Dyes	None	All

coconut oil and sunflower oil have been most widely used for infant massage [65,66]. Sunflower oil protects the integrity of stratum corneum and improves hydration [67]. Olive oil can promote atopic dermatitis and aggravate existing dermatitis [70].

Ahmed *et al.* 2007 suggested that those who received an oil massage, the most commonly-used product was mustard oil, which was applied to 73 (88%) of the 83 babies massaged; other products mentioned were coconut oil in eight (9.6%) cases, and olive oil, and proprietary baby lotion in one each. In this study, the "mean oxygen saturation" was enhanced in babies massaged with sunflower oil [68].

In general, vegetable oils that are high in linoleic acid are gentler on baby skin. Linoleic acid is an essential fatty acid that helps to protect the barrier of skin, for example, Sunflower oil and grape seed oil. Vegetable oils high in oleic acid may be harsher on your baby's skin, for example, olive oil. Perfume-free baby mineral oils are another option if your baby has dry, broken skin. Mineral oil is derived from petroleum [69,70]. Petroleum-based skin softeners (emollients) are effective and safe for treating skin problems such as dermatitis and eczema (Table 1).

#### Powders

Powders are generally used to control excess moisture due to sweat and to reduce the friction between skin [76]. The talcum-based baby powder is prepared from the mineral talc, which comprises mostly silicon,

magnesium, and oxygen. It absorbs moisture and decreases friction between skin, which helps avert rashes especially diaper rash. Talcum powder contains two main ingredients: Talc and fragrance [77]. Baby powders contain either talc or corn starch as the moisture-absorbing ingredient (Table 2). Medicated powders used for diaper rash contain zinc oxide in the powders. This acts as an antibacterial as well as an astringent (Table 2).

#### Baby shampoo

Baby shampoo is a baby hair care product employed to remove the dirt, oil, dandruff, and other particles from the scalp. The ingredients used for baby shampoo are milder when compared to an adult shampoo [78]. The building blocks of shampoo include - surfactants, thickeners, foaming agents, preservatives, and conditioning agents (Table 3).

The pH of 6–7 and ideally should contain only mild surfactants such as mixtures of non-ionic and amphoteric substances or mild anionics such as sulfosuccinates, isethionates, and protein fatty acids condensates [79,80]. It should contain ingredients that are harmless to the scalp, hair, as well as less irritating to the eyes. To avoid eye-contact, the viscosity of the shampoo could be increased (Table 3).

#### Creams and lotions

Creams and lotions are semi-solid dosage forms that are applied topically and provide a protective layer around the body, keep moisture

Table 5: The excipients recommended and to be avoided in the formulation of a bubble bath. [72-74,97]

Excipients		
Category	Recommended	Avoided
Surfactants	Sodium lauryl glycol carboxylate Sodium cocoyl alkyl Esters Decyl glucoside Lauryl glucoside Disodium cocoamphodiacetate Disodium-coco glucoside sulfosuccinate Glyceryl Oleate Coco- glucoside Sodium Lauroamphoacetate Betaine Sorbitan Laurate Sodium cocoyl Isethionate Sodium-coco sulfate	Sodium lauryl sulfate Sodium laureth sulfate Ammonium laureth sulfate Carboxylates Quaternary ammonium salts Amine oxides Sulfoxides Ethoxylates Poloxamers
Foamer	Disodium oleamide	Propylene glycol
Humectant	Glycerine Gluconolactone	
Emollient	Caprylyl glycol Caprylyl glycol Glyceryl caprylate	Cyclopentasiloxane
Preservatives	Sodium benzoate Phenoxyethanol	Parabens Formaldehyde donors Phthalates
Other Excipients	Citric acid (pH stabilizing agent) Acetic acid (ph modifier)	Ethylhexyl glycerine (conditioning agent)

Table 6: The excipients recommended and to be avoided in the formulation of baby soap [72-74,98]

Excipients		
Category	Recommended	Avoided
Fats/oils	Saponified olive oil Saponified coconut oil [99] Saponified palm oil Cocoa butter Sodium palmate Citrus peel oil Sodium olivate Saponified castor oil Potassium chocolate	
Alkali	Potassium hydroxide Sodium chloride	
Humectants	Glycerine	Propylene glycol
Surfactant	Sodium myristoyl sarcosinate Sodium lauroamphoacetate Cocoamphoacetate  Palm acid Polyglycerol 2-oleyl ether  Glutamate Glucosides	Sodium lauryl sulfate  Sodium laureth sulfate Ammonium laureth sulfate Carboxylates Quaternary ammonium salts Amine oxides Sulfoxides Ethoxylates Poloxamers
Preservatives	Sorbates Phenoxyethanol Sodium benzoate [100]	Parabens Formaldehyde donors Phthalates

in, and toxin out regulates body temperature. Lotions are lighter and low viscous than creams. Moisturizing the baby is very vital irrespective of the seasons [85]. It helps to seal or lock the moisture on the skin to keep it soft and supple. In case of starting skin damage, water-in-oil (w/o) creams or water-free ointments with talc, kaolin, and zinc oxide as actives are advised. During winter, barrier creams protect baby's face from freezing cold and wind. The lipid phase often contains petrolatum.

These barrier creams are effective around the nose and mouth. They usually also contain moisturizers, soothing active ingredients, and non-ionic emulsifiers [93].

Ingredients used for formulating baby creams and lotions should be mild and non-irritating. They should moisturize the skin and give an emollient action (Table 4). The pH of the cream/lotion should be maintained around pH 6.5 and should be scrutinized for dermal and ocular safety, including clinical assessment for dermal irritation, dermal sensitization potential, and ocular irritation (Table 4).

#### Bubble bath

A bubble bath is a filled bathtub with a layer of surfactant foam on the surface of the water and consequently the surfactant product used to produce the foam. Less commonly, aerated or carbonated baths are called bubble baths. Mixtures of surfactants, foam stabilizers, emollients, humectants are the main constituents of bubble bath formulation. The surfactants used in bubble baths should be mild. It should not contain any chemical fragrances [97] (Table 5).

#### Baby soap

Baby soap is the salt of fatty acid, which is used for cleansing the baby and should leave the baby skin moisturized [98]. It should cleanse the dirt and oils properly from the skin it should contain ingredients that should be non-irritable, scent and dye free. The fatty acids used for the baby soap are usually obtained from natural oils such as saponified olive oil and coconut oil (Table 6).

#### CONCLUSION

The delicate skin of infants can be considered as the biggest challenge for formulation scientist because the diversity associated with different skin types again poses a significant constraint for selecting safer formulation ingredients. Although this review incorporates a better insight into care as well as formulation needs, the ingredients incorporated in infant care products requires thorough screening for their safety. Products used for infant's care should be safe and free of fragrance, coloring agents, synthetic preservatives, and any unexplored natural and synthetic material. Although it is an era of herbal cosmetics, the herbal ingredients should not be accepted blindly, as formulation additives.

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