Neonate Skin Products Used in Oxygen-Enriched Environments May Pose Risks Associated with Flammability and Skin Breakdown

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Abstract

Neonatal health care has continued to advance over a period spanning three decades. However, the treatment of preterm and term infant skin has lagged behind. Current AWHONN and NANN guidelines call for the use of a petrolatum-based product in the neonate setting. Petrolatum may pose significant risks associated with NICU fire hazards, barrier occlusion, microbial contamination and toxin absorption. In order to reduce infant mortality and improve neonatal skin care, advanced emollient technologies should be considered. Semipermeable silicone derivatives have demonstrated a reduced rate of combustion as compared to petrolatum. Silicone derivatives also sustain transcutaneous respiration while preventing e-TEWL. Certain silicone-based emollients have further demonstrated a reduced rate of microbial contamination and toxin absorption. The purpose of this report is to review the risks associated with current highly-flammable and occlusive infant skin care products and discuss the benefits of oxygen-compatible, silicone-based neonatal emollients.

Introduction

Skin is the largest organ of the human body and provides protection against the external environment. Skin consists of three layers; the dermis, epidermis and the protective, semi-permeable stratum corneum that permits terrestrial life[1]. The stratum corneum becomes fully keratinized in utero between 32 and 34 weeks gestational age[2]. During pregnancy in utero skin undergoes two-dimensional growth to cover the surface area of the developing embryo and fetus[3]. At birth, the term neonate's natural covering, the vernix, is wiped off or shed. As

neonatal skin evolves, it uptakes oxygen from the atmosphere and protects against excessive transepidermal water loss (e-TEWL), mechanical trauma, microbial infection, temperature variation and percutaneous toxin absorption[4]. Conversely, premature neonates are frequently delivered with underdeveloped stratum corneum and epidermal skin layers. Immature skin does not provide the numerous protective functions provided by fully developed skin.

The Evidence-Based Clinical Practice Guideline for neonatal skin care recommends 2-4 weeks of emollient application in order to prevent e-TEWL in preterm neonates delivered prior to 32 weeks gestation[5]. An emollient is simply defined as an agent that softens or soothes skin[6]. The Guideline has been validated by the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) and the National Association of Neonatal Nurses (NANN)[5,7]. Currently, the AWHONN and the NANN recommend Aquaphor Healing Ointment® from Beiersdorf AG, a petrolatum-based mixture containing lanolin and mineral oil, as the neonate skin care emollient of choice. However, the use of petrolatum-based products in the neonatal intensive care unit (NICU) may be dangerously inconsistent with the safety regulations advocated by the NANN and AWHONN due to flammability issues. NICU personnel are required to adhere to specific protocol in order to reduce infant mortality, yet the same personnel are advised to use emollients that may compromise neonate health and safety[8].

Flammability Risks in Oxygen-Enriched Environments

Neonatal incubators provide oxygen-enriched environments to preterm infants while monitoring humidity, oxygen saturation and inspired oxygen concentration. Premature infants may receive

oxygen from a variety of systems, including low-flow systems, reservoir systems, high-flow systems and enclosure systems. Low-flow systems utilize endotracheal tubes and nasopharyngeal catheters to supply oxygen directly into the neonates' nasopharynx. Reservoir systems and high-flow systems employ specialized masks that fit around the infants' noses and connect to external oxygen supply tubing. Enclosure systems, or headbox set-ups, utilize oxygen hoods designed to surround the head of the neonate and provide a continuous flow of humidified oxygen[8]. The enclosed system blends the oxygen to obtain the necessary oxygen concentration and subsequent oxygen saturation. The total flow of gases is between 6-8 liters per minute, providing an oxygen-enriched atmosphere between 23-100% oxygen content[9].

Air Flow (L/min)	Oxygen Flow (L/min)	Percent Oxygen in Enclosure System (%)
9	1	30
8	2	40
6	4	50
5	5	60
4	6	70
2.5	7.5	80
1	9	90

Table I. Enclosure systems combine oxygen to obtain the oxygen saturation required for infant survival. The system provides an enriched oxygen atmosphere with an oxygen concentration most commonly between 23-90%, although the system is capable of achieving concentrations of 100%[9].

Petrolatum-based skin care emollients such as Aquaphor® are composed of highly flammable hydrocarbons. Petrolatum itself is a semisolid mixture of hydrocarbons obtained by the fractional distillation of petroleum[10]. Paraffin and liquid paraffin are lower grades of petrolatum; both are composed of highly flammable hydrocarbons[11]. Lizhong *et al.* noted that hydrocarbon-oxygen mixtures are extremely explosive, especially in confined spaces[12]. Each year numerous

medical centers report fires caused by ignition in an oxygen-enriched environment. Sheffield *et al.* confirmed that enclosed fires occur in enriched oxygen atmospheres and in the presence of abundant, flammable substances. Furthermore, fires ignited in enclosed areas enriched with greater than 28% oxygen were associated with the highest rates of mortality[13]. Victims exposed to hydrocarbon-oxygen fires frequently die from extreme heat before carbon monoxide inhalation becomes a significant factor. The severe heat is intensified by the water vapor created during hydrocarbon combustion[14]. In summary, the application of petrolatum based emollients to preterm infants in oxygen-enriched systems may endanger neonate survival.

Utilizing Silicone Derivatives to Diminish Flammability Risks

Utilizing advanced silicone excipients over petrolatum-based products diminishes risks associated with flammability, occlusion, microbial contamination and toxicity. Silicones are currently used in numerous transdermal delivery systems, catheters and specialized medical devices[15,16]. A substantial advantage of using silicone over petrolatum-based products for neonatal skin care is silicone's oxygen compatibility. Wendell Hull & Associates, Inc. reported that certain tested silicone-based creams have achieved superior oxygen compatibility results compared with petrolatum-based emollients.

Oxygen compatibility is determined via autogenous ignition temperature testing, oxygen index testing and heat of combustion testing. Emollients with a high autogenous ignition temperature, a high oxygen index and a low heat of combustion are recognized as being more compatible for application in oxygen-enriched environments[17].

- Autogenous ignition temperature is a relative indication of a substance's propensity for ignition.

- Oxygen index is a relative indication of a substance's flammability, or propensity for fire propagation and sustained burning.

- Heat of combustion is an absolute value of a material's energy release upon burning, which is an indication of its damage potential.

Furthermore, an Acceptability Index based on the above factors is used to rank the oxygen-compatibility of various substances. The Index is based on the following equation[18]:

$[(\text{oxygen index})^2 \times (\text{autogenous ignition temperature})] / (\text{heat of combustion})$

The heat of combustion value of the industry standard, Aquaphor Healing Ointment® from Beiersdorf AG, was more than five times greater than silicone-based Nutrashield™ and Skin Repair Cream™ from Medline Inc. Aquaphor® had a heat of combustion value of 10869 calories/gram, ranking near gasoline at 10400 cal/g and mineral oil at 10930 cal/g. Subsequently, Skin Repair Cream™ and Nutrashield™ received an Acceptability Index rating approximately 13 times and 8 times greater than Aquaphor®, respectively[17].

Material	Autogenous Ignition Temperature (°C)	Oxygen Index (%)	Heat of Combustion (calories/gram)

Aquaphor®	186	25	10869
Nutrashield™	224	55	2111
Skin Repair Cream™	179	50	1989

Table III. Autogenous ignition temperature indicates a substance's propensity for ignition; oxygen index indicates a substance's flammability; heat of combustion is an absolute value of a material's energy release upon burning. Oxygen compatible Nutrashield™ and Skin Repair Cream™ maintain a high oxygen index while preserving a low heat of combustion[17].

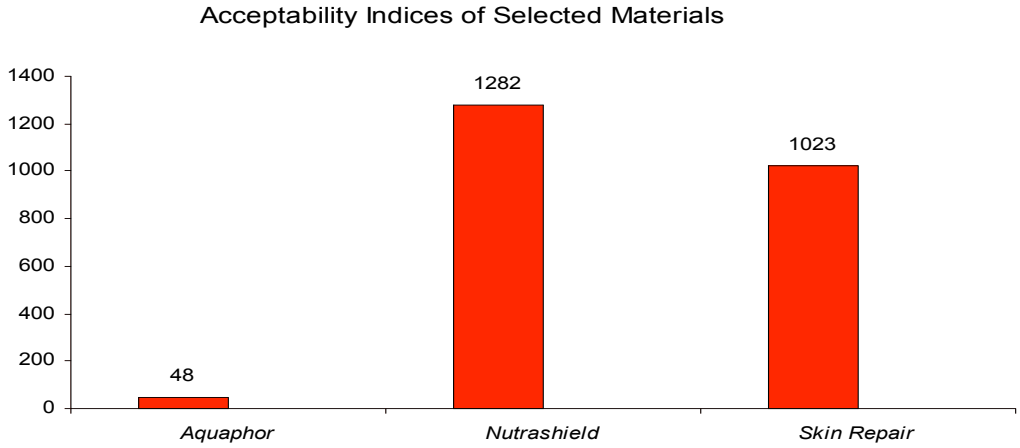

Figure I. The Acceptability Index is used to rank oxygen compatibility based on the following equation:

$$\mathbf{[(oxygen\ index)^2 \times (autogenous\ ignition\ temperature)] / (heat\ of\ combustion)}$$

Silicone-based skin care products received substantially higher Acceptability Indices than petrolatum-based products[17]. In particular, petrolatum-based Aquaphor® burns with an extremely high energy release, comparable with gasoline[18].

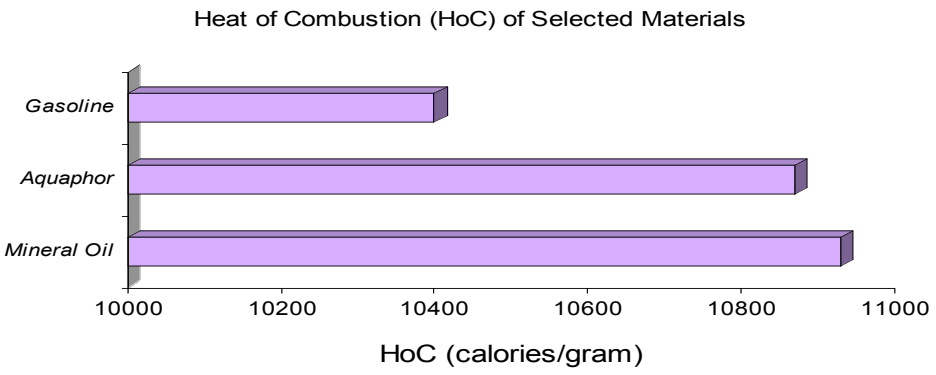

Figure II. Heat of combustion is an absolute value of a material's energy release upon burning, which is an indication of its damage potential. Petrolatum-based Aquaphor® was found to have a heat of combustion greater than gasoline. Furthermore, Aquaphor® contains mineral oil, which was also found to release more energy upon burning than gasoline[17].

Each of the following components is considered necessary for combustion to occur under standard conditions. Reducing or eliminating one or more of the combustion requirements may diminish risks associated with fire in the NICU[19,20].

- Presence of burnable material (petrolatum, paraffin, etc.)

- Source of ignition (electrical systems, etc.)

- Oxygen

Occlusive Barriers Reduce Transcutaneous Respiration and Sustain Microbial Contamination

Skin care for high-risk neonates requires knowledge of the unique anatomy and physiology of infant dermis, epidermis and stratum corneum[21]. During the neonatal period, many infants develop preventable, clinically apparent skin problems. Moreover, preterm neonates frequently experience morbidity caused by compromised skin barrier integrity[22]. Physiological differences in immature skin, especially in the epidermis and stratum corneum, place term and preterm infants at significant risk of complete barrier breakdown[23]. In fact, one NICU study conducted at All Children's Hospital in St. Petersburg, Florida found that 21% of extremely low birth weight infants suffered skin breakdown during the first week of life[24]. In order to reduce the risk of infant mortality, improving neonatal emollient treatment should be considered. Additional studies are recommended to determine which products can provide proper neonatal skin care while maintaining strict fire safety standards.

Application of petrolatum-based products, such as Aquaphor®, occludes the stratum corneum. Occlusion is problematic because while blocking TEWL, it also reduces the transcutaneous respiration necessary for normal barrier repair. It has been known since 1851 that human skin consumes oxygen from the atmosphere[25]. Recently, Stucker *et al.* utilized the innovative oxygen fluxoptode to make local measurements of the transcutaneous oxygen uptake of human skin. Published data on the oxygen diffusion properties of skin and intracutaneous profiles of oxygen partial pressure indicated that on normal, humidified skin, the stratum corneum and epidermis are almost exclusively supplied by external oxygen up to a depth of 0.25-0.40 micrometers[25,26,27].

The width of the epidermis varies from 0.04 to 0.15mm with the average of 0.1 mm or 40 to 150 micrometers. Oxygen transport into the epidermis via the microcirculation within the dermis had a negligible influence on the upper layers of the skin. W. Wang further supported the importance of transcutaneous respiration by displaying the significant effect of skin surface conditions on the partial pressure of epidermal oxygen[28]. Occluding neonatal skin with petrolatum-based products prevents transcutaneous respiration, thereby interfering with cellular respiration and impeding barrier development.

In addition, studies demonstrate that the occlusive effects of petrolatum trap microorganisms in the layer of water derived from the transepidermal water confined between the stratum corneum and the applied petrolatum barrier [29,30]. Long term studies reflect a concern over the use of petrolatum-based products in NICUs[31,32,33]. One such study was conducted at a 48 bed NICU private hospital in Houston, Texas. Clinical trials were performed in order to determine the cause of a three-fold increase in the rate of systemic candidiasis per 1000 NICU patient days. The rate had increased from 5.1% in 1996 to 17.4% in 1997. Researchers concluded that the application of topical petrolatum ointments enhanced the adherence of *Candida albicans* to the stratum corneum, thus increasing the rate of systemic candidiasis[34]. Petrolatum application may increase the risk of infection by trapping microorganisms under the occlusive barrier and enhancing microbial adherence to cutaneous surfaces.

Silicone-Based Emollients Allow Transcutaneous Respiration While Preventing e-TEWL

Silicone-based emollients are semipermeable, allowing for normal transcutaneous respiration

while preventing e-TEWL. The stratum corneum controls TEWL, which is a normal activity required for proper barrier function. However, e-TEWL activates an inflammatory response in the epidermis and dermis, initiating the repair process[35]. Dow Corning conducted an independent *in vitro* study to determine the effectiveness of silicone-based products such as Nutrashield™ and Skin Repair Cream™ in reducing e-TEWL. In the study, collagen samples were pre-coated with 0.1 grams of each test emollient and placed over a Fischer Payne Permeability Cups containing 3.0 grams of water. The samples were placed in an oven and the weight of the remaining water was monitored for 24 hours. The researchers concluded that silicone-based Nutrashield™ and Skin Repair Cream™ effectively reduced e-TEWL without occlusion[36]. In particular, Nutrashield™ conserved nearly four times the quantity of water of the control group.

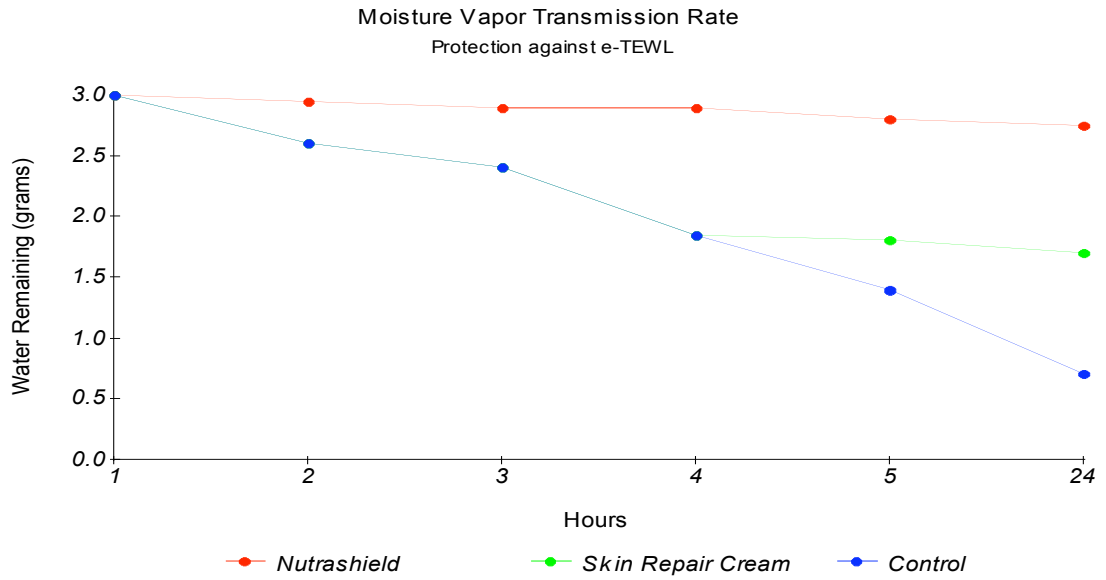

Figure IV. An *in vitro* study tested the moisture transmission rate of collagen samples coated with silicone-based products such as Nutrashield and Skin Repair Cream. The moisture transmission rate was used as an effective measure of e-TEWL prevention. It was concluded that both Nutrashield and Skin Repair Cream effectively reduced e-TEWL without occlusion[36].

Preventing e-TEWL while allowing for normal TEWL, as well as normal transcutaneous respiration, is the key to providing proper neonatal skin care. Agren *et al.* calculated that infants delivered at 24 to 25 weeks gestation experienced approximately 58.4 grams/meter^2/hour of TEWL during the first postnatal day. TEWL then decreased significantly to approximately 48.3 g/m^2/h at three days postnatal age[37]. Semipermeable silicone-based emollients may reduce neonatal e-TEWL by as much fourfold while allowing for normal barrier repair. Conversely, petrolatum-based products completely occlude neonatal skin, prevent barrier repari and interfere with transcutaneous respiration and proper barrier function.

High molecular weight silicones also maintain skin protection through multiple cleansing sessions. Silicone-based Nutrashield™ was tested in a wash-off study against petrolatum-based emollients such as Aquaphor® and other recommended skin care products. The study revealed that Nutrashield™ outperformed petroleum-based emollients while providing a semipermeable barrier versus an occlusive barrier. Numerous clinical trials have concluded that silicone-based products effectively treat barrier breakdown resulting from disordered and damaged skin[38,39,40]. Furthermore, silicone-based products that contain natural skin lipids such as omega 3 and omega 6 fatty acids reduce the incidence of microbial contamination. Law *et al.* found that, dissimilar to petrolatum, skin surface lipids inhibit the adherence of *Candida albicans* to the stratum corneum[41]. It seems silicone-based emollients containing natural skin lipids provide superior barrier protection without the risks associated petrolatum, lanolin and mineral oil application. In sum, underdeveloped neonatal skin may significantly benefit from Nutrashield™ and Skin Repair Cream™ application, as opposed to treatment with the currently recommended emollient Aquaphor®.

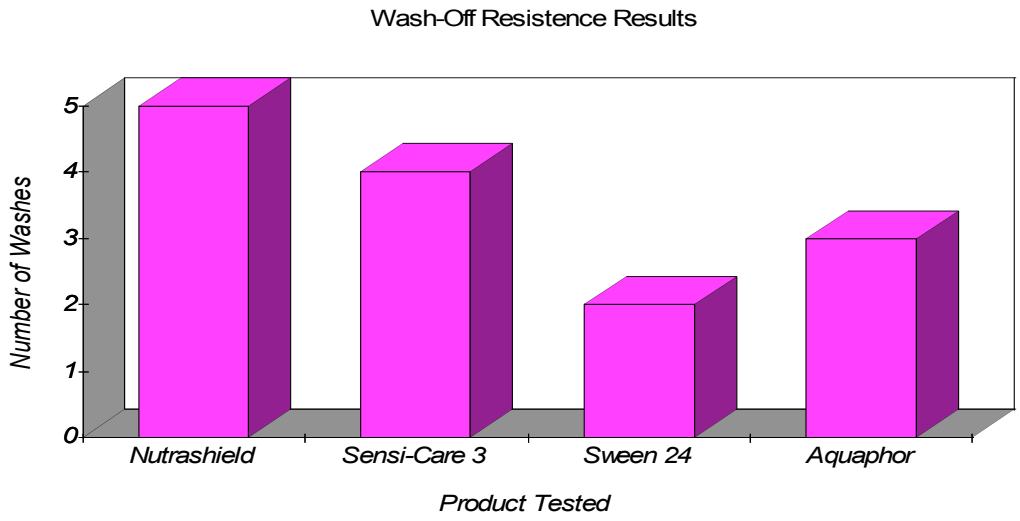

Figure V. High molecular weight silicones found in products such as Nutrashield™ maintain a protective barrier through multiple cleansing sessions. Silicone-based Nutrashield™ outperformed products containing up to 49% petrolatum, as well as petrolatum combined with 15% zinc oxide. In addition, both Sensi-Care 3® and Sween 24® contain higher concentrations of dimethicone than Nutrashield™. The extended performance of Nutrashield™ is linked to the addition of divinyldimethicone / dimethicone copolymer, which has an internal phase viscosity greater than 100,000,000 cst[36,38].

Toxicity of Ingredients Present In Recommended Neonatal Skin Care Products

Recommended neonatal emollients contain numerous hazardous ingredients that are detrimental to the development of infant skin. Aquaphor's® twenty-five year old formula consists of petrolatum, lanolin and mineral oil. Petrolatum is a fraction of petroleum, which consists of hydrocarbon molecules, including oxygen, nitrogen and sulfur atoms. The hydrocarbon constituents of petroleum form paraffins, olefins, and cycloparaffins, which are used to produce gasoline, kerosene, diesel fuel, asphalt, tar and petrolatum. The processing of petroleum to

petrolatum removes various toxins via sulphuric acid treatment and earth filtering[42]. However, petroleum contamination during the poorly regulated purification process remains a considerable risk. In sum, the toxic impurities of petrolatum provide strong evidence against the application of petrolatum-based products to sensitive neonatal skin[43,44].

Lanolin originates as a secretion from the sebaceous glands in sheepskin. The substance is removed from the wool by scouring and high-speed centrifugal separators. Thirty-three alcohols and 36 fatty acids have been identified as constituents of lanolin, including aliphatic, steroid and triterpinoid alcohols; as well as saturated nonhydroxylated, unsaturated nonhydroxylated and hydroxylated acids. Furthermore, approximately 26 pesticide residues are found in commercial lanolin, which have a concentration allowance of 40 parts per million[45]. Chemical sheep dips used to control lice and other sheep parasites commonly include organochlorine, which consists of chlorinated benzene rings, DDT, lindane, dieldrin and aldrin. Organochlorine is linked to numerous adverse side effects, most notably, the induction of serious nervous disorders[46]. Sheep dip pesticides also include synthetic parathyroid, insect growth regulators, sinuses, ivermectins and magnesium fluorosilicate. La Leche League International, a central advocate for infant health, recommends against topical lanolin application based on the substance's pesticide content[47,48]. Neonatal emollients containing lanolin may be hazardous to infant skin, including risks associated with pesticide absorption.

Mineral oil is yet another popular ingredient derived from petroleum that is found in recommended neonatal emollients. The petroleum-derivative is used industrially in machine shops as a cutting fluid and lubricating oil. Similar to petrolatum, mineral oil is highly

flammable and imposes the risk of occluding the skin, thus trapping microorganisms and toxins between the stratum corneum and the applied barrier. Consequently, the skin becomes irritated, infected and incapable of performing proper barrier functions. Moreover, the FDA requires infant skin care products such as Johnson's® baby oil to print the following label warning[49]:

Do not apply to irritated skin. If rash occurs discontinue use.

Numerous reports have found that mineral oils contain strong concentrations of potent carcinogens, namely polycyclic aromatic compounds. Roy *et al.* compared the mutagenicity, polynuclear aromatic compound content and skin carcinogenicity of a series of petroleum-derived mineral oil mixtures. The study found that mineral oil carcinogens are strongly linked to mutagenic and dermal carcinogenic activities[50]. Therefore, mineral oil application to underdeveloped neonatal skin may contribute to barrier breakdown and dysfunction.

Discussion

Neonatal skin care is an emerging science. Since the reduced risk of infant mortality is paramount, improved infant skin care treatments deserve thoughtful consideration. Current recommended neonatal emollients may pose significant risks associated with flammability, occlusion, microbial contamination and toxicity. The body weight to skin ratio of preterm neonates is four times greater than the body weight to skin ratio of adults[51]. Therefore, utilizing modern emollient technologies in order to provide proper infant skin care is appropriate. The application of products containing petrolatum, lanolin and/or mineral oil should be avoided. Instead, semipermeable silicone-based emollients with natural skin lipids should be considered. Further research is necessary to confirm which emollients are most suitable for providing proper skin treatment in the NICU.

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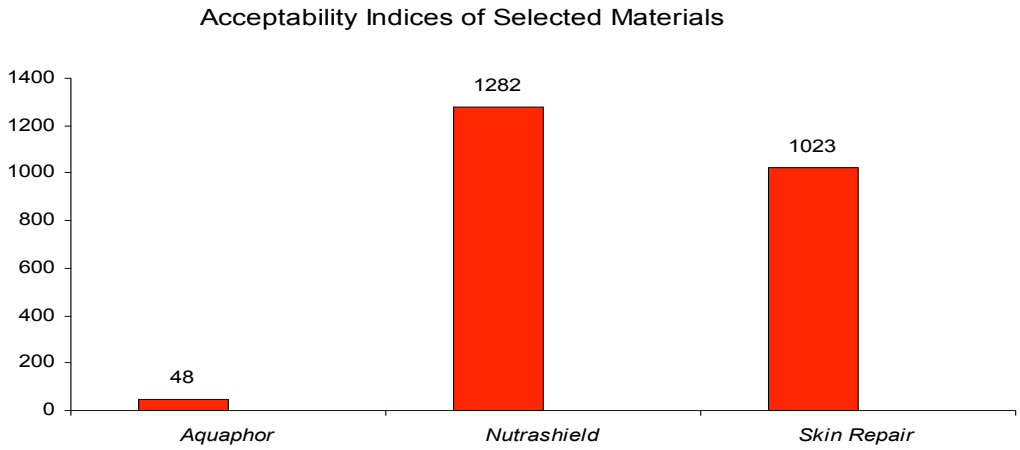
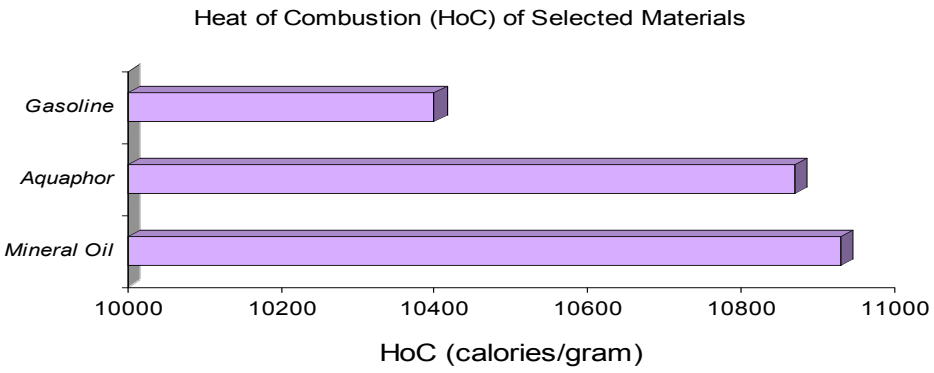
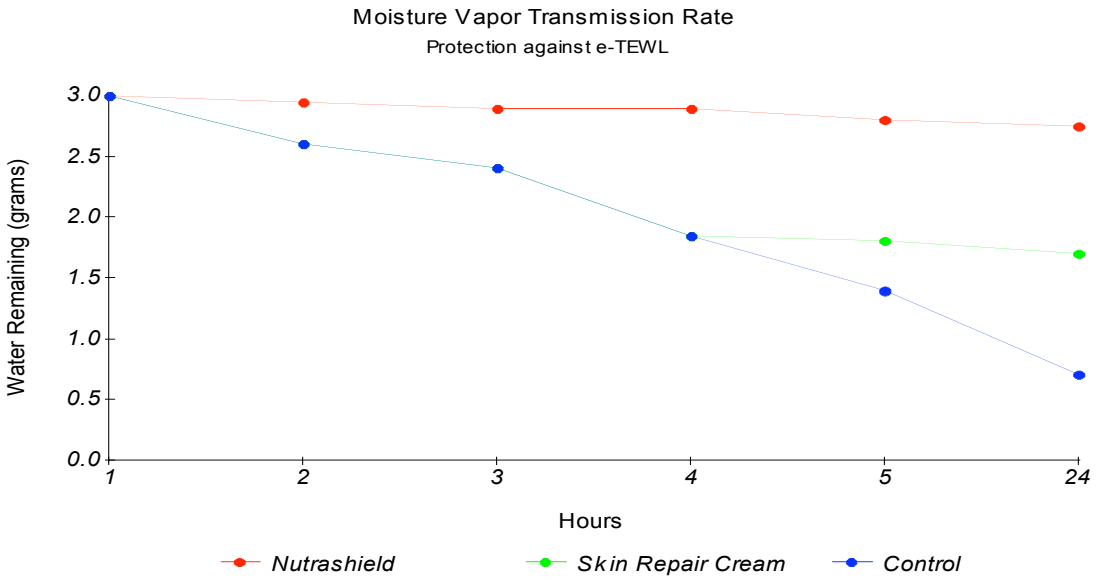
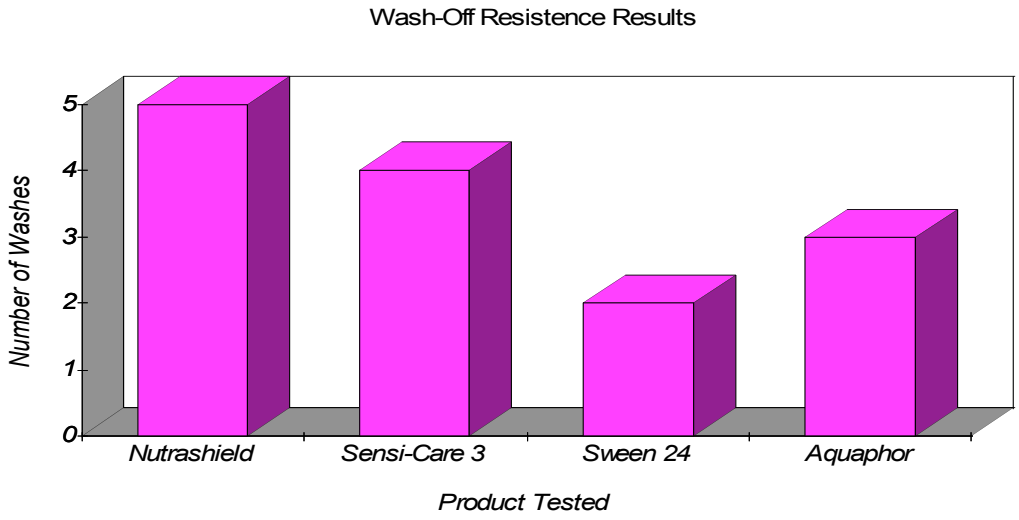

Acceptability Indices of Selected Materials
1400
1200
1000
800
600
400
200
0
48
1282
1023
Aquaphor
Nutrashield
Skin Repair


Heat of Combustion (HoC) of Selected Materials
Gasoline
Aquaphor
Mineral Oil
10000
10200
10400
10600
10800
11000
HoC (calories/gram)


Moisture Vapor Transmission Rate
Protection against e-TEWL
Water Remaining (grams)
3.0
2.5
2.0
1.5
1.0
0.5
0.0
1
2
3
4
5
24
Hours
Nutrashield
Skin Repair Cream
Control


Wash-Off Resistence Results
Number of Washes
0
1
2
3
4
5
Nutrashield
Sensi-Care 3
Sween 24
Aquaphor
Product Tested