

# 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<sup>1</sup>. The stratum corneum becomes fully keratinized in utero between 32 and 34 weeks gestational age<sup>2</sup>. During pregnancy in utero skin undergoes two-dimensional growth to cover the surface area of the developing embryo and fetus<sup>3</sup>. At birth, the term neonate's natural covering, the vernix, is wiped off or shed. As

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

33

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

46

#### 47 **Flammability Risks in Oxygen-Enriched Environments**

48

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

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

60

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

61

62 **Table I.** Enclosure systems combine oxygen to obtain the oxygen saturation required for infant survival. The  
 63 system provides an enriched oxygen atmosphere with an oxygen concentration most commonly between 23-90%,  
 64 although the system is capable of achieving concentrations of 100%<sup>9</sup>.

65

66

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

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

80

### 81 **Utilizing Silicone Derivatives to Diminish Flammability Risks**

82

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

90

91 Oxygen compatibility is determined via autogenous ignition temperature testing, oxygen index  
92 testing and heat of combustion testing. Emollients with a high autogenous ignition temperature,  
93 a high oxygen index and a low heat of combustion are recognized as being more compatible for  
94 application in oxygen-enriched environments<sup>17</sup>.

- 95
- 96 • Autogenous ignition temperature is a relative indication of a substance's propensity for
- 97 ignition.
- 98
- 99 • Oxygen index is a relative indication of a substance's flammability, or propensity for fire
- 100 propagation and sustained burning.
- 101
- 102 • Heat of combustion is an absolute value of a material's energy release upon burning,
- 103 which is an indication of its damage potential.

104 Furthermore, an Acceptability Index based on the above factors is used to rank the oxygen-

105 compatibility of various substances. The Index is based on the following equation<sup>18</sup>:

106

$$107 \quad \mathbf{[(\text{oxygen index})^2 \times (\text{autogenous ignition temperature})] / (\text{heat of combustion})}$$

108

109 The heat of combustion value of the industry standard, Aquaphor Healing Ointment® from

110 Beiersdorf AG, was more than five times greater than silicone-based Nutrashield™ and Skin

111 Repair Cream™ from Medline Inc. Aquaphor® had a heat of combustion value of 10869

112 calories/gram, ranking near gasoline at 10400 cal/g and mineral oil at 10930 cal/g.

113 Subsequently, Skin Repair Cream™ and Nutrashield™ received an Acceptability Index rating

114 approximately 13 times and 8 times greater than Aquaphor®, respectively<sup>17</sup>.

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116

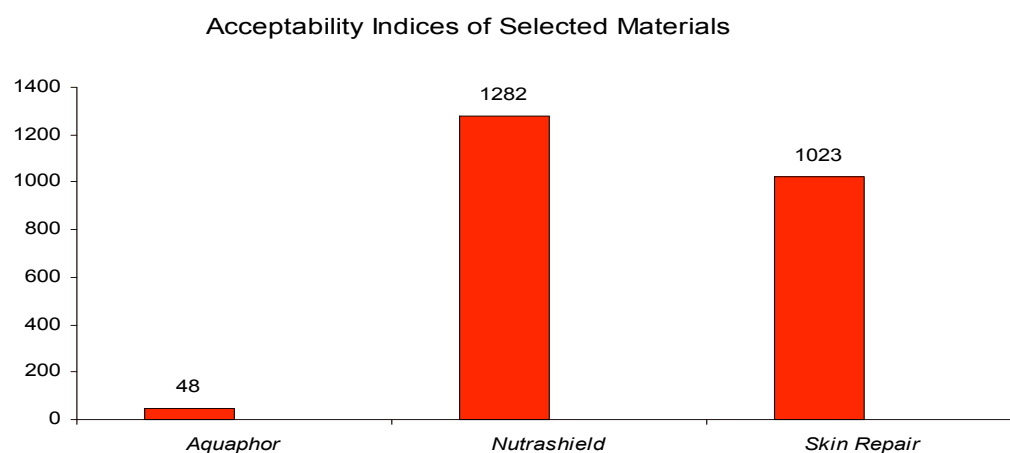
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Material	Autogenous Ignition Temperature (°C )	Oxygen Index (%)	Heat of Combustion (calories/gram)
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Aquaphor®	186	25	10869
Nutrashield™	224	55	2111
Skin Repair Cream™	179	50	1989

118  
 119 **Table III.** Autogenous ignition temperature indicates a substance's propensity for ignition; oxygen index indicates  
 120 a substance's flammability; heat of combustion is an absolute value of a material's energy release upon burning.  
 121 Oxygen compatible Nutrashield™ and Skin Repair Cream™ maintain a high oxygen index while preserving a low  
 122 heat of combustion<sup>17</sup>.

123  
 124



125  
 126 **Figure I.** The Acceptability Index is used to rank oxygen compatibility based on the following equation:

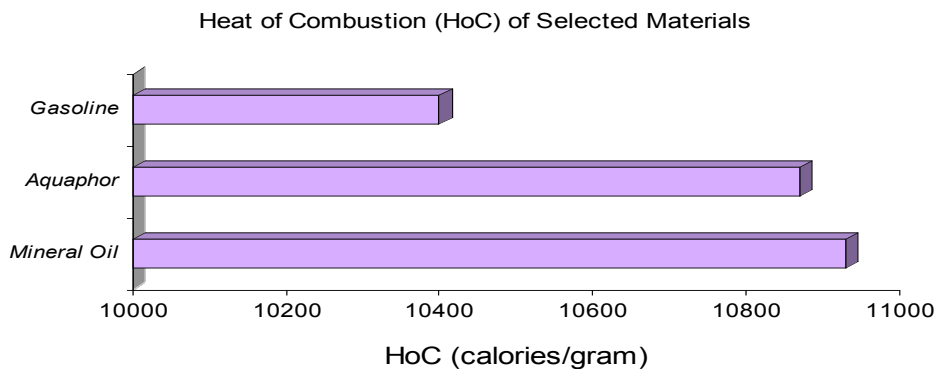
$$127 \quad [(\text{oxygen index})^2 \times (\text{autogenous ignition temperature})] / (\text{heat of combustion})$$

128 Silicone-based skin care products received substantially higher Acceptability Indices than petrolatum-based

129 products<sup>17</sup>. In particular, petrolatum-based Aquaphor® burns with an extremely high energy release, comparable

130 with gasoline<sup>18</sup>.

131



131  
132 **Figure II.** Heat of combustion is an absolute value of a material's energy release upon burning, which is an  
133 indication of its damage potential. Petrolatum-based Aquaphor® was found to have a heat of combustion greater  
134 than gasoline. Furthermore, Aquaphor® contains mineral oil, which was also found to release more energy upon  
135 burning than gasoline<sup>17</sup>.

136

137

138 Each of the following components is considered necessary for combustion to occur under  
139 standard conditions. Reducing or eliminating one or more of the combustion requirements may  
140 diminish risks associated with fire in the NICU<sup>19,20</sup>.

141

142 • Presence of burnable material (petrolatum, paraffin, etc.)

143

144 • Source of ignition (electrical systems, etc.)

145

146 • Oxygen

147

148

149 **Occlusive Barriers Reduce Transcutaneous Respiration and Sustain Microbial**

150 **Contamination**

151

152 Skin care for high-risk neonates requires knowledge of the unique anatomy and physiology of

153 infant dermis, epidermis and stratum corneum<sup>21</sup>. During the neonatal period, many infants

154 develop preventable, clinically apparent skin problems. Moreover, preterm neonates frequently

155 experience morbidity caused by compromised skin barrier integrity<sup>22</sup>. Physiological differences

156 in immature skin, especially in the epidermis and stratum corneum, place term and preterm

157 infants at significant risk of complete barrier breakdown<sup>23</sup>. In fact, one NICU study conducted at

158 All Children's Hospital in St. Petersburg, Florida found that 21% of extremely low birth weight

159 infants suffered skin breakdown during the first week of life<sup>24</sup>. In order to reduce the risk of

160 infant mortality, improving neonatal emollient treatment should be considered. Additional

161 studies are recommended to determine which products can provide proper neonatal skin care

162 while maintaining strict fire safety standards.

163

164 Application of petrolatum-based products, such as Aquaphor®, occludes the stratum corneum.

165 Occlusion is problematic because while blocking TEWL, it also reduces the transcutaneous

166 respiration necessary for normal barrier repair. It has been known since 1851 that human skin

167 consumes oxygen from the atmosphere<sup>25</sup>. Recently, Stucker *et al.* utilized the innovative oxygen

168 fluxoptode to make local measurements of the transcutaneous oxygen uptake of human skin.

169 Published data on the oxygen diffusion properties of skin and intracutaneous profiles of oxygen

170 partial pressure indicated that on normal, humidified skin, the stratum corneum and epidermis

171 are almost exclusively supplied by external oxygen up to a depth of 0.25-0.40 micrometers<sup>25,26,27</sup>.



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

179

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

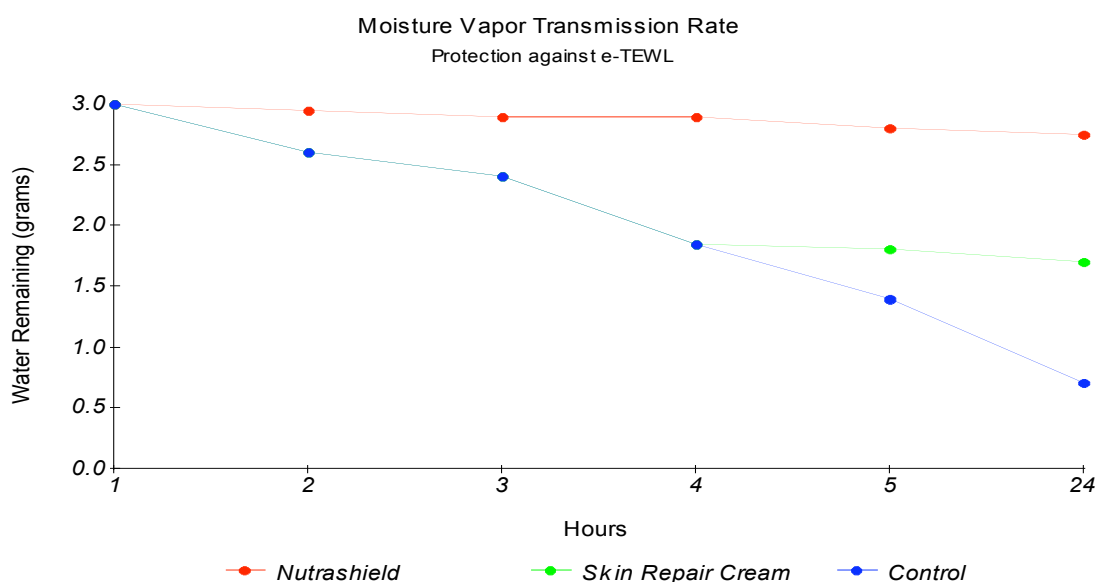
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192 **Silicone-Based Emollients Allow Transcutaneous Respiration While Preventing e-TEWL**

193

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

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



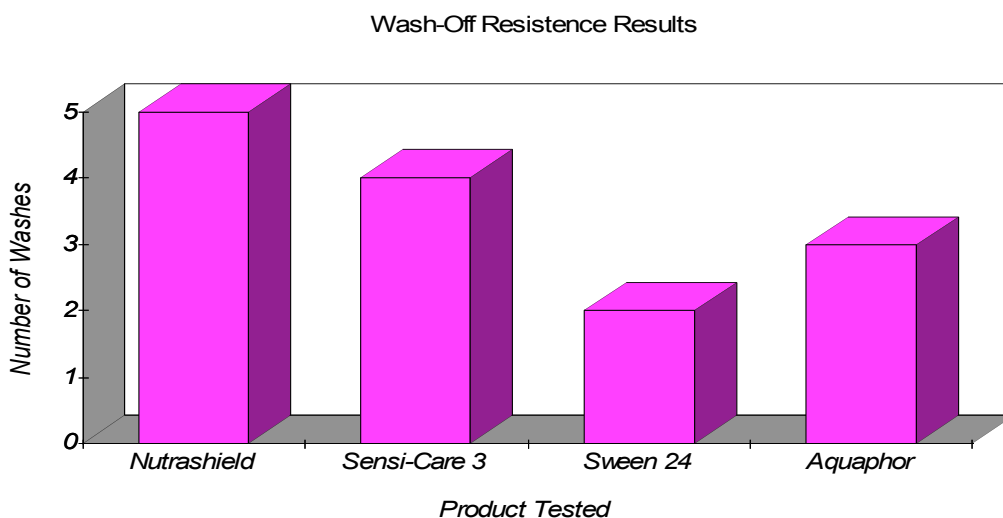
206 **Figure IV.** An *in vitro* study tested the moisture transmission rate of collagen samples coated with silicone-based  
 207 products such as Nutrashield and Skin Repair Cream. The moisture transmission rate was used as an effective  
 208 measure of e-TEWL prevention. It was concluded that both Nutrashield and Skin Repair Cream effectively reduced  
 209 e-TEWL without occlusion<sup>36</sup>.  
 210  
 211

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

220  
221 High molecular weight silicones also maintain skin protection through multiple cleansing  
222 sessions. Silicone-based Nutrashield™ was tested in a wash-off study against petrolatum-based  
223 emollients such as Aquaphor® and other recommended skin care products. The study revealed  
224 that Nutrashield™ outperformed petroleum-based emollients while providing a semipermeable  
225 barrier versus an occlusive barrier. Numerous clinical trials have concluded that silicone-based  
226 products effectively treat barrier breakdown resulting from disordered and damaged skin<sup>38,39,40</sup>.

227 Furthermore, silicone-based products that contain natural skin lipids such as omega 3 and omega  
228 6 fatty acids reduce the incidence of microbial contamination. Law *et al.* found that, dissimilar  
229 to petrolatum, skin surface lipids inhibit the adherence of *Candida albicans* to the stratum  
230 corneum<sup>41</sup>. It seems silicone-based emollients containing natural skin lipids provide superior  
231 barrier protection without the risks associated petrolatum, lanolin and mineral oil application. In  
232 sum, underdeveloped neonatal skin may significantly benefit from Nutrashield™ and Skin  
233 Repair Cream™ application, as opposed to treatment with the currently recommended emollient  
234 Aquaphor®.

235



236

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

243

## 244 Toxicity of Ingredients Present In Recommended

### 245 Neonatal Skin Care Products

246

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

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

257

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

272

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

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

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

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

287

## 288 **Discussion**

289

290 Neonatal skin care is an emerging science. Since the reduced risk of infant mortality is  
291 paramount, improved infant skin care treatments deserve thoughtful consideration. Current  
292 recommended neonatal emollients may pose significant risks associated with flammability,  
293 occlusion, microbial contamination and toxicity. The body weight to skin ratio of preterm  
294 neonates is four times greater than the body weight to skin ratio of adults<sup>51</sup>. Therefore, utilizing  
295 modern emollient technologies in order to provide proper infant skin care is appropriate. The  
296 application of products containing petrolatum, lanolin and/or mineral oil should be avoided.

297 Instead, semipermeable silicone-based emollients with natural skin lipids should be considered.

298 Further research is necessary to confirm which emollients are most suitable for providing proper

299 skin treatment in the NICU.

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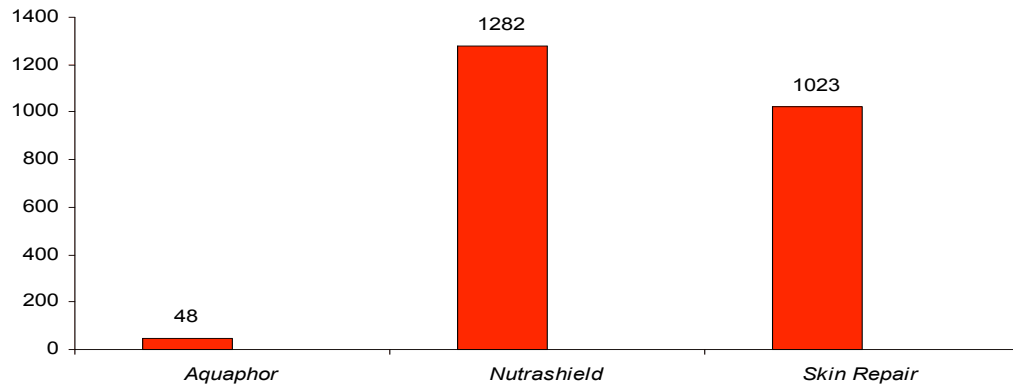
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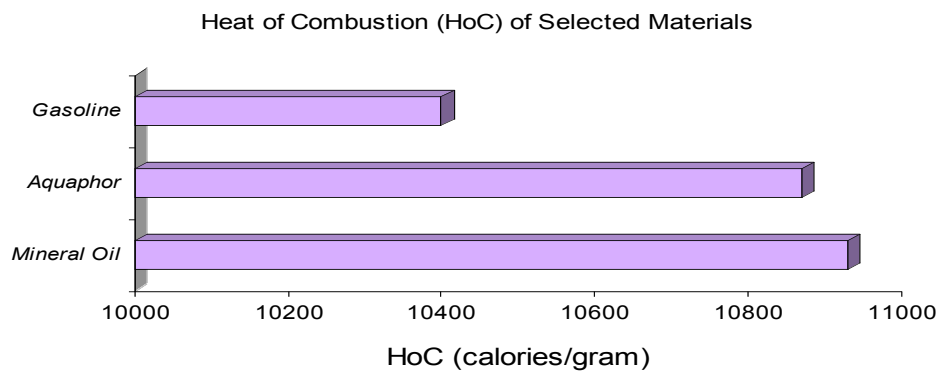
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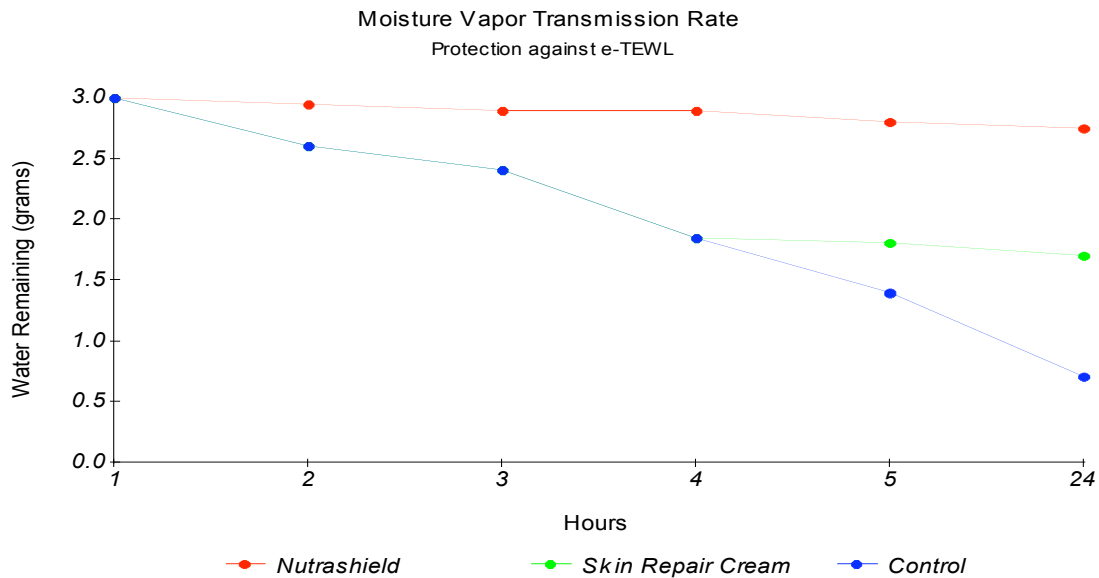
Air Flow (L/min)	Oxygen Flow (L/min)	Percent Oxygen in Enclosure System (%)
9	1	30
8	2	40
6	4	50
5	5	60
4	6	70
2.5	7.5	80
1	9	90

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

Acceptability Indices of Selected Materials









Wash-Off Resistance Results

