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INGREDIENTS

# Controversial Ingredients: One Brand's Perspective

A number of ingredients have been vilified, and ingredient myths have perpetuated. Scientific evidence suggests that some should be eliminated from formulations; the use of others, while safe according to the available scientific data, should be considered for commercial reasons related to consumer perception.

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BY ADA POLLÀ AND ANNE POUILLOT

**B**uilding a skin care brand is both exhilarating and challenging. One of the factors that contributes to both feelings, on a very regular basis, is the truism that the only constant is change. As we have worked to build Alchimie Forever over the past six years, we have changed courses a few times along the way. From medical distribution, we shifted course to spa and specialty retail. From independent sales representatives, we shifted to full-time direct sales representatives, before choosing to partner with Universal Companies as our exclusive distributor. The packaging for our men's line evolved from jars to tubes. And most recently, we decided to reformulate our products to remove two "controversial ingredients"—parabens and propylene glycol. The latter change involved significant internal debate for us, as it has for our industry as a whole in the past few years.

The following is one brand's perspective on the debate about "controversial" ingredients. We will:

- provide an overview of why certain ingredients have developed a bad reputation;
- discuss available scientific data that either supports or refutes such a reputation; and
- present which, if any, alternative ingredients are available to the industry.

In response to some activist groups perpetuating ingredient myths, we aim to separate fact from fiction, science from the so-called "junk science."<sup>1</sup> And most importantly, perhaps, we highlight two independent, sometimes complementary, reasons to change a product's formulation: science and commerce.

Let's start with a look at the most talked-about controversial ingredients.

**PRESERVATIVES: FORMALDEHYDE RELEASERS AND PARABENS**

Preservatives inhibit the development of microorganisms in cosmetic products by damaging the internal structures and cellular membranes to produce cell death. They serve to enhance the safety of cosmetic products, enabling products to remain bacteria-free over the long-term (three to five years). The controversy over the use of preservatives stems from the fact that anything that kills microorganisms is potentially toxic to mammalian cells. What needs to be taken into consideration is the concentration of these preservatives, as well as the contact time and point, which are determined to avoid side effects.

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The ideal preservative should have the following properties:

- A broad-spectrum antimicrobial effect at low concentrations and optimal pH;
- Combination of bactericidal and fungicidal effects;
- Low allergenicity and toxicity, and be nonirritating;
- Stability and water solubility;
- Compatibility with other ingredients (i.e., be both odorless and colorless); and
- Ease of use.

In 1987, a study was undertaken on 5,202 patients tested for possible contact dermatitis upon application of cosmetics; 5.9% of this population was shown to be intolerant to cosmetics. The principal allergens were fragrances and preservatives—in particular, formaldehyde and formaldehyde releasers.<sup>2</sup>

## Formaldehyde and Formaldehyde Releasers

**What are they?** While formaldehyde is a preservative that has both bactericidal and fungicidal activities, it is a strong skin sensitizer. Deutsches Institut für Medizinische Dokumentation und Information—German Institut of Medical Documentation and Information (DIMDI)—classifies formaldehyde in groups A or C, meaning it has a strong potential to provoke contact allergies.<sup>2</sup> Its use has been abandoned in cosmetics except in nail hardeners.

Formaldehyde has been replaced by formaldehyde releasers, which are easier to handle and less likely to lead to contact allergies. These formaldehyde releasers are named: 2-bromo-2-nitropropane-1,3-diol, diazolidinyl urea, DMDM hydantoin, imidazolidinyl urea, quaternium-15, sodium hydroxymethylglycinate.

**Why the bad reputation?** Formaldehyde releasers generate formaldehyde particularly when in contact with water. The chemical reaction causing the release of formaldehyde depends on many factors, i.e., pH of the formula, solution temperature and duration of product storage. All compounds do not release formaldehyde in equal amounts, which makes the assessment of the formaldehyde percentage truly present in the product during its use rather inaccurate.

**Should they be replaced?** Probably. Formaldehyde is an allergen (class A of

DIMDI). The Japanese Ministry of Health has prohibited the use of formaldehyde, and in the European Union formaldehyde is a Category 3 CMR (Carcinogen, Mutagen or Toxic to reproduction). This regulatory framework could affect formaldehyde releasers in the near future. Alchimie Forever has not used formaldehyde releasers for a number of years.

**What are the alternatives?** See the following discussion regarding the alternatives of parabens.

## Parabens

**What are they?** Parabens have been used to replace more controversial preservatives, including formaldehyde releasers. Parabens have been the subject of numerous studies that have established, in addition to their broad spectrum of action against microorganisms, their efficacy, stability and lack of side effects.

**Why the bad reputation?** In the late 1990s, several studies suggested that parabens had an estrogenic activity.<sup>3</sup> Then, in 2004, British researchers detected traces of parabens in breast tumor tissue samples.<sup>3</sup> In this study, parabens were extracted from breast tumor tissue samples and individual paraben molecules were identified, quantified and compared to those present in a control group (obtained with the same procedures of extraction but without breast tumors). Parabens were found in higher concentrations in the breast tumor tissue samples than in the control samples, but the latter also contained considerable concentrations of parabens (see Table 1).

The control samples were contaminated by parabens of an unknown source; the parabens discovered in the tumor samples could, thus, also come from an external contamination rather than from the breast tumor tissue. Despite these inconclusive results, the media widely diffused the inaccurate news: Parabens used in cosmetics, most notably in deodorants, could cause breast cancer.

Table 1: Study results of parabens in breast tumor tissue samples.

ng/g of tissue	Tumor Samples		Control Samples	
	mean	higher value	mean	higher value
methylparaben	27.09	53.0	12.8	29.3
ethylparaben	3.6	9.6	2.0	7.4
propylparaben	10.9	18.8	2.6	10.4
isobutylparaben	2.4	5.2	0.9	5.2
butylparaben	10.1	29.5	2.3	10.7
benzylparaben	0.0	0.0	0.0	0.0

The fear of parabens propagated quickly, leading consumers to ask for paraben-free products and manufacturers to embrace that demand. It should be noted, however, that regulatory bodies, both European and American, overall continue to support the use of parabens, and have recently reiterated that there is no epidemiological evidence linking parabens to breast cancer.<sup>4,7</sup>

**Should they be replaced?** Probably, although essentially for reasons linked to consumers' fears and preferences. At this point, the controversy is primarily consumer-based; there are no scientific data to conclusively prove the nefarious effects of parabens. However, there are alternatives that are as safe while enabling the industry to avoid the continued debate with consumers about parabens.

The regulatory framework may also be changing, which is another reason to replace parabens. Indeed, in France on May 3, 2011, a proposition of a law requiring a ban of parabens in all industries was submitted to the French National Assembly and was adopted. While at the time of this article's printing this is just a proposition of law, it may be an indication of the changing regulatory environment.

Finally, we have recently discovered another concern with parabens, unrelated to the consumers' misplaced fears about these ingredients. As parabens have a low aqueous solubility, they will dissolve in most systems at temperatures above 70°C. However, as parabens are slightly soluble in cold water, they tend to clump together in cold water and form crystals. Such crystals pose a challenge to formulators and may present one more reason to replace these ingredients. Alchimie Forever has decided to remove parabens from products for commercial reasons.

**What are the alternatives?** An effective preservative must be nontoxic, nonirritating and have a broad spectrum of action while providing protection at a useful range of pH levels and temperatures. A hostile environment must be created for

the growth of microorganisms, which requires optimization of the formulation and compatibility between preservatives.



Further discussion of alternatives, including a table of COSMOS-approved alternatives, is available in the online version of this feature.

"Preservative-free" formulas contain ingredients such as essential oils, which can have preservative-like qualities.<sup>8</sup> However, essential oils are also considered allergens. Indeed, in Europe, 26 essential oils must be listed on a product label if the concentration is greater than 0.001% for non-rinsed products, and 0.01% for rinsed products, because of potential allergenicity (20–30% of intolerance reactions).

Preservation through packaging should also be discussed in this context.<sup>9</sup> Indeed, brand owners may choose to move away from packaging such as jars that are consistently exposed to air and high levels of hands-on contamination and replace them with tubes or pumps that minimize the air channel and hand-to-product contact. This type of packaging allows for the use of less robust preservative systems since microorganism exposure is reduced.

Overall, we believe the current best alternative to parabens is the association of benzyl alcohol, benzoic acid and sorbic acid. This is the combination of ingredients we have chosen to replace parabens. Furthermore, as we do not believe that parabens are nefarious from a scientific perspective, we have chosen *not* to communicate this reformulation with the usual "paraben-free" verbiage, which in our opinion contributes to the consumers' misplaced fear of these preservatives.

## INGREDIENTS OF INGREDIENTS

### Cleansing agents

**What are they?** Ingredients with salts of sulfated ethoxylated fatty alcohols are primarily used in cleansing products—including bubble baths, soaps, detergents and shampoos. Among the alkyl ether sulfate ingredients, sodium laureth sulfate is most commonly used in cosmetics and personal care products. It has come to replace its family member, sodium lauryl sulfate, known to be very irritating to the skin. Sodium laureth sulfate did not yield adverse effects in a number of safety studies—including acute, subchronic and chronic oral exposure, reproductive and developmental toxicity, carcinogenicity and photosensitization studies.<sup>10</sup>

**Why the bad reputation?** Trace amounts of 1,4-dioxane, a byproduct of ethoxylation,

may be found in the salts of sulfated ethoxylated fatty alcohols. The presence of 1,4-dioxane, even as a trace contaminant,<sup>11</sup> is cause for concern because it accumulates in the body and is linked to liver and bladder cancer in animals.<sup>12</sup> Moreover, in a 2003 study, German dermatologists found that patch testing sodium laureth sulfate increased transepidermal water loss (TEWL), or dehydration of the skin.<sup>13</sup>

**Should it be replaced?** Not necessarily. The potential presence of 1,4-dioxane is well-known, and can be controlled through purification steps to minimize it from ingredients before integrating them in cosmetic formulations.<sup>14</sup> Alchimie Forever offers consumers two cleansers: one that contains sodium laureth sulfate and one that does not. We have ensured the appropriate purification steps for our foaming cleanser that does contain sodium laureth sulfate, so that 1,4-dioxane is not present in our formula. We have never used sodium lauryl sulfates.

**What are the alternatives?** Alternative detergents can be used in cosmetics—including saponins, decyl glucoside and cocoamide betaine. Saponins are natural cleansing agents found in many plants, especially those growing in desert climates. Saponins consist of polycyclic aglycones attached to one or more sugar side chains. Saponins exhibit cleansing properties because their structures contain both hydrophilic (sugar chain) and lipophilic (steroid or triterpene structure) components.

Decyl glucoside is a mild nonionic surfactant ideal for sensitive skin. However, its texture is not comparable to that of foam obtained using anionic surfactants. For this reason it is advisable to combine decyl glucoside with cocamide betaine. Cocamidopropyl betaine, the chemical name of coco betaine, is derived from coconut oil. It is used as a mild surfactant and is generally well-tolerated by sensitive skin. However some people may have allergic reactions to coconut oil derivatives.

We recommend either using alternative ingredients or minimizing its concentration<sup>15</sup> and working with manufacturers, contract formulators or internal R&D teams to verify the purification steps.

### Silicone

**What is it?** Dimethicone and methicone are silicone-based polymers, which are

derivatives of silica. The only difference between these two polymers is that the repeating unit of dimethicone contains two methyl groups, while the repeating unit of methicone contains one methyl group. These silicones facilitate the spreading of creams and yield a smooth and silky feel.<sup>16</sup>

**Why the bad reputation?** Silicone polymers have been known to form a non-oily film on the surface of the skin, which can obstruct pores. Furthermore, the synthetic origin of silicone polymers is not in accordance with some brand positioning. Although derived from a natural resource (sand), the processes necessary to obtain the actual silicone polymer have been unwelcome.

**Should it be replaced?** Not necessarily. Scientific data suggest that silicones are neither dangerous nor allergenic. Indeed silicone has been utilized in many consumer/medical products for 50 years without causing significant side effects.<sup>17</sup>

**What are the alternatives?** There is currently no alternative that provides the silky feel that silicone creates in a cosmetic product. We propose that it is adequate to keep dimethicone in formulations for which a silky texture is preferable.<sup>18</sup> Alchimie Forever uses silicone derivatives in a single product, so far without any adverse consequences on the skin such as pore-clogging.

### Mineral oil

**What is it?** Mineral oil or paraffinum oil belongs to the class of chemicals called hydrocarbons, i.e., residues from the distillation of petroleum. Mineral oil used in cosmetics is purified by a refining process. Mineral oil is used in oil phase products as an emollient because of its low volatility and smooth texture.<sup>19</sup> Mineral oil has hydrophobic effects, namely it protects the skin against moisture loss.

**Why the bad reputation?** Mineral oil is derived from petroleum. That very word has negative connotations among consumers. Furthermore, mineral oil creates a film on the skin,<sup>20</sup> potentially leading to clogged pores and obstructing the skin.

**Should it be replaced?** Probably. Consumers are increasingly rejecting raw materials derived from petroleum and hydrocarbons, and easy-to-use alternatives are available.

**What are the alternatives?** To obtain an oil phase product, natural waxes such as

candelilla and carnauba waxes can be used as alternatives to mineral oil.<sup>21</sup>

## Aluminum salts

**What are they?** Antiperspirants reduce sweat and decrease the pH of the skin, thus preventing bacteria from growing and causing foul odors. Aluminium salts, an important component in antiperspirants, minimize the sweating process by tightening pores and reducing the secretion of sweat.

**Why the bad reputation?** Exposure to aluminum via the repeated use of antiperspirant is regularly criticized and has been implicated in causing various diseases, including breast cancer.<sup>22</sup> While to this day, a link to breast cancer has not been confirmed, the transcutaneous passage of aluminum, although low, is proven.<sup>23</sup> After dermal application, the penetration of aluminum continues through hair follicles.

**Should they be replaced?** Probably. Aluminum salts can be irritating. They should not be applied to broken skin, and their use should be stopped immediately in case of itching.

**What are the alternatives?** Instead of aluminum salts, natural active ingredients such as triethyl citrate, alum stone and perlite can be used. Citric acid from the juices of cherry or currant inhibits the enzymes responsible for the decomposition of sweat. Alum stone (potassium alum) neutralizes odor and regulates perspiration without preventing the natural breathing of the skin. Perlite, a mineral extracted from volcanic rock, acts as a sponge to absorb moisture without preventing the natural breathing of the skin.<sup>24</sup> Alchimie Forever does not use aluminum salts.

## Propylene glycol

**What is it?** Propylene glycol, also known as 1,2-propanediol, is an organic alcohol. It attracts water, reduces flaking and restores the skin's suppleness. Propylene glycol is also used to help stabilize formulas and is a solvent that dissolves natural extracts.

**Why the bad reputation?** Consumers associate propylene glycol with brake and hydraulic fluids and antifreeze, not understanding that there are different grades of this product. Moreover, its effect on the skin is drying, as it will partially dissolve the intercellular cement of the

stratum corneum and decrease corneocyte cohesion, hence increasing TEWL.<sup>25</sup>

Indeed, high concentrations of propylene glycol in water kept in contact with human skin can cause irritation.<sup>26</sup> No reaction was observed when tested in the open air on human subjects. One report indicates rare eczematous skin reactions and, even more rarely, an allergic reaction following exposure to propylene glycol.<sup>27</sup>

**Should it be replaced?** Probably. In the U.S. propylene glycol is listed as GRAS (Generally Recognized As Safe) for use in food and pharmaceuticals in the U.S. Food and Drug Administration document *US—Pharmacopoeia* (Ref21CFR). However, given its use in other industries, consumers are confused and are afraid of propylene glycol. Furthermore, given its drying effect, it is best to limit its use, e.g., in the case of a difficult dissolution of an active ingredient or the use of hydroglycolic plant extracts.

**What are the alternatives?** Butylene glycol or glycerin easily replace propylene glycol as a solvent to extract plants under the same conditions. Butylene glycol has been shown to have better skin tolerance.<sup>28</sup> Oil extracts can also be used if one formulates with plants steeped in natural oils, synthetic triglycerides or synthetic fatty esters. Of course, this extraction process should be reserved for plants with liposoluble actives. Solid extracts, obtained by evaporating the solvent, can also be used. These solid extracts remain stable when introduced in the aqueous phase of formulas, yet can lead to the appearance of more- or less-visible particles. We recommend using a combination of glycerin, jojoba oil and solid plant extracts. Alchimie Forever has been working to replace propylene glycol with butylene glycol. Once again, it is primarily a question of the consumers' perception, but as there is a perfectly adequate alternative, the question really becomes, "Why not?"

## Fragrances and Phthalates

**What are they?** Phthalates are composed of a benzene ring and two carboxylate groups in ortho position; the size of the alkyl chain can vary. Phthalates are commonly used to soften plastics. In cosmetics, a single phthalate is used in the U.S., Europe and Japan: diethyl phthalate (DEP). The use of DEP prolongs the

scent of perfumes, and renders alcoholic products unfit for oral consumption.

The use of DEP as an alcohol denaturant also continues to be approved by the U.S. Alcohol Tax & Trade Bureau.<sup>29</sup> DEP is also used in nail polish so that the polish does not peel off. Another phthalate, dibutyl phthalate (DBP) is still sometimes used in nail polishes, but as it is prohibited in most countries, its use has been discontinued by many manufacturers.<sup>30</sup>

**Why the bad reputation?** Phthalates are accused of being endocrine disruptors that reduce fertility.

**Should they be replaced?** Probably. While the Scientific Committee on Consumer Products (SCCP) confirmed in 2002 and 2003 that DEP is not an endocrine disruptor,<sup>31,32</sup> the suspicion of reduced fertility is concerning enough to replace them. Moreover, given that DBP is prohibited in some countries, there is a general mistrust of the use of DEP in cosmetic products.

Finally, the regulatory environment may be changing. Indeed, the same French bill proposal that would ban parabens would also ban phthalates in all industries.

**What are the alternatives?** One alternative, of course, is to offer fragrance-free products, but many consumers still prefer cosmetic products that smell good. For brand owners who choose to continue to use fragrance, natural fragrances and synthetic fragrances formulated without phthalates are available.<sup>33</sup> At Alchimie Forever, we strongly believe in the benefits of smell and aromatherapy. The sensorial properties of our skin care products are essential to our skin care philosophy and are much appreciated by our consumers. Our fragrances are certified phthalate-free.

## Conclusion

As a skin care brand owner, I continually learn from science, from new developments in our industry and from our consumers. As such, I periodically make changes to our formulas, some of which have been discussed. A number of ingredients, such as the ones reviewed in this article, have been vilified in the past few years by various activist groups perpetuating ingredient myths. Scientific evidence suggests that some of these ingredients, i.e., formaldehyde releasers, should be eliminated from cosmetic formulations. Other ingredients, i.e., parabens,

while safe according to the available scientific data, should be eliminated for commercial reasons, and replaced with less controversial alternatives that are as safe and effective. Finally, some ingredients are adequate to formulate with, such as silicone or fragrances.

We firmly believe in our industry's ability to self-regulate, and to play a role in educating, re-educating, informing, and reassuring consumers. We firmly stand against marketing tactics that take advantage of consumers' confusion about the terms natural or organic. We also firmly stand against marketing scare tactics that focus on what is not in a product ("free of"). Finally, we firmly believe that if a brand is going to reformulate its products, it should be up front about the process and the motivations behind the change. We are indeed reformulating our products to remove parabens and propylene glycol, and doing so for commercial reasons rather than for scientific reasons. We do believe, most importantly, this change will make our products more appealing to consumers without compromising their quality of efficacy. ■ GCI

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**ADA POLLA** is the co-creator of the Swiss antioxidant skin care line Alchimie Forever, which launched in the U.S. in 2004. Her strategic focus and implementation have yielded double-digit annual revenue growth for the company. She holds an MBA from Georgetown University, majored in art history and political science at Harvard University and graduated magna cum laude with a Bachelor of Arts degree in 1998. She is also a GCI magazine editorial advisor.



**ANNE POUILLOT** joined Alchimie Forever in February 2006 as an intern, then was promoted to scientific and technical assistant. She graduated from Dijon University (France) in June 2005 with a Bachelor of Arts degree in biochemistry. In February 2006, she obtained her master's in biochemistry with a specialization in plant molecules. She is involved in the conception and formulation of Alchimie Forever products, works closely with laboratories and manufacturers, and participated in the promotion and commercial development of Alchimie Forever in Europe.