



Skin Inc, February 2012

A close-up photograph of several dark, glossy, oval-shaped capsules or pills, some with a small blue question mark on them, resting in a white container. The lighting is soft, highlighting the smooth texture and reflections on the surface of the capsules.

Controversial Ingredients: Setting the Record Straight

By Ada Polla and Anne Pouillot

Skin care is very intimate, and the beauty and cosmetics industry has to be based on trust, in addition to regulation. The regulatory framework of the industry changing, as indicated in the United States by the Safe Cosmetics Act of 2010, which was introduced in the U.S. House of Representatives on July 20, 2010. Unfortunately, the skin care industry is getting caught up in untruths, half-lies, exaggerations and sometimes misnomers.

This article will discuss ingredients that have developed a bad reputation, separating fact from opinion. Indeed, when clients come to you with ingredient questions, it is your duty as a skin care professional to educate, sometimes re-educate, and set the record straight.

This article originally appeared in the December 2011 issue of *GCI* magazine and is being reprinted with permission. All rights reserved.

58 February 2012 © Skin Inc. www.SkinInc.com Reproduction in English or any other language of all or part of this article is strictly prohibited. © 2012 Allured Business Media.

Preservatives: Formaldehyde-releasers and parabens

Preservatives inhibit the development of microorganisms in cosmetic products by damaging internal structures and cellular membranes to produce cell death. They serve to enhance the safety of cosmetic products, enabling them to remain bacteria-free for approximately three to five years. The controversy about 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.

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.¹

Formaldehyde and formaldehyde-releasers.

Although 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.² 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 and sodium hydroxymethylglycinate.

Formaldehyde-releasers have a bad reputation because they generate formaldehyde, particularly when in contact with water. The chemical reaction causing the release of formaldehyde depends on many factors, such as the pH of the formula, the solution temperature and the 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.

What are the alternatives? See the following information regarding the alternatives of parabens.

Parabens

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.

Parabens have a bad reputation because, in the late 1990s, several studies suggested that parabens had an estrogenic activity.³ Then, in 2004, British researchers detected traces of parabens in breast tumor tissue samples.⁴ 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.

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 that parabens used in cosmetics, most notably in deodorants, could cause breast cancer.

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.^{5,6}

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 is 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, the proposition of a law requiring a ban of parabens in all industries was submitted to the French National Assembly and was adopted. Although 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, another concern with parabens has recently been discovered, 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.

In regard to 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.

"Preservative-free" formulas contain ingredients such as essential oils, which can have preservative-like qualities.⁷ 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 nonrinsed 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.⁸ 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, because microorganism exposure is reduced.

Cleansing agents

Ingredients with salts of sulfated ethoxylated fatty alcohols are primarily used in cleansing

When clients come to you with ingredient questions, it is your duty to set the **record straight**.

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.⁹

These ingredients have a bad reputation because trace amounts of 1,4-dioxane, a by-product of ethoxylation, may be found in the salts of sulfated ethoxylated fatty alcohols. The presence of 1,4-dioxane, even as a trace contaminant,¹⁰ is cause for concern because it accumulates in the body and is linked to liver and bladder cancer in animals.¹¹ Moreover, in a 2003 study, German dermatologists found that patch testing sodium laureth sulfate increased transepidermal water loss (TEWL), or dehydration of the skin.¹²

These ingredients should not necessarily be replaced, however. 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.¹³

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. These 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. This 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. This is the chemical name of coco betaine, which is derived from coconut oil. It is used as a mild surfactant and is generally well-tolerated by sensitive skin. However, some clients may have allergic reactions to coconut oil derivatives.

It is recommended to either use alternative ingredients or minimize its concentration¹⁴ and work with manufacturers, contract formulators or internal R&D teams to verify the purification steps.

Silicone

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.¹⁵

Silicone polymers have a bad reputation because they have been known to form a nonoily film on the skin's surface, 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.

However, it should not necessarily be replaced. Scientific data suggests 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.¹⁶

There is currently no available alternative that provides the silky feel that silicone creates in a cosmetic product. It is adequate to keep dimethicone in formulations for which a silky texture is preferable.¹⁷

Mineral oil

Mineral oil, or *paraffinum liquidum*, belongs to the class of chemicals called hydrocarbons—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.¹⁸ Mineral oil has hydrophobic effects; namely, it protects the skin against moisture loss.

Mineral oil has a bad reputation because it is derived from petroleum. That very word has negative connotations among consumers. Furthermore, mineral oil creates a film on the skin,¹⁹ potentially leading to clogged pores and obstructing the skin.

It should probably be replaced. Consumers are increasingly rejecting raw materials derived from petroleum and hydrocarbons, and easy-to-use alternatives are available. To obtain an oil-phase product, natural waxes, such as candelilla and carnauba waxes, can be used as alternatives to mineral oil.²⁰

Aluminum salts

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.

Aluminum salts have a bad reputation because exposure to aluminum via the repeated use of antiperspirant is regularly criticized and has been implicated in causing various diseases, including

The skin care industry is getting caught up in untruths, half-lies, **exaggerations** and sometimes misnomers.

breast cancer.²¹ Although to this day, a link to breast cancer has not been confirmed, the transcutaneous passage of aluminum, although low, is proven.²² After dermal application, the penetration of aluminum continues through hair follicles.

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

Instead of aluminum salts, natural active ingredients, such as triethyl citrate, alum stone (potassium alum) and perlite, can be used as alternatives. Citric acid from the juices of cherry or currant inhibits the enzymes responsible for the decomposition of sweat. Alum stone 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.²³

Propylene glycol

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.

It has a bad reputation because 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, because it partially dissolves the intercellular cement of the stratum corneum and decreases corneocyte cohesion, hence increasing TEWL.²⁴ Indeed, high concentrations of propylene glycol in water kept in contact with human skin can cause irritation.²⁵ 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.²⁶

Propylene glycol should probably be replaced. In the United States, it is listed as GRAS (generally recognized as safe) for use in food and pharmaceuticals in the U.S. Food and Drug Administration (FDA) document US—Pharmacopoeia (Ref21CFR). However, given its use in other industries, consumers are confused and are afraid of propylene glycol. Furthermore, because of its drying effect, it is best to limit its use, especially in the case of a difficult dissolution of an active ingredient or the use of hydroglycolic plant extracts.

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.²⁷ Oil extracts can also be used if formulating 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. A combination of glycerin, jojoba oil and solid plant extracts can be used.

Fragrances and phthalates

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 United States, 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.²⁸ 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 because it is prohibited in most countries, its use has been discontinued by many manufacturers.²⁹

Work with your skin care **suppliers** in order to **ensure** you are retailing and using products that meet your ingredient expectations.

Phthalates have a bad reputation because they are accused of being endocrine-disruptors that reduce fertility. They probably should be replaced. Although the Scientific Committee on Consumer Products (SCCP) confirmed in 2002 and 2003 that DEP is not an endocrine-disruptor,^{30, 31} 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 its use 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.

One available 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.³²

Ingredient expectations

A number of ingredients have been vilified in the past few years by the media, as well as various activist groups perpetuating ingredient myths. Scientific evidence suggests that some of these ingredients, such as formaldehyde-releasers, should be eliminated from cosmetic formulations. Other ingredients, such as 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, such as silicone or fragrances, are adequate for formulation. It is important to work with your skin care suppliers in order to ensure you are retailing and using products that meet your ingredient expectations, as well as those of your clients. X

REFERENCES

1. W Broeckx, A Blondeel, A Doms-Goossens and G Achten, Cosmetic intolerance, *Contact Dermatitis* 16(4) 189-94 (1987)
2. www.dimdi.de (Accessed Dec 21, 2011)
3. EJ Routledge, J Parker, J Odum, J Ashby and JP Sumpter, Some alkyl hydroxyl benzoate preservatives (parabens) are estrogenic, *Toxicol Appl Pharm* 153 12-19 (1998)
4. PD Darbre, A Aljarrah, WR Miller, NG Coldham, MJ Sauer and GS Pope, Concentrations of parabens in human breast tumours, *J Appl Toxicol* 24 5-13 (2004)
5. www.afssaps.fr/var/afssaps_site/storage/original/application/a04645817043e01235bf03bc49f76f07.pdf (Accessed Dec 21, 2011)
6. www.fda.gov/cosmetics/productandingredient/safety/selectedcosmeticingredients/ucm128042.htm (Accessed Dec 21, 2011)
7. A Kunicka-Styczynska, M Sikora and D Kalembo, Lavender, tea tree and lemon oils as antimicrobials in washing liquids and soft body balms, *Int J Cosm Sci* 33 53-61 (2010)
8. Preservative-free and self-preserving cosmetic and drug products: Principles and practices, J Kabara and D Orth, eds, *Cosmetic Science and Technology* series 16, (1997)
9. www.cosmeticsinfo.org/ingredient_more_details.php?ingredient_id=519 (Accessed Dec 21, 2011)
10. www.fda.gov/Cosmetics/ProductandIngredientSafety/PotentialContaminants/ucm101566.htm (Accessed Dec 21, 2011)
11. JA Stickney, SL Sager, JR Clarkson, LA Smith, BJ Locey, MJ Back, R Hartung and SF Olp, An updated evaluation of the carcinogenic potential of 1,4-dioxane, *Regul Toxicol Pharmacol* 38 (2) 183-195 (2003)
12. H Löffler and R Happle, Profile of irritant patch testing with detergents: sodium lauryl sulfate, sodium laureth sulfate and alkyl polyglucoside, *Contact Dermatitis* 48(1) 26-32 (2003)
13. RE Black, FJ Hurley and DC Havery, Occurrence of 1,4-dioxane in cosmetic raw materials and finished cosmetic products, *J AOAC Int* 84(3) 666-670 (2001)
14. KP Ananthapadmanabhan, DJ Moore, K Subramanian, M Misra and F Meyer, Cleansing without compromise: The impact of cleanser on the skin

barrier and the technology of mild cleansing, *Dermatol Ther* 17(1) 16–25 (2004)

15. www.silicones-europe.com (Accessed Dec 21, 2011)

16. DP Clark, CW Hanke and NA Swanson, Dermal implants: safety of products injected for soft tissue, *J Am Acad Dermatol* 21 992–998 (1989)

17. AL Girboux and M Storch, Formulation with silicone and natural lipids, *Happi* 42(12) 100–104 (2005)

18. ME Parente, A Gambaro and G Solana, Study of sensory properties of emollients used in cosmetics and their correlation with physicochemical properties, *J Cosmet Sci* 56 175–182 (2005)

19. K Keis, CL Huemmer and YK Kamath, Effect of oil films on moisture vapor absorption on human hair, *J Cosmet Sci* 58(2) 135–145 (2007)

20. DF Williams, *Chemistry and Manufacture of Cosmetics, Vol 3, Book 2*, Allured Publishing Corp., Carol Stream, IL p 1089f (2002)

21. DK Mirick, S Davis and DB Thomas, Antiperspirant use and the risk of breast cancer, *J Natl Cancer Inst* 94(20) 1578–1580 (2002)

22. O Waswchinek, W Petek and J Lang, The determination of aluminium in human plasma, *Mikrochim Acta* 1,335–1,339 (1982)

23. GA Camacho-Bragando, F Dixon and A Colonna, Characterization of the response to moisture of talc and perlite in the environmental scanning electron microscope, *Micron* 42(3) 257–262 (2011)

24. DK Shah, S Khandavilli and R Panchagnula, Alteration of skin hydration and its barrier function by vehicle and permeation enhancers: a study using TGA, FTIR, TEWL and drug permeation or markers, *Methods Find Exp Clin Pharmacol* 30(7) 499–512 (2008)

25. C Foti, D Bonamonte D, N Cassano, A Conserva and GA Vena, Allergic contact dermatitis to propyl gallate and pentylene glycol in an emollient cream, *Australas J Dermatol* 51(2) 147–148 (2010)

26. Anderson and Starr, High concentrations of propylene glycol in water when held in contact with human skin under closed conditions have been reported to cause skin irritation, *Cosm & Toil* 99 83–91 (1984)

27. Final report on the safety assessment of butylene glycol, hexylene glycol, ethoxydiglycol, and dipropylene glycol, *J Am Coll Toxicol* 5 223–248 (1985)

28. HJ Koo and BM Lee, Estimated exposure to phthalates in cosmetics and risk assessment, *J Tox Environ Health* 67(23–24) 1901–1914 (2004)

29. EM Jackson, Subungual penetration of dibutyl phthalate in human finger nails, *Skin Pharmacol Physiol* 21(1) 10–14 (2008)

30. ec.europa.eu/health/ph_risk/committees/sccp/documents/out168_en.pdf (Accessed on Dec 21, 2011)

31. ec.europa.eu/health/ph_risk/committees/sccp/documents/out246_en.pdf (Accessed on Dec 21, 2011)

32. C Villa, B Trucchi, R Gambaro and S Baldassari, Green procedure for the preparation of scented alcohols from carbonyl compounds, *Int J Cosm Sci* 30(2) 139–144 (2008)



Ada Polla is the president, CEO and co-creator of the Swiss antioxidant skin care line Alchimie Forever. She was a founding member and is the treasurer of the Washington Spa Alliance, contributes to numerous magazines, and frequents leading universities and industry conferences as a guest speaker. She was featured on the cover of *Business Week Small Biz* and was a nominee for the Emerging Entrepreneur of the Year award for *Entrepreneur* magazine.



Anne Pouillot joined Alchimie Forever in February 2006 as an intern, then was promoted to scientific and technical assistant, when she obtained her master's degree 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.