Narrative Review Article

Non-sensitizing Alternatives to Diazolidinyl Urea and Imidazolidinyl Urea as Preservatives in Cosmetics

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ABSTRACT

Cosmetic products are often water-based and prone to growing bacteria and fungi. Therefore, preservatives like formaldehyde-releasers are used in formulations to inhibit bacterial growth, with 20% of cosmetic products in the U.S. containing at least one type of formaldehyde-releaser. Diazolidinyl urea and imidazolidinyl urea are two widely used formaldehyde-releasing agents that act as preservatives in cosmetic products by gradually decomposing to release formaldehyde. Exposure to formaldehyde and formaldehyde-releasers can irritate the skin, eyes, nose, and throat, and cause contact dermatitis in sensitized individuals, highlighting the necessity to find skin-safe alternatives. Natural compounds and essential oils like cinnamaldehyde and tea tree oil are safer and cheaper alternatives to harmful formaldehyde-releasers. Their antimicrobial effects and lower toxicity levels emphasize the need to continue researching their synergistic effects with each other in cosmetic formulations.

Keywords: cosmetics; preservatives; formaldehyde; formaldehyde-releasers; diazolidinyl urea; imidazolidinyl urea; sensitization, skin irritation

INTRODUCTION

The term cosmetics is used to refer to a broad range of products applied to the human body. The U.S. Food and Drug Administration (FDA) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance" (1). Examples of cosmetics include soaps, cleansers, moisturizers, lotions, serums, makeup (e.g., foundation, lipstick, mascara, eyeshadow), perfumes, shampoo, hair spray, deodorant, and nail polish. The components found in cosmetics are often water-based and prone to the growth of microorganisms like bacteria and fungi. For example, when a consumer dips their finger into a jar of moisturizer, they may inoculate organisms which grow and multiply quickly in the wet and nutrient-rich environment. This highlights the necessity for skin-safe cosmetic preservatives, antimicrobial agents that extend the shelf-life of products and protect consumers from expired chemicals (2).

Formaldehyde, a gaseous carcinogen, has the ability to damage DNA and proteins, which triggers apoptosis, cell death, and prevents the survival and growth of microorganisms (3). Thus, formaldehyde and, more commonly, formaldehyde-releasers that gradually release formaldehyde to prevent bacterial growth are used as preservatives in cosmetics (4). In 2009, de Groot *et al.* found that in the U.S., approximately 20% of cosmetic

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products contain at least one formaldehyde-releaser, like diazolidinyl urea, imidazolidinyl urea, bronopol, bromonitrodioxane, dimethylol-dimethyl (DMDM) hydantoin, quaternium-15, or sodium hydroxymethylglycinate (5). This work focuses specifically on imidazolidinyl urea and diazolidinyl urea as they have similar properties and are the first and third-most prevalent formaldehyde-releasers in U.S. cosmetic products, as seen in de Groot and Veenstra's study in 2010, with imidazolidinyl urea present in 7% of cosmetic products and diazolidinyl urea present in 4.5% of cosmetic products in the U.S. (6). Additionally, past studies show that diazolidinyl urea itself may cause sensitization in 2.4% to 3.7% of patients exposed to concentrations of 1% or 2% w/w, while imidazolidinyl urea itself may cause sensitization in 1.3% to 3.3% of patients when exposed to concentrations of 2% w/w (5).

Furthermore, the release of formaldehyde into cosmetics is detrimental as exposure to it or its aqueous form, formalin, can irritate the skin eyes, nose, and throat, causing contact dermatitis in sensitized individuals who have an increased probability to experience an inflammatory response (7). In studies conducted in the late 20th century, researchers tested the effects of formaldehyde exposure on skin. In 1973, Rudner *et al*. found that 43 out of 1,200 dermatology patients reacted to a solution of 2% formalin, the equivalent of 0.8% formaldehyde under an occlusive patch—a barrier that controls allergen exposure on a patch of skin (8). In 1974, Marzulli and Maibach found that 1 out of 5 formaldehyde-sensitized patients react to formaldehyde at a concentration of 0.01% or lower (9).

A vast number of people use cosmetics globally, and diazolidinyl urea and imidazolidinyl urea's harmful effects on human health show the necessity of finding non-sensitizing alternatives for use as cosmetic preservatives. In current research, there is a lack of an integrated, comparative evaluation of alternatives to formaldehyde-releasers and their antimicrobial efficacy, sensitization risk, and formulation feasibility.

Considering that modern formaldehyde quantities in cosmetic products fall within sensitization ranges, the present work aims to review alternative, non-formaldehyde releasing agents, their antimicrobial activity and potential for skin sensitization, and the process of formaldehyde release for diazolidinyl urea and imidazolidinyl urea. This paper also seeks to analyze whether the alternatives can serve as viable replacements mechanistically and economically.

NATURAL PRODUCT PRESERVATIVES

Carbohydrates, sugars, oils, proteins, and water are nutrient sources for bacteria that allow them to thrive in warm environments. Common pathogenic micro-organisms that are found in cosmetics include *Escherichia coli* (*E. coli*), *Burkholderia cepacia*, *Klebsiella oxytoca*, *Staphylococcus aureus* (*S. aureus*), *Pluralibacter gergoviae*, *Candida albicans* (*C. albicans*), *Pseudomonas aeruginosa* (*P. aeruginosa*), and *Serratia marcescens* (10). In cosmetics, microorganisms cause discoloration, changes in consistency (i.e. sedimentation of suspended ingredients or loss of viscosity), and odors (11). Exposure to bacteria like *Staphylococcus spp.* and *P. aeruginosa* can cause eye infections (10). In some rare cases, bacteria exposure can cause allergic contact dermatitis, skin irritation, or infection, especially if exposed to the mouth, eyes or wounds (11). Since cosmetics are a whole-body industry, these exposures are of serious concern and are not limited to the above risks.

Table 1 below shows ten compounds commonly found in essential oils and their usages and limitations in cosmetics. Reported findings from past studies show that their antimicrobial properties extend to

Table 1. *Cosmetic Uses, Minimum Inhibitory Concentrations (MICs; μg/mL or % v/v) Against Common Microbes, and Limitations of Ten Natural Compounds Found in Essential Oils or Foods.*

Natural Compound	Cosmetic use	Target Microbes and MICs	Limitations	References
Limonene cyclic monoterpene found in essential oils of citrus fruits	Fragrance (citrus scent)	7.0 μg/mL: *Bacillus subtilis (B. subtilis)* 8.0 μg/mL: *Staphylococcus epidermidis (S. epidermis), S. aureus* 10.0 μg/mL: *E. coli, P. aeruginosa*	Skin irritant at high concentrations and oxidizes into limonene oxide and limonene hydroperoxides which have greater potential for irritation and sensitization	(12, 13)

Continued Table 1. *Cosmetic Uses, Minimum Inhibitory Concentrations (MICs; µg/mL or % v/v) Against Common Microbes, and Limitations of Ten Natural Compounds Found in Essential Oils or Foods.*

Natural Compound	Cosmetic use	Target Microbes and MICs	Limitations	References
Linalool acyclic monoterpenoid found in essential oils of lavender, citrus, and coriander	Fragrance (floral scent)	4.0 µg/mL: *B. subtilis, S. epidermidis* 5.0 µg/mL: *S. aureus* 6.0 µg/mL: *E. coli* 7.0 µg/mL: *P. aeruginosa*	Mild skin irritant at 32% concentration	(12, 14)
Carvacrol monoterpenoid phenol found in essential oils of oregano and thyme	Fragrance (spice scent) and antimicrobial agent for acne-treatment and deodorant	20 µg/mL: *S. aureus* 250 µg/mL: *S. epidermidis* 500 µg/mL: *E. coli, P. aeruginosa, C. acnes*	Volatile, hydrophobic, and sensitive to degradation in aqueous solutions	(12, 15, 16)
Eucalyptol monoterpenoid and bicyclic ether found in essential oils of eucalyptus	Fragrance (mint scent) and cooling sensation	4000 µg/mL: *S. epidermidis, B. subtilis* 5000 µg/mL: *S. aureus* 7000 µg/mL: *P. aeruginosa, C. acnes*	Skin irritant at high concentrations and Toxic when ingested	(12, 17, 18)
Triacetin triglyceride found in fats and oils but produced synthetically	Solvent and plasticizer	22400 µg/mL: *Bacillus cereus (B. cereus), B. subtilis, E. coli, S. aureus*	Potential skin irritant at high concentrations (based on animal testing) but generally recognized as safe by the FDA	(19, 20)
Cinnamaldehyde phenylpropanoid found in essential oil of cinnamon trees	Fragrance (cinnamon scent)	0.25 µg/mL: *E. coli, S. aureus, P. aeruginosa*	Skin irritant at high concentrations (10/63 volunteers at 3% and 5/5 volunteers at 8%) and volatile	(21, 22)
Menthol monoterpenoid found in essential oils of mint plants	Fragrance (mint scent) and cooling sensation	0.5 µg/mL: *B. subtilis* 1.0 µg/mL: *S. epidermidis, S. aureus, E. coli* 3.0 µg/mL: *P. aeruginosa*	Skin irritant at high concentrations	(12, 23)
Geraniol monoterpenoid and alcohol found in essential oils of rose and palmarosa	Fragrance (floral scent)	2500 to 40000 µg/mL: *Streptococcus pneumoniae, S. epidermidis, S. aureus*	Skin irritant at high concentrations	(24, 25)
Terpinen-4-ol monoterpenoid and alcohol found in essential oil of tea tree	Fragrance (wood scent) and antimicrobial and anti-inflammatory agent for acne and dandruff treatment	0.25% v/v: *C. acnes* 250-2000 µg/mL: *S. aureus, P. aeruginosa, E. coli*	No skin irritation at 1.5% concentration	(26, 27, 28)
α-Pinene bicyclic monoterpene found in essential oils of pine trees and rosemary	Fragrance (pine scent)	5.0 µg/mL: *B. subtilis* 6.0 µg/mL: *S. epidermidis, S. aureus* 8.0 µg/mL: *E. coli* 10.0 µg/mL: *P. aeruginosa*	Skin irritant at high concentrations and reacts with hydroxyl radicals, nitrate radicals, or ozone to form acetone, formaldehyde, formic acid, and more	(12, 29)

a variety of organisms including skin pathogens (*S. aureus, Cutibacterium acnes)*, gut microbes (*E. coli*), environmental microbes (*Salmonella spp., P. aeruginosa*), and yeast (*C. albicans*). All the compounds except triacetin are used as fragrances, while triacetin is used as a solvent or plasticizer. Some, like terpinen-4-ol and eucalyptol, are also already used in cosmetics for acne-treatment due to their antimicrobial properties against *Cutibacterium acnes* (*C. acnes*).

The compounds presented in Table 1 have limitations when used in cosmetics. Many of the compounds may be volatile or hydrophobic. This can lead to degradation or reduced efficacy in aqueous formulations. Most can also be skin irritants, especially to highly sensitive individuals at high concentrations. Two compounds, limonene and α-Pinene, easily oxidize and become compounds with even greater potential for irritation. For some of the compounds, like eucalyptol, triacetin, and geraniol, their antimicrobial effects are present only in high concentrations, which can cause skin irritation or even contact dermatitis (18, 20, 25).

The compounds found in essential oils disrupt and damage the phospholipid structures of cytoplasmic membranes in bacterial cells due to the presence of phenols, aldehydes, and alcohols (30). Hydroxyl groups on phenols interact with bacterial cell membranes to increase membrane permeability, which induces the leakage of necessary intracellular materials like K^+ ions and adenosine triphosphate (ATP), leading to cellular depolarization and cell death (30, 31). Aldehydes and alcohols function similarly by damaging and softening bacterial cell membranes. (30, 32). Alcohols also denature proteins, ultimately leading to cell death (30). Thus, certain essential oils or combinations of essential oils may be effective in preserving cosmetics by preventing bacterial growth (30). Table 2 below shows the previous findings on the antimicrobial activities of ten essential oils extracted from various plants with potential applications in cosmetics as preservatives.

Many of the essential oils listed contain compounds listed in Table 1, like 1,8-cineole (eucalyptol), thymol, cinnamaldehyde, α-pinene, and linalool. These compounds are responsible for the essential oils' antimicrobial effects on various bacteria that can contaminate cosmetics like *Staphylococcus spp.*, *E. coli*, *P. aeruginosa*, and *Bacillus spp.* Table 2 also shows the MICs of the essential oils, with essential oils from oregano, thyme, tea tree, and cinnamon bark having the highest antimicrobial efficacy.

Table 2. *Main Components and MICs (μg/mL or %) Against Common Microbes of Ten Essential Oils*

Essential Oil	Main Components	Target Microbes and MICs	References
Tea Tree *Melaleuca alternifolia*	terpinen-4-ol: 30%-48% γ-terpinene: 10%-28% 1,8-cineole (eucalyptol): trace-15% α-terpinene: 5%-13%	0.01-2% v/v: *S. aureus* 0.11-4.36% v/v: *C. acnes* 0.14-1.79% v/v: *S. epidermidis* 0.3-0.77% v/v: *B. subtilis*	(33, 34)
Oregano *Origanum vulgare*	carvacrol: 77.61%-85.7% thymol: 1.65%-2.43%	250-8000 μg/mL: *Enterococcus faecium, E. coli* 500-4000 μg/mL: *S. aureus, Enterococcus faecalis*	(35, 36)
Thyme *Thymus vulgaris*	thymol: 47.59% γ-terpinene: 30.90% p-Cymene: 8.41%	99.2 μg/ml: *B. cereus* 99.5-204.9 μg/ml: *E. coli* 198.4 μg/ml: *S. aureus* 941 μg/ml: *P. aeruginosa*	(37, 38)
Lavender *Lavandula spp.*	linalool: 23.54%-40.68% linalyl acetate: 16.68%-33.30% 1,8-cineole: 2.22%-9.29%	0.75 μg/mL: *Aspergillus niger* 6 μg/mL: *P. aeruginosa, Bacillus spp.*	(39)
Lemongrass *Cymbopogon citratus*	citral: 30.07%-93.28%	0.06%: *S. aureus*, *B. cereus*, *B. subtilis* 0.12%: *E. coli* 0.50%: *Klebsiella pneumoniae*	(40, 41)
Rose Geranium *Pelargonium graveolens*	citronellol: 24.54%-37.5% geraniol: 6%-15.33%	22800 μg/mL: *E. coli*, *S. epidermis*	(42, 43)

Continued Table 2. *Main Components and MICs (µg/mL or %) Against Common Microbes of Ten Essential Oils*

Essential Oil	Main Components	Target Microbes and MICs	References
Rosemary *Salvia rosmarinus*	1,8-cineole: 26.54% α-pinene: 20.14% camphor: 12.88% camphene: 11.38%	0.03% v/v: *S. aureus* 0.1% v/v: *S. epidermis*, *B. subtilis*, *P. aeruginosa* 0.3% v/v: *E. coli*	(44)
Citrus Peel *Citrus spp.*	iso-limonene: 39.37% erucylamide: 28.43% citral: 23.12% limonene: 21.78%	600-5000 µg/mL: *E. coli*, *Klebsiella pneumoniae* 0.03%-1% v/v: *Mycoplasma pneumoniae*	(45)
Cinnamon Bark *Cinnamomum verum*	cinnamaldehyde: 71.50% linalool: 7.00% β-caryophyllene: 6.40% eucalyptol: 5.40%	780 µg/mL: *S. aureus* 1560 µg/mL: *B. cereus* 3125 µg/mL: *P. aeruginosa* 6250 µg/mL: *E. coli*	(46)
Peppermint *Mentha × piperita*	menthol: 40.7% menthone: 23.4%	0.062% v/v: *B. cereus* 0.125% v/v: *B. subtilis* 0.25% v/v: *S. aureus* 0.5% v/v: *E. coli*	(47, 48)

Overall, this data illustrates essential oils as potential natural alternatives to synthetic preservatives. Their antimicrobial effects may reduce the likelihood of bacterial contamination in cosmetic products. Cosmetic companies could consider incorporating these essential oils or compounds—individually or synergistically with each other—in commercial formulations, and in concentrations that are skin-safe, to extend the shelf-life of products.

FORMALDEHYDE RELEASE

To understand the properties of synthetic preservatives substantially used in commercial cosmetics, a mechanistic understanding of the decomposition and subsequent release of formaldehyde was explored. Diazolidinyl urea and imidazolidinyl urea both undergo decomposition in solution to formaldehyde. At concentrations of 0.2%, diazolidinyl urea released 191 parts per million (ppm) of formaldehyde while imidazolidinyl urea released 132 ppm (49). In essence, one mole of diazolidinyl urea releases 2.1 moles of formaldehyde during evaluations. This release of formaldehyde from imidazolidinyl urea depends on several solution parameters: pH, temperature, and storage time. As each parameter changes in an aqueous solution, formaldehyde release changes in turn (49).

A mechanism shown in Figure 1 was proposed by Taguchi *et al.* to explain the degradation pathway of diazolidinyl urea into decomposition products, releasing formaldehyde at each step (50). The first step of degradation involves a net proton transfer from the terminal alcohol of a hemiaminal to the β-tertiary amine, resulting in release of formaldehyde as a leaving group and the formation of a secondary amine. Because diazolidinyl urea starts with four hemiaminal groups, this mechanism is able to repeat through several different isomers, as seen in Figure 1. Taguchi demonstrated that (4-hydroxymethyl-2,5-dioxo-imidazolidin-4-yl)-urea (Figure 1) was a common end product of these conversions, though it still retains a hemiaminal group (50).

This mechanism explains the slow release of formaldehyde as diazolidinyl urea and imidazolidinyl urea gradually break down through a stepwise degradation to reach a stable endpoint (50, 51). This is crucial because it demonstrates that diazolidinyl urea and imidazolidinyl urea's antimicrobial efficacy is dependent on the release of formaldehyde, whereas natural alternatives use other modes of action, like direct membrane disruption, protein denaturation, or osmotic stress, that do not involve formaldehyde (30, 52).

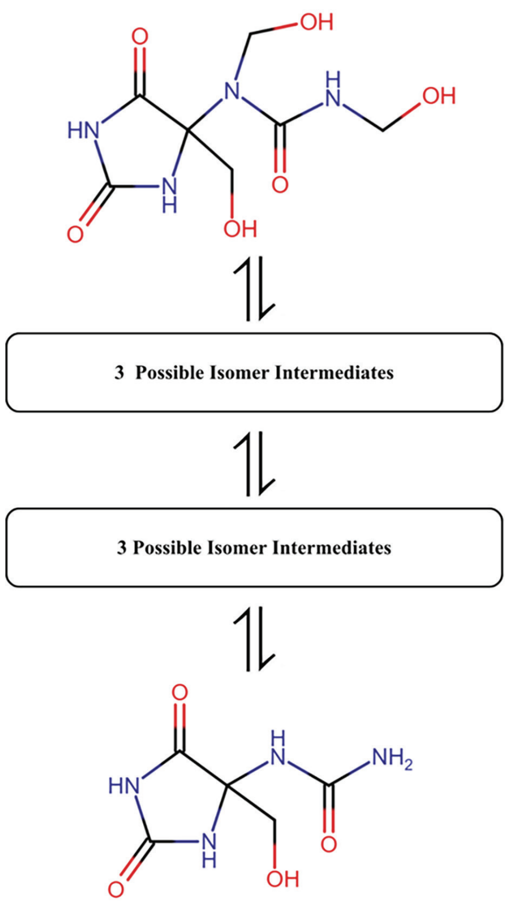

Figure 1. *Proposed decomposition pathway of diazolidinyl urea into (4-hydroxymethyl-2,5-dioxo-imidazolidin-4-yl)-urea (50).*

CONCLUSION

Many natural compounds, such as essential oils from thyme, oregano, tea tree, or cinnamon bark, as seen in Table 2, are viable cosmetic preservative alternatives to diazolidinyl urea and imidazolidinyl urea due to their antimicrobial efficacy at concentrations under the threshold for skin irritation. Molecules such as cinnamaldehyde are abundant in the environment and pleasing to smell. Additionally, some natural compounds are less expensive to obtain than diazolidinyl urea and imidazolidinyl urea. Sigma Aldrich, which sells chemicals, biochemicals, and laboratory equipment, prices diazolidinyl urea at $0.74 per gram and imidazolidinyl urea at $1.16 per gram (costs obtained from bulk prices listed on Sigma Aldrich's company website), while cinnamaldehyde costs $0.16 per gram and linalool costs $0.30 per gram (53). Thus, using natural preservatives may be substantially cost-effective for cosmetic companies (53).

Although it may be plausible that a cure-all essential oil which exhibits antimicrobial effects against all types of bacteria at all concentrations does not exist, it may be possible for companies to create synthetic essential oils that combine potent, natural, and less sensitizing small molecules for preserving cosmetics. Research can be conducted on the synergistic effects of various compounds or essential oils to assess their antimicrobial activity and degree of sensitization within cosmetic formulations.

As such, Tables 1 and 2 above are not an exhaustive list—they do not cover every known natural compound that has potential to act as a preservative. Therefore, there remain many prospects to explore other compounds and essential oils, formulation stability, synergistic preservative systems, and long-term sensitization data in real-world cosmetic use for the sake of consumer safety. For the benefit of both manufacturers and consumers, it is crucial to use safer, cheaper, and more sustainable cosmetic preservative alternatives.

CONFLICT OF INTEREST

The author declares that there are no conflicts of interest related to this work

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