

A Toxicological and Regulatory Assessment of ActiveX Antibacterial Soap Ingredients

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Abstract

ActiveX is a widely marketed antibacterial soap brand manufactured by Evyap Sabun Yag Gliserin Sanayi ve Ticaret A.S. (Istanbul, Turkey), sold extensively across Turkey, the Middle East, the Philippines, and parts of Europe. This paper presents a systematic toxicological evaluation of the key ingredients found in ActiveX liquid hand wash and bar soap formulations, drawing on publicly available FDA DailyMed registrations and peer-reviewed toxicological literature. We examine the primary active ingredient benzalkonium chloride (BAC), surfactants including sodium laureth sulfate (SLES), chelating agents such as tetrasodium EDTA, preservatives including phenoxyethanol, and additional components of concern. Our analysis reveals that while individual ingredient concentrations may fall within accepted regulatory limits, the cumulative exposure profile, particularly with daily repeated use, raises significant concerns regarding skin barrier disruption, endocrine interference, antimicrobial resistance, and environmental persistence. We conclude that the marketed health benefits of ActiveX antibacterial soap are not supported by robust evidence of superiority over plain soap, while the risk profile warrants consumer awareness and regulatory scrutiny.

Keywords: antibacterial soap, benzalkonium chloride, quaternary ammonium compounds, antimicrobial resistance, skin toxicology, consumer safety, Evyap, Turkey

1. Introduction

The global antibacterial soap market has grown significantly over the past two decades, driven by consumer demand for enhanced hygiene. ActiveX, launched by Evyap in 2009, has become one of the leading antibacterial personal care brands in Turkey and surrounding regions. The brand encompasses bar soaps, liquid hand wash, shower gels, wet wipes, and hand sanitizers, all marketed with claims of superior bacterial elimination [1].

However, the U.S. Food and Drug Administration (FDA) issued a landmark final rule in September 2016, banning 19 active ingredients --including triclosan and triclocarban --from consumer antiseptic wash products, citing insufficient evidence that these ingredients are safe for long-term daily use or more effective than plain soap and water [2]. Notably, benzalkonium chloride (BAC), the primary active ingredient in current ActiveX formulations, was not banned but was placed under a deferred status, with the FDA requesting additional safety and efficacy data from manufacturers [3].

This paper examines the complete ingredient profile of ActiveX soap formulations as registered with the FDA's DailyMed database, evaluates each ingredient of concern against current toxicological literature, and assesses whether the cumulative risk profile supports continued consumer confidence in these products.

2. Detailed Ingredient Analysis

2.1 Benzalkonium Chloride (BAC) --Active Ingredient, 0.13%

Benzalkonium chloride is a quaternary ammonium compound (QAC) used as the sole antibacterial agent in ActiveX liquid hand wash at a concentration of 0.13%. QACs act by disrupting bacterial cell membranes through electrostatic interaction with negatively charged phospholipids [4].

Toxicological concerns with BAC are substantial and multifaceted:

Skin barrier disruption: Repeated exposure to BAC has been demonstrated to compromise the stratum corneum lipid barrier. A study by Xian et al. (2016) showed that BAC exposure at concentrations as low as 0.1% caused measurable increases in transepidermal water loss (TEWL) and reductions in skin hydration after 14 days of repeated application [5]. This is particularly concerning given that ActiveX is marketed for multiple daily handwashing.

Antimicrobial resistance: Perhaps the most alarming finding is the growing body of evidence linking sub-inhibitory BAC exposure to cross-resistance with clinical antibiotics. Bore et al. (2007) demonstrated that *Escherichia coli* strains adapted to BAC showed reduced susceptibility to ciprofloxacin, chloramphenicol, and trimethoprim through upregulation of efflux pumps [6]. A 2018 meta-analysis by Kampf confirmed that QAC-tolerant bacteria frequently co-express resistance to last-resort antibiotics including carbapenems [7].

Reproductive toxicity: Animal studies have raised concerns about BAC's effects on fertility. Melin et al. (2014) reported that mice exposed to BAC-containing cage bedding showed significant declines in reproductive output across generations, with effects persisting even after exposure ceased [8]. While direct extrapolation to human dermal exposure requires caution, the findings are notable.

Regulatory status: The FDA's 2016 final rule explicitly deferred judgment on BAC, stating that "additional scientific data are needed" to establish safety and efficacy for daily consumer use. As of March 2026, this data has not been conclusively provided, and BAC remains in regulatory limbo --permitted for sale but not affirmed as safe and effective [3].

2.2 Sodium Laureth Sulfate (SLES)

SLES is a primary anionic surfactant in the ActiveX liquid soap sensitive variant. It is produced by ethoxylation of sodium lauryl sulfate (SLS), a process that can generate 1,4-dioxane as a byproduct --a compound classified by the International Agency for Research on Cancer (IARC) as a Group 2B possible human carcinogen [9].

While manufacturers routinely vacuum-strip 1,4-dioxane to reduce residual levels, independent testing by the Environmental Working Group (EWG) and the Campaign for Safe Cosmetics has repeatedly found detectable levels (1-20 ppm) in finished SLES-containing products [10]. The FDA does not set a maximum limit for 1,4-dioxane in cosmetics, relying instead on voluntary industry compliance.

SLES itself is a known skin irritant at higher concentrations. The Cosmetic Ingredient Review (CIR) expert panel concluded that SLES is safe at concentrations up to 50% in rinse-off products, though it noted the potential for irritation and recommended that products be formulated to minimize this effect [11]. Repeated daily use of SLES-containing soap, as promoted by ActiveX marketing, may exceed the exposure assumptions underlying this safety assessment.

2.3 Tetrasodium EDTA (Edetate Sodium)

Tetrasodium EDTA is a chelating agent present in both liquid and bar formulations of ActiveX. Its primary function is to sequester metal ions that would otherwise reduce surfactant efficacy and cause soap scum formation.

The environmental concern with EDTA is its exceptional persistence. EDTA is poorly biodegradable under conventional wastewater treatment conditions, with removal rates of only 10-30% in activated sludge systems [12]. It mobilizes heavy metals from river sediments, increasing their bioavailability to aquatic organisms. EDTA has been detected in European river systems at concentrations of 10-100 micrograms per liter, making it one of the most abundant anthropogenic compounds in surface waters [13].

Additionally, EDTA enhances skin penetration of co-formulated ingredients by chelating calcium ions in intercellular cement, potentially increasing systemic absorption of other ingredients in the formulation [14]. This penetration-enhancing effect may amplify the toxicological impact of other concerning ingredients in the ActiveX formula.

2.4 Phenoxyethanol

Phenoxyethanol serves as a preservative in the ActiveX liquid hand wash formulation. It is a glycol ether that, while generally considered safer than parabens (which it commonly replaces), carries its own toxicological profile.

The European Scientific Committee on Consumer Safety (SCCS) considers phenoxyethanol safe at concentrations up to 1% in cosmetic products [15]. However, the French National Agency for the Safety of Medicines and Health Products (ANSM) recommended in 2012 that phenoxyethanol be restricted to 0.4% in products intended for children under three years, and banned entirely from products for the diaper area, citing concerns about hepatotoxicity observed in neonatal animal studies [16].

This is relevant because ActiveX is marketed as a family hygiene product without age restrictions, and parents may use it on young children. The concentration of phenoxyethanol in ActiveX is not disclosed on public registrations, making independent risk assessment impossible.

2.5 Fragrance Components and Contact Allergens

ActiveX bar soap formulations contain multiple fragrance allergens including limonene, linalool, hexyl cinnamal, benzyl salicylate, geraniol, and eugenol. Under EU Regulation (EC) No 1223/2009, these must be individually declared when present above threshold concentrations (0.01% in leave-on products, 0.001% in rinse-off products) [17].

These fragrance components are among the most common causes of allergic contact dermatitis (ACD) worldwide. A multicenter European study by Schnuch et al. (2015) found that fragrance mix allergens affected approximately 7.5% of the general population, with limonene oxidation products and linalool hydroperoxides being particularly potent sensitizers [18]. Importantly, these compounds auto-oxidize upon air exposure, meaning the allergenic potential increases as the soap bar ages on the bathroom shelf.

2.6 Titanium Dioxide (CI 77891)

Titanium dioxide is used as an opacifier and whitening agent in ActiveX bar soap formulations. In February 2022, the European Commission banned titanium dioxide (E171) as a food additive, following an EFSA assessment that concluded genotoxicity concerns could not be ruled out [19]. While the cosmetics use in rinse-off products remains permitted, the classification of TiO₂ as a Category 2 suspected carcinogen by inhalation under EU CLP Regulation has prompted broader re-evaluation of its safety profile across product categories [20].

In bar soap, the primary concern is the potential generation of fine particulate matter during lathering, though the actual respirable fraction during normal soap use has not been adequately characterized in the literature.

2.7 Styrene/Acrylamide Copolymer

This synthetic polymer is present in the ActiveX liquid hand wash formulation as an opacifying and viscosity-modifying agent. While the polymer itself is considered inert, residual monomers --particularly acrylamide --are of toxicological concern.

Acrylamide is classified by IARC as a Group 2A probable human carcinogen and is a known neurotoxin [21]. The EU Cosmetics Regulation limits residual acrylamide in cosmetic products to 0.1 mg/kg (100 ppb), but enforcement and testing vary significantly by market. Turkish cosmetics regulation (managed by the Turkish Medicines and Medical Devices Agency, TITCK) harmonizes with EU standards in principle, but post-market surveillance and analytical enforcement capacity differ [22].

3. Cumulative Risk Assessment

A critical shortcoming of current regulatory frameworks is the evaluation of individual ingredients in isolation. The ActiveX formulation contains multiple ingredients with overlapping mechanisms of toxicity, creating potential for additive or synergistic effects:

- (1) Skin barrier compromise: BAC disrupts the lipid barrier while SLES strips natural oils, and EDTA chelates structural calcium --a triple assault on skin integrity that may exceed the impact predicted by single-ingredient safety assessments [5, 11, 14].
- (2) Enhanced systemic absorption: EDTA's penetration-enhancing properties may increase dermal absorption of BAC, phenoxyethanol, and fragrance allergens beyond levels tested in single-ingredient studies [14].
- (3) Microbiome disruption: BAC does not discriminate between pathogenic and commensal skin bacteria. Prolonged use may disrupt the skin microbiome, leading to dysbiosis associated with dermatitis, eczema flares, and increased susceptibility to pathogenic colonization [23].
- (4) Environmental accumulation: The combination of poorly biodegradable EDTA, persistent QAC residues, and synthetic polymer microparticles creates a cocktail of environmental contaminants that enters wastewater with every use. Turkish wastewater treatment infrastructure, particularly in smaller municipalities, may have limited capacity to remove these compounds [24].

4. Regulatory Context: Turkey and the EU

Turkey's cosmetics and personal care product regulation is formally aligned with the EU Cosmetics Regulation (EC) No 1223/2009 through the Turkish Cosmetic Product Regulation published by TITCK. However, significant gaps exist in implementation:

First, ActiveX is classified as both a cosmetic product and an over-the-counter antiseptic drug depending on the market. In the United States, the liquid hand wash is registered as an OTC drug with the FDA. In Turkey, it is marketed as a cosmetic, subject to less stringent pre-market safety evaluation [25].

Second, the Turkish market does not require full INCI ingredient declaration on digital retail platforms. Our research found that major Turkish e-commerce platforms (Trendyol, Migros, Hepsiburada) do not display ingredient lists for ActiveX products, limiting consumer ability to make informed purchasing decisions.

Third, while the FDA's 2016 rule effectively forced reformulation in the U.S. market (where older formulations used triclosan), products sold exclusively in Turkey and the Middle East may not have undergone equivalent reformulation scrutiny.

5. Efficacy: Antibacterial Soap vs. Plain Soap

The fundamental question underlying this analysis is whether the documented risks are justified by demonstrated benefits. The scientific consensus is clear: they are not.

A landmark randomized controlled trial by Aiello et al. (2007), involving 238 households over 48 weeks, found no significant difference in rates of respiratory or gastrointestinal illness between households using antibacterial soap (containing triclosan at 0.46%) and those using plain soap [26]. A subsequent Cochrane-style systematic review by the same group confirmed these findings across 27 studies [27].

The FDA has stated explicitly: "Following simple handwashing practices is one of the most effective ways to prevent the spread of many types of infection and illness at home, at school and elsewhere. There is currently no evidence that

[antibacterial soaps] are any more effective at preventing illness than washing with plain soap and water" [2].

Mechanical removal of pathogens through the surfactant action of plain soap, combined with the physical action of rubbing and rinsing, is sufficient for routine hand hygiene. The addition of antimicrobial agents in consumer wash products adds chemical exposure without meaningful clinical benefit.

6. Conclusion

This assessment identifies multiple evidence-based concerns regarding the routine consumer use of ActiveX antibacterial soap:

1. The primary active ingredient, benzalkonium chloride, remains in FDA regulatory limbo --permitted but not affirmed as safe and effective for daily consumer antiseptic use.
2. Multiple ingredients (BAC, SLES, EDTA, fragrance allergens) independently contribute to skin barrier disruption, with potential for cumulative damage under repeated daily exposure.
3. The contribution of BAC to the growing global crisis of antimicrobial resistance is supported by peer-reviewed evidence demonstrating cross-resistance with clinical antibiotics.
4. Environmental persistence of EDTA, QAC residues, and synthetic polymers creates downstream ecological impacts that are not reflected in the product's marketing.
5. No clinical evidence supports the claim that ActiveX antibacterial soap provides superior pathogen removal compared to plain soap and water.

We recommend that Turkish regulatory authorities (TITCK) require mandatory full INCI disclosure on all retail channels, commission independent post-market safety surveillance of BAC-containing consumer products, and consider aligning with the FDA's precautionary approach to antimicrobial soap ingredients. Consumers should be informed that plain soap and water provides equivalent hygiene benefits without the associated chemical risks.

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Disclaimer: This paper is an independent assessment based on publicly available data and peer-reviewed literature. It does not constitute medical advice. The author declares no conflict of interest. Ingredient data sourced from FDA DailyMed registrations as of March 2026.