american cleaning institute®

February 25, 2025

Katherine Butler, MPH
Department of Toxic Substances Control
California Environmental Protection Agency
1001 I St.
Sacramento, California 95814

Dear CA Department of Toxic Substances Control:

The American Cleaning Institute (ACI) appreciates the opportunity to provide comments to the California Department of Toxic Substances Control (DTSC) on the Background Document on Quaternary Ammonium Compounds in Cleaning Products and Beauty, Personal Care, and Hygiene Products. In these comments, we: (1) advise that DTSC remain mindful of the preemption by U.S. Food and Drug Administration (FDA) regulations on topical antiseptics, (2) provide insights on chemical grouping strategies for QACs, (3) point to sources where DTSC can seek additional data on the environmental fate and toxicology of these substances, and (4) reference safety decisions made by other regulatory authorities.

ACI[1] is the home of the U.S. Cleaning Products Industry® and represents the $60 billion U.S. cleaning product supply chain. ACI members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors.

ACI also represents the topical antiseptics industry including manufacturers of hand sanitizers and antimicrobial washes. We lead multiple Over-the-Counter Industry Working Groups (OTC IWGs[2]) to plan, design and execute research studies on the safety and efficacy of two QACs that are active ingredients in hand hygiene products. This is an area of active research that we have been working on with the U.S. Food & Drug Administration.

Best regards,

James Kim

James Kim, PhD, DABT
American Cleaning Institute

[1] For more information: www.cleaninginstitute.org
[2] https://www.fda.gov/media/155864/download

## Introduction

Quaternary ammonium compounds (QACs) are a broad class of diverse chemicals characterized as ammonium cations with various alkyl or aryl groups. They are used in a wide variety of industrial and consumer applications due to a diverse range of properties.

In its Background Document, DTSC reiterates that all QACs have been identified as Candidate Chemicals, and outlines possible next steps that the Department may take, including: (1) conducting additional research, and (2) potentially listing one or more products containing QACs (specifically within the cleaning and personal care product categories) as Priority Products. To this end, DTSC is considering prioritizing QAC-product combinations for further research, specifically calling out products in which QACs are used as antimicrobials due to the availability of robust published toxicity and exposure data. The Department also requests additional information to fill data gaps.

ACI shares DTSC's goals of protecting human health and the environment, and appreciates the Department's effort to ensure a scientifically rigorous process by soliciting input and data from relevant stakeholders. However, we contend that the manner in which DTSC is soliciting information is premature and needs to be better informed. At the outset, we recommend that DTSC adopt a risk-based approach to reviewing and prioritizing the QAC-product combinations by considering the product specific exposures of the QACs. With this perspective, DTSC needs to review all of the available regulatory information and risk assessments on the QACs in order to determine how they could be classified or clustered, with the understanding that many QACs may not need to be evaluated in this effort. In this way, DTSC will have a clearer view of the landscape, the information needed, and the questions to ask stakeholders. To that end, we are providing links or citations to publicly available information. We would also like to extend our partnership to work with DTSC throughout this review process, as our member companies can offer regulatory and toxicological expertise.

For topical antiseptics, we would like to remind DTSC that federal law preempts regulatory requirements for over-the-counter (OTC) drugs that do not strictly align with requirements administered by the U.S. Food and Drug Administration (FDA) for such drugs. For cleaning and fabric care products, we provide insights on chemical grouping strategies and point to sources where DTSC can seek additional data and safety determinations made based on the environmental fate and toxicology of these substances. For more information, please see the comments below.

## US FDA is the Regulatory Authority for QACs in Topical Antiseptics, Preempting Any Divergent Requirements Established under State Law.

In its Background Document, DTSC states it intends to focus on identifying Priority Products in which QACs are used as antimicrobials, including hand sanitizers, antiseptic skin wipes, and antibacterial hand soaps and body washes. However – as DTSC itself acknowledges in the Background Document – topical antiseptics for hand hygiene products, including antiseptic skin wipes, hand sanitizers, and antibacterial soaps and body washes, are regulated by FDA as OTC drugs. Currently, there are two QACs that are Category III drugs that are lawfully marketed in these OTC drug product types while research supporting their general recognition as to safety and efficacy are ongoing: benzalkonium chloride (BAC) and benzethonium chloride (BZT).

Importantly, the Federal Food, Drug, and Cosmetic Act includes an express preemption provision that prohibits state governments from imposing any requirement that is "different from or in addition to, or that is otherwise not identical with" federal law.[3] Thus, any additional requirements implemented by DTSC in California law regarding the use of BAC and BZT in OTC drug products will be preempted by federal law. This would include preemption of any requirements by DTSC for manufacturers to notify DTSC within 60 days of a Priority Product listing under 22 CCR § 69503.7, or for manufacturers to conduct an Alternative Analysis under 22 CCR § 69505. Furthermore, any Regulatory Response by DTSC under 22 CCR § 69506 would also be preempted, including requirements for manufacturers to provide product information to consumers regarding BAC or BZT in OTC drugs regulated by FDA, restrictions on the use of BAC or BZT in OTC drugs that are different from or in addition to FDA's requirements, or prohibition of the sale of OTC drugs containing BAC or BZT that are otherwise lawfully marketed in accordance with FDA's requirements. Although there are some limited exceptions to the federal preemption provision (e.g. application by a state for an exemption, state requirements related to the practice of pharmacy, state requirements enacted prior to September 1, 1997), those exceptions do not apply here.

**Exclusion of QACs from the Background Document List**

In the Background Document on QACs, DTSC heavily relies on BAC and diallyldimethylammonium chloride (DADMAC) for the reasoning underlying the concerns of potential adverse impacts to human health. The inclusion of zwitterionic compounds, esterquats and polymeric quaternary ammonium compounds in the list is not justified in the Background Document except for the mention that the list was compiled from the Mintel Global New Product Database. It is important to note that both zwitterionic compounds (betaine-type chemistry) and polymeric quaternary ammonium compounds exhibit fundamentally different toxicokinetic and toxicodynamic profiles. For this reason, we recommend that DTSC consider a similar approach as the EPA and exclude the following from the review: 1) zwitterionic QACs, 2) esterquats, and 3) polyquaterniums.

1) Zwitterionic QACs.

Pooling cationic quaternary ammonium compounds (QACs) and zwitterionic QACs together in terms of safety overlooks several critical differences between these two classes of compounds. Cationic QACs carry a positive charge (Figure 1), which can lead to strong interactions with negatively charged biological membranes. This interaction can cause cell lysis and irritation, making some cationic QACs effective antimicrobials at low concentrations. In contrast, zwitterionic QACs, such as alkyl betaines and their derivatives, possess both positive and negative charges within the same molecule, rendering them overall neutral (Figure 1). This charge neutrality reduces their potential to disrupt cell membranes, making them generally milder and less irritating. Zwitterionic QACs have been thoroughly evaluated and many are on the Safer Chemicals Ingredients List (SCIL) (Table 1, Table 4, Table 5, Table 6).

[3] 21 U.S.C. § 379r.

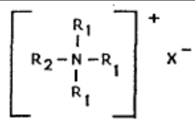
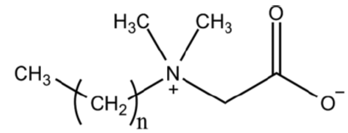
| Cationic quat | Zwitterionic quat |
|---|---|
| <br>where $R_1$ = methyl, ethyl, hydroxyethyl or hydroxypropyl<br>$R_2$ = $C_nH_{2n+1}$ or $C_nH_{2n}$; n = 8 - 18; X = any anionic species | <br>Alkyl Betaines<br>Wherein n is a value from about 10 to 22 |

**Figure 1.** Base molecular structures of a group 1 cationic QACs example (adapted from EPA clustering, 1998) and alkyl betaines as an example of zwitterionic QAC (adapted from CIR, 2018).

In terms of environmental behavior, there are also differences distinguishing these compounds. Cationic QACs tend to bind to negatively charged particles in the environment, leading to very low concentrations of dissolved QAC in aquatic systems. This binding to particles does not necessarily hinder biodegradation, as the antimicrobial QACs described in the background document (BAC and DADMAC) are readily biodegradable, have been shown to be well-removed by wastewater treatment plants and are well biodegraded in aerobic soil studies. Furthermore, they show no potential for bioaccumulation in fish and mammals (see BPR assessment reports). A key factor in evaluating the safety of QACs is their bioavailability. Research indicates that the toxicity of QACs is mainly related to their freely dissolved concentrations in water (Arnold et al., 2023; Hora et al., 2020). Organic and mineral materials in the environment can bind to QACs, reducing the amount available to cause harm. In fact, studies have shown that bioavailability can be reduced by as much as 95% (De Leo et al., 2020; Landis et al., 1993). This reduction is important to consider when interpreting laboratory studies that do not account for real-world environmental conditions, as they might overestimate the potential hazards of QACs and underestimate how easily they break down. In contrast, the zwitterionic QACs have a neutral charge, which reduces their tendency to bind to environmental particles, and have been shown to be biodegradable. For instance, betaines, a type of zwitterionic QAC, are readily biodegradable under aerobic conditions, with primary biodegradability approaching 100% for compounds like C12 alkyl betaine and cocoamidopropyl betaine, as noted by the Danish Environmental Protection Agency[4].

The toxicity profiles of these compounds also demonstrate differences. Cationic QACs, due to their interactions with cellular membranes at site of contact, have a higher potential for acute toxicity and can be more irritating to the skin, eyes and mucous membranes. The repeat dose toxicity studies on the antimicrobial QACs (BAC and DADMAC) consistently demonstrate local effects occurring at first site of contact, with any other effects (e.g., body weight loss) being secondary effects due to inflammation or irritation at site of contact (BPR Assessments; Osimitz and Droge, 2022; Luz, et al 2020). The regulatory evaluations of the data on these substances have concluded that they are not genotoxic, sensitizing, carcinogenic, or toxic to development or reproduction (BPR assessments, US EPA 2006a,b). Zwitterionic QACs generally exhibit low acute toxicity and are less irritating. The Cosmetic Ingredient Review (CIR) Expert Panel

[4] Danish Environmental Protection Agency: https://www2.mst.dk/udgiv/publications/2001/87-7944-596-9/html/kap06_eng.htm

reviewed the safety of eleven alkyl betaines used in cosmetics and concluded that these compounds are safe for use in cosmetics when formulated to be non-irritating (CIR, 2014). The assessment was based on their shared chemical core structure, similar functions, and concentrations in cosmetics, as well as the expected similarities in physicochemical properties.

Mainly, these zwitterionic compounds exhibit low systemic toxicity in single and repeated dose oral animal studies, no significant reproductive or developmental toxic effects, no genotoxicity based on in vitro and in vivo studies, and low irritation potential when formulated to be non-irritating (Table 1). Importantly, the skin sensitization potential of alkyl betaines is related to the amidoamine and 3-dimethylaminopropylamine (DMAPA) impurities, which is discussed in detail in the CIR review of cocamidopropyl betaine (CAPB) (CIR, 2012). The review panel concluded that CAPB is safe for use in cosmetic formulations provided that the content of cocamidopropyl dimethylamine (amidoamine) and DMAPA are below levels that would induce sensitization. Foti et al. (2003) studied the role of DMAPA and amidoamine and concluded that, as demonstrated in vivo, purified CAPB is not a sensitizer. In other words, skin sensitization is not an intrinsic property of CAPB and by analogy, other alkyl betaines and their derivatives. It is for this reason that publicly available data on alkyl betaines suggesting skin sensitization, including from REACH, should be understood within this context.

**Table 1**: CIR safety assessments and NICNAS public reports on zwitterionic QACs

| **Ingredient** | **Status** | **Date/Reference** |
|---|---|---|
| Almondamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Apricotamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Avocadamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Babassuamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Behenamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Behenyl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Canolamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Canolamidopropyl Betaine | Public Report | 25 November 2016 |
| Capryl/Capramidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Cetyl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Cocamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Cocamidopropyl Betaine | Published Report | JACT 10(1):33-52, 1991 |
| Coco/Oleamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Coco/Sunfloweramidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Coco-Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Cupuassuamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Decyl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Hydrogenated Tallow Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Isostearamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Lauramidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Lauryl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Meadowfoamamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |

| | | |
|---|---|---|
| Methacryloyl Ethyl Betaine/Acrylates Copolymer | Final Report | December 04, 2018 |
| Methacryloyl Ethyl Betaine/Acrylates Copolymer | Published Report | IJT 21(Suppl. 3):1-50, 2002 |
| Milkamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Minkamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Myristamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Myristyl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Oatamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Oleamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Oleyl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Olivamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Palm Kernelamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Palmamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Palmitamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Ricinoleamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Sesamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Shea Butteramidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Soyamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Stearamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Stearyl Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Tallow Betaine | Published Report | IJT 37(Suppl.1):28-46, 2018 |
| Tallowamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Undecylenamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |
| Wheat Germamidopropyl Betaine | Published Report | IJT 31(Suppl. 1):77-111, 2012 |

2) Esterquats

Esterquats, a unique group of quaternary ammonium salts (QASs) containing an ester bond in the structure of the cation, were introduced in the early 1980s as a more environmentally friendly alternative to conventional alkyl quats. They have undergone extensive review and evaluation, including detailed assessments in HERA reports (Table 2, Table 4, Table 5) and numerous scientific publications (Garcia et al., 2000; Jowsey et al, 2007). These cationic surfactants, such as the dialkyl ester of triethanol ammonium methyl sulfate (TEAQ), the di-(tallow fatty acid) ester of di-2-hydroxyethyl dimethyl ammonium chloride (DEEDMAC), and the di-[hardened tallow fatty acid] ester of 2,3-dihydroxypropyl-trimethyl ammonium chloride (HEQ), are widely used due to their effective conditioning properties and favorable environmental profile. Studies demonstrate that esterquats biodegrade well and pose no significant risk to aquatic, sediment, or terrestrial organisms. The ester bonds in the cationic structure of esterquats facilitate enzymatic and chemical hydrolysis, breaking down QACs into less toxic metabolites such as glycine betaine and fatty alcohols. As it relates to human health, toxicological studies indicate that esterquats have low toxicity, causing only mild irritation at high concentrations, and are not considered skin sensitizers or genotoxic. Repeated dose toxicity studies show that esterquats have a low level of systemic toxicity, with no major clinical effects observed even at high doses, and no evidence of genotoxicity, mutagenicity, or toxicity to the fetus (HERA, 2008).

**Table 2**: Australia NICNAS public reports on Esterquats

| Ingredient | CIR Report | Date/Reference |
|---|---|---|
| Distearoylethyl dimonium chloride | Public Report | September 2016 |
| Dioleoylethyl hydroxyethylammonium methosulfate | Public Report | December 2007 |

3) Polymeric QACs

Polymeric quats, because of their high molecular weight and polarity, have very limited absorption, limiting their systemic toxicity. This is supported by extensive safety evaluations (Table 3) that have consistently shown that polymeric QACs do not elicit systemic toxicity under normal use conditions. In the CIR reports of Polyquaternium 6 and 10, it is also noted that no inhalation toxicity was observed under experimental conditions; moreover, in the CIR review of Polyquaternium 22 and Polyquaternium 39, it is noted that incidental inhalation would not be a significant source of toxicologic concern. EPA's Interim Registration Review Decision for Polyquaternium 6 (homopolymer; CAS 26062-79-3) in December 2015 (Case Number 5024[5]) concluded that no additional data or risk assessments were needed, confirming that it is a polymeric QAC with low toxicity.

**Table 3**: CIR safety assessments and NICNAS[6] public reports on polyquaternium compounds

| Ingredient | CIR Report | Date/Reference |
|---|---|---|
| Polyquaternium-6 | Final Report | 14-Sep-21 |
| Polyquaternium-7 | Published Re-review Not Opened | IJT 30(Suppl. 2):73-127, 2011 |
| Polyquaternium-7 | Published Report | JACT 14(6):476-484, 1995 |
| Polyquaternium-10 | Published Re-review Not Opened | IJT 27(Suppl. 1):77-142, 2008 |
| Polyquaternium-10 | Published Report | JACT 7(3):335-351, 1988 |
| Polyquaternium-11 | Re-evaluation - Report not opened | 13-Jun-23 |
| Polyquaternium-11 | Published Re-review Not Opened | IJT 24(Suppl. 1):1-102, 2005 |
| Polyquaternium-11 | Published Report | JACT 2(5):161-178, 1983 |
| Polyquaternium-14 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-22 | Published Report | IJT 35(Suppl.3):47-53, 2016 |
| Polyquaternium-28 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-32 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-33 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |

[5] https://www.regulations.gov/document/EPA-HQ-OPP-2015-0255-0005

[6] National Industrial Chemicals Notification and Assessment Scheme, Australia

| | | |
|---|---|---|
| Polyquaternium-35 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-36 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-37 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-39 | Published Report | IJT 35(Suppl.3):47-53, 2016 |
| Polyquaternium-45 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-47 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-48 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-51 | Final Report | 17-Jun-22 |
| Polyquaternium-53 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-61 | Final Report | 17-Jun-22 |
| Polyquaternium-63 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-68 | Public Report | August 2009 |
| Polyquaternium-73 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |
| Polyquaternium-76 | Public Report | June 2009 |
| Polyquaternium-91 | Published Report | IJT 31(Suppl. 3):296-341, 2012 |

**QACs are too diverse to be regulated as a single group, so chemical clustering is needed.**

Due to the significant variation in chemical structures and toxicological profiles of substances classified as QACs, they cannot be appropriately regulated as a single group. DTSC should define the criteria on how to cluster the wide array of QACs such as toxicity, functionality, and biodegradability. One example of this is the U.S. Environmental Protection Agency's (EPA)[7] classification on QACs into four clusters:

- **Group I:** The alkyl or hydroxyalkyl (straight chain) substituted QACs
- **Group II:** The non-halogenated benzyl substituted QACs (includes hydroxybenzyl, ethyl benzyl, hydroxyethybenzyl, napthylmethyl, dodecyl benzyl, and alkyl benzyl)
- **Group III:** The di- and tri-chlorobenzyl substituted
- **Group IV:** QACs with unusual substituents (charged heterocyclic ammonium compounds)

Further subdivision of these clusters may be possible, which could strengthen safety assessment techniques to address data gaps (such as read-across).

Further to the physical, chemical properties and hazard profiles of QACs, their functionality and use in consumer products needs to be built into the criteria for clustering such that it enables a risk-based prioritization of additional data review. In addition, the criteria should clearly define the scope of QACs that are intentionally added and functioning in the finished good vs. incidental (functioning in the raw material) or unintentional.

[7] https://www.epa.gov/sites/default/files/2015-09/documents/pr88-2.pdf

**Data are available on QACs in Cleaning Products.**

ACI maintains an online database of cleaning product ingredients called Cleaning Chemistry Catalog[8] (C3). To determine which QACs are found within cleaning products, DTSC's list of QACs (N = 263) was cross-checked against C3, and the following matches (N = 30) were identified (Table 4).

Through the European Union's Registration, Authorization, Restriction of Chemicals (REACH) regulations[9], manufacturers and importers of regulated substances are required to submit dossiers that include physicochemical, toxicological, and eco-toxicological data to the European Chemicals Agency (ECHA). ECHA publishes information from these dossiers to their website, serving as a great resource to other regulatory and scientific authorities. Several (N = 13) of the QACs used in cleaning products have an abundance of data available through REACH dossiers, linked in Table 4. Polymeric QACs are not regulated under REACH and no Dossiers are available for those compounds. However, safety assessments on these compounds are available in Table 3 (above).

**Table 4:** Quaternary Ammonium Compounds (QACs) used in cleaning products, identified by appearance on the Cleaning Chemistry Catalog (C3). Nearly half of the identified QACs have environmental fate and toxicity data available through Registration, Authorization, Restriction of Chemicals (REACH) dossiers.

| Component | CAS # | REACH Dossier Available |
|---|---|---|
| Acrylamidopropyltrimonium Chloride/acrylamide Copolymer | 75150-29-7 | |
| Alkyl C14,C12,C16) Dimethylbenzyl Ammonium Chloride | 68424-85-1 | Yes |
| Benzalkonium Chloride | 63449-41-2 | |
| Benzalkonium Saccharinate | 68989-01-5 | |
| C12-14-Alkyl((Ethylphenyl)Methyl)Dimethyl, Chlorides | 85409-23-0 | Yes |
| Cetyl Betaine | 693-33-4 | Yes |
| Cocamidopropyl Betaine | 61789-40-0 | Yes |
| Denatonium Benzoate | 3734-33-6 | Yes |
| Diallyldimethyl Ammonium Chloride | 7398-69-8 | Yes |
| Dicocoylethyl Hydroxyethylmonium Methosulfate | 91032-11-0 | |
| Didecyldimonium Chloride | 7173-51-5 | Yes |
| Diethyl Ester Dimethyl Ammonium Chloride | 1079184-43-2 | Yes |
| Dihydrogenated Tallow Hydroxyethylmonium Methosulfate | 91995-81-2 | |
| Dipalmitoylethyl Hydroxyethylmonium Methosulfate | 161294-46-8 | |
| Distearoylethyl Dimonium Chloride | 67846-68-8 | Yes |
| Hydroxypropyltrimonium Hydrolyzed Keratin | 69430-36-0 | |
| Lauralkonium Chloride | 139-07-1 | Yes |
| Lauramidopropyl Betaine | 4292-10-8 | Yes |
| Laurtrimonium Chloride | 112-00-5 | Yes |
| Myristalkonium Chloride | 139-08-2 | Yes |

[8] https://www.cleaninginstitute.org/industry-priorities/science/cleaning-chemistry-catalog
[9] https://echa.europa.eu/regulations/reach/understanding-reach

| | | |
|---|---|---|
| PEG-15 Cocomonium Chloride | 61791-10-4 | |
| Polyquaternium-15 | 35429-19-7 | |
| Polyquaternium-33 | 69418-26-4 | |
| Polyquaternium-37 | 26161-33-1 | |
| Polyquaternium-5 | 26006-22-4 | |
| Polyquaternium-6 | 26062-79-3 | |
| Polyquaternium-7 | 26590-05-6 | |
| Polyquaternium-78 | 1023302-86-4 | |
| Quaternium-15 | 4080-31-3 | |
| Quaternium-24 | 32426-11-2 | |

The European initiative of Human and Environmental Risk Assessment (HERA), represented by members of AISE and Cefic, has conducted and published risk assessments of QACs used in cleaning products. Under the Biocidal Products Regulation, use of certain QACs for disinfectant purposes, have been evaluated and approved. The links to these assessment reports have been provided in Table 5.

**Table 5:** QACs with risk assessments for use in cleaning or disinfectant purposes.

| Component | Risk assessment |
|---|---|
| Esterquats | HH RA Report<br>Env RA Report |
| Cocamidopropyl betaine | HH RA Report |
| Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16)) | PT01 Factsheet<br>PT02 Factsheet<br>PT03 Factsheet<br>PT04 Factsheet<br>PT08 Factsheet |
| Didecyldimethylammonium chloride | PT01 Factsheet<br>PT02 Factsheet<br>PT03 Factsheet<br>PT04 Factsheet<br>PT08 Factsheet |

As these QAC-use combinations have been assessed previously, these should not be considered once again by DTSC in their review.

**EPA Safer Chemical Ingredients List.**

Several (N = 6) of the QACs used in cleaning products appear on EPA's Safer Chemical Ingredients List (SCIL)[10] (Table 6). SCIL is a list of ingredients, arranged by functional-use class, for which EPA has evaluated all available hazard information (i.e., environmental fate, toxicological data) and provided a determination to be safer than traditional ingredients. For

[10] https://www.epa.gov/saferchoice/safer-ingredients

inclusion on the SCIL, substances must pass stringent safety criteria, including: (1) no carcinogens, mutagens, or reprotoxicants (CMR), (2) no persistent, bioaccumulative, or toxic chemicals (PBT), (3) no asthmagens, (4) no sensitizers, and (5) no substances on authoritative lists of chemicals of concern.

**Table 6:** Zwitterionic QACs used in cleaning products that appear on the Safer Chemicals Ingredients List (SCIL). All have been designated with a green circle, the highest possible designation, indicating that they are verified to be of low concern based on experimental and modeled data.

| Component | CAS # | Usage | EPA Safer Choice / DfE Listing |
|---|---|---|---|
| Cetyl Betaine | 693-33-4 | Surfactants | Green Circle |
| Lauryl betaine | 683-10-3 | | Green Circle |
| Myristyl betaine | 2601-33-4 | | Green Circle |
| Cocamidopropyl betaine | 61789-40-0 | | Green Circle |
| Betaines, coco alkyldimethyl | 68424-94-2 | | Green Circle |
| Betaines, C12-14-alkyldimethyl | 66455-29-6 | | Green Circle |

**Conclusion**

The American Cleaning Institute appreciates the opportunity to provide information on QACs to the California Department of Toxic Substances Control. It is our hope that the information provided will assist DTSC in information organization because of the wide diversity in chemical and physical properties across this large group compounds. We look forward to further engagements with DTSC as you continue to evaluate product categories for the Safer Consumer Products Program.

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