Newsletter
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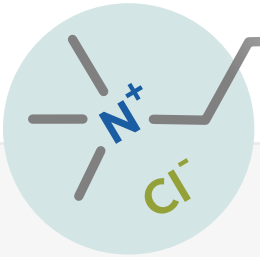

Analytica Alimentaria

Cetrimonium chloride

Pesticide or contaminant?

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Summary

- Cetrimonium chloride was detected by CVUA Stuttgart in a sample of grapes from Brazil.
- Cetrimonium chloride has surface-active and disinfectant effects and is used in a wide variety of areas, for example in cosmetics, as a biocide (disinfectant) and for finishing textiles.
- Use or approval as a pesticide active ingredient has not yet been reported in the literature.
- Nevertheless, the EU formally classifies cetrimonium chloride as a pesticide active ingredient.
- However, the applicable maximum residue limit of 0.01 mg/kg is not representative of the most likely routes of entry via different sources of contamination.
- A toxicological evaluation as a contaminant is appropriate. Cetrimonium chloride has a low toxicity.
- Analogous to the original assessment of benzalkonium chloride and DDAC when they appeared in 2012, the establishment of toxicologically derived reference values by the European Commission would be a good way to deal with cetrimonium chloride levels in food.
- In view of the high level of hygiene required as a result of the Corona pandemic, the occasional occurrence of residues from disinfectants must generally be expected.

Introduction

In April 2020, the Chemical and Veterinary Investigation Office (CVUA) Stuttgart published test results from 2019 for residues and contaminants in fruit [1]. In addition to the expected "typical" pesticide findings, a maximum level exceedance for the substance cetrimonium chloride was also reported in grapes from Brazil.

What is cetrimonium chloride?

From a chemical point of view, cetrimonium chloride belongs to the quaternary ammonium compounds family (QACs), just like benzalkonium chloride. QACs have surface-active properties, which means that they can be used as biocides for disinfection purposes among other things.

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Legal status

Plant protection products

Cetrimonium chloride falls withing the alkyltrimethylammonium chloride (ATAC) grouping which the EU considers pesticide-active substances [2]. ATACs are not approved for application as pesticides in the EU, so a default maximum residue level of 0.01 mg/kg applies (Art. 18 (1) b) EU Regulation (EC) No. 396/2005).

Biocide

Because cetrimonium chloride is able to damage the cell walls of microorganisms, the use of cetrimonium chloride is permitted as a biocide in the EU (so-called Art. 95 list of the European Chemicals Agency ECHA [3]). The US Environmental Protection Agency (EPA) also lists cetrimonium chloride as an "antimicrobial" agent [4].

Cosmetics

Due to its biocidal properties, cetrimonium chloride is used as a conditioner in hair care products (up to 2.5%) and as a preservative (up to 0.1%) (EU Cosmetics Regulation (EC) No. 1223/2009).

Other applications

Cetrimonium chloride can also be used as a disinfectant in **human and veterinary medicine**, as well as to **finish textiles**; the European Chemical Agency (ECHA) documents a number of other areas of application [5].

Rating

As shown above, there are many uses for cetrimonium chloride. It is a "multiple source" substance, meaning that a positive result cannot be clearly attributed to a pesticide application.

In the case of detection in food, the following routes of entry in particular must be considered:

Use as a biocide

Permitted use of cetrimonium chloride in biocides can lead to contamination of food, especially via surfaces, but also via hands or droplets. Typical examples include packing lines that are cleaned or disinfected, whereby residues of biocides can remain on the surfaces after cleaning and subsequently contaminate goods packed on them.

Use as a cosmetic

In some cosmetic hair care products, levels of cetrimonium chloride of up to 2.5% are permissible (according to the EU Cosmetics Regulation). This concentration is 2.5 million times higher than the above-mentioned default MRL of 0.01 mg/kg for non-approved pesticide active ingredients in food. This large difference illustrates the risk of contamination via hair care products if no sufficient protective measures are taken (e.g. hair coverings).

Other areas of application

A large number of other areas of application (see above) suggest contamination from a wide variety of sources.

Due to the wide range of possible applications, the presence of centrimonium chloride on food via contamination seems much more likely than via application as a pesticide. Furthermore, we are currently unaware of any commercially available plant protection products containing cetrimonium chloride.

In our opinion, this is fundamentally different from active substances such as matrin, whose only known source of residues in fruits and vegetables to date is from use as a plant protection product. For such cases, the so-called "default value" of 0.01 mg/kg has

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been established in order to be able to regulate every plant protection product —regardless of its approval status in the EU— with a maximum control.

Considering this information, an evaluation of cetrimonium chloride as a pesticide-active substance with the default value (0.01 mg/kg) does not seem appropriate; rather, an evaluation as a contaminant would be more appropriate.

No maximum levels for cetrimonium chloride are regulated in contaminant legislation, in particular in the EU Maximum Contaminant Levels Regulation (EC) No. 1881/2006, such that a toxicological evaluation is required.

Toxicological evaluation

According to ECHA, a NOAEL (No Observed Adverse Effects Level) of 113 mg/kg body weight was determined in animal studies [6]. From this, an acute reference dose (ARfD) of 1.13 mg/kg body weight can be derived using a safety factor of 100.

This value results in a comparatively **low acute toxicity**; only a very small percentage of the ARfD value is exhausted by cetrimonium chloride concentrations in food reported to date. The reference value mentioned is also applicable for chronic toxicity (in case of long-term intake).

Foods with non-edible peel (such as avocados, bananas, or pumpkin varieties) can be assumed to pose a particularly low toxicological risk because cetrimonium chloride as a contaminant is primarily found on the peel, which is not consumed.

Recommendations for action

In the case of positive findings, research into entry routes and ways of minimizing them is recommended to prevent legal problems in the EU.

Ideally, evaluation as a contaminant should be carried out according to toxicological criteria. Here, a case-by-case assessment is currently necessary until reference values have been set by the EU.

Analytics

In Analytica Alimentaria GmbH laboratories, cetrimonium chloride has now been integrated into the multiresidue pesticide screen and can be analyzed in routine with a 0.01 mg/kg detection limit (at no additional cost to our clients).

Literature:

Legal bases mentioned in the version valid on 11.02.2021.

Other basics:

[1] E. Scherbaum, N. Korte, K. Hacker, Chemisches und Veterinäruntersuchungsamt (CVUA) Stuttgart: Residues and Contaminants in Fresh Fruit from Conventional Cultivation, 2019, published on 15.04.2020, available online : ttps://www.cvuas.de/pesticides/beitrag_en.asp?subid=1&Thema_ID=5&ID=3167&Pdf=No&lang=EN, retrieved on 11.02.2021.

[2] European Commission: EU Pesticides Database, online verfügbar: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&as_id=320 ; abgerufen am 11.02.2021

[3] European Chemicals Agency (ECHA): Article 95 List, Prepared as of 15 January 2021

[4] US Environmental Protection Agency (EPA), Office of Pesticide Programs: Entry "Alkyl* trimethyl ammonium chloride *(70%C18, 27%C16, 3%C14)", online verfügbar: https://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:3::::1,3,31,7,12,25:P3_XCHEMICAL_ID:1157 ; abgerufen on 22.01.2021

[5] European Chemicals Agency (ECHA): Substance infocard "cetrimonium chloride", online verfügbar: https://echa.europa.eu/de/substance-information/-/substanceinfo/100.003.571, abgerufen am 11.02.2021

[6] European Chemicals Agency (ECHA): Registration Dossier, entry "Cetrimonium chloride", available online: https://echa.europa.eu/registration-dossier/-/registered-dossier/14219/7/1, accessed on 26/01/2021.

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