

ppm of the two quaternary ammonium compounds in this solution, of which this particular chemical must comprise 60%. EPA's regulation exempts this chemical substance from the requirement of a tolerance in sanitizing solutions up to 240 ppm, which is 60% of the 400 ppm authorized in the FDA regulations. The second chemical is listed in 40 CFR 180.940 as "Quaternary ammonium compounds, alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides." The end use concentration as specified in 21 CFR 178.1010(b)(22) and 21 CFR 178.1010(c)(17) for this chemical would be 40% of 400 ppm or 160 ppm. Because other solutions in 21 CFR 178.1010 included chemical substances within the description "quaternary ammonium compounds, alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides" without molecular weight limitations and/or with higher concentration limits, the description of this chemical in 40 CFR 180.940 is more broad than that of 21 CFR 178.1010(b)(22).

Based on one comment, the Agency was made aware of a typographical error in the December 3, 2002 **Federal Register** notice which has been corrected in this notice of proposed rulemaking. In 40 CFR 180.940(a) the upper limit should be not 150 ppm, but 200 ppm for C₁₂-C₁₆ benzyl dimethyl ammonium chloride (mw 351-380). With the change in upper limit to 200 ppm, C₁₂-C₁₆ benzyl dimethyl ammonium chloride (mw 351 to 380) can be appropriately held under the more inclusive quaternary ammonium compounds alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides.

Another commenter requested that the Agency change the language describing the upper limit concentration for all quaternary ammonium compounds. The commenter has suggested the use of the phrase "when ready to use, the end-use concentration is not expected to exceed 'X' ppm of this active quaternary ammonium compound," instead of the phrasing used by the Agency "when ready for use, concentration is not to exceed 'X' ppm of active quaternary compound." The commenter cited the concern that state enforcement personnel would apply the limitation for a particular quaternary ammonium compound to a mixture. The Agency believes that the language it has used is clear and concise. The concentration limits specified in 40 CFR 180.940 apply only to the chemical substance described in the particular table entry. However, the 30-day comment period will allow the Agency to take further comment on this issue.

A commenter asked that the Agency not distinguish between food-contact surfaces in public eating places, dairy-processing equipment, and food processing equipment and utensils. These categories were originally created by the FDA and reflect different assumptions especially with regard to dietary exposure to sanitizer residues, and thus are an intrinsic part of FDA's risk assessments. Although EPA has the authority to reconsider FDA's risk assessments, EPA can do so only upon fully reassessing these tolerance exemptions in accordance with FFDCA section 408, as amended by FQPA. EPA is not reassessing these tolerance exemptions at this time, but instead merely duplicating FDA's previous clearances in a format consistent with EPA's authority under FFDCA section 408. EPA is required under FFDCA section 408(q)(1)(C) to complete tolerance reassessment for all pesticide chemicals by 2006, and will consider the commenter's suggestion during tolerance reassessment.

Although not raised by commenters, EPA has made three additional changes from the December 3, 2003 **Federal Register** notice. D&C Blue No. 1 (methylene blue) is now referenced as methylene blue. Similarly, FD&C Yellow No. 5 (tartrazine) is now referenced as FD&C Yellow No. 5. A CAS No. was added to one entry (quaternary ammonium compounds, alkyl (C₁₂-C₁₈) benzyl dimethyl, chlorides) in 40 CFR 180.940(a).

V. Addition of Non-Designated, Prior Approved Chemical Substances

21 CFR 178.1010 allows the use of GRAS chemical substances and chemical substances "permitted by prior sanction or approval," that are not expressly identified. These chemical substances were subject to the sanitizer formulation approval under FDA's regulation before these uses became FFDCA section 408 tolerance exemptions under FFDCA section 408(j)(2). Accordingly, many food-contact sanitizing solutions that presently are authorized for use under 21 CFR 178.1010 contain ingredients which are not identified in this direct final rule. As discussed in this unit, EPA is asking registrants to identify these other ingredients that they believe should be included in 40 CFR 180.940. EPA intends to publish a revision to 40 CFR 180.940 adding these chemical substances. In the interim, to preserve the use of food-contact surface sanitizing solutions that were cleared for use before FQPA's enactment and that contain chemical substances that are not specifically identified in 21 CFR

178.1010, EPA has decided to honor those approvals under 21 CFR 178.1010 until EPA has received and reviewed registrant's claims with respect to unspecified pesticide chemicals, as discussed in this unit.

FDA's regulations (21 CFR 178.1010(b)) allowed the addition to food-contact surface sanitizing solutions of GRAS components, and components permitted by prior sanction or approval or subject to a letter of no objection. Much of this information should be in EPA's files. The Agency will access this information. However, EPA may not have ready access to all information on all chemicals in existing food-contact surface sanitizing solution formulations which could meet these criteria. Submission of this information to EPA would also reduce the possibility of an existing food-contact surface sanitizing solution having a component that lacks a tolerance exemption under 40 CFR 180.940. Therefore, registrants who believe that components of their food-contact surface sanitizing solutions are exempted under 21 CFR 178.1010(b) should advise EPA in writing that these chemical substances (along with the CAS No.) should be included in 40 CFR 180.940. The submission of this information facilitates EPA's process for adding these chemical substances cleared under 21 CFR 178.1010(b), but not specifically listed by name, to 40 CFR 180.940. The EPA will also need any available information documenting the claim that the component is GRAS, prior sanctioned or approved, or subject to a letter of no objection.

Claims and supporting documentation should be sent to the person listed under **FOR FURTHER INFORMATION CONTACT**. Claims are not comments on this direct final rule and should be identified on the subject line as "Submission of Non-designated Prior Approved Chemical Substance." If you have any questions about the many types of information that could be submitted please consult the person listed under **FOR FURTHER INFORMATION CONTACT**. The Agency does not anticipate that registrants will be required to submit an excessive amount of information, and, in fact, believes that most registrants will be able to submit the necessary information with minimal effort. EPA will review and evaluate the information provided. Chemical substances identified in claims received not later than October 1, 2003, may be eligible for inclusion in 40 CFR 180.940 under FFDCA section 408(j)(2). EPA anticipates publishing a notice of proposed rulemaking identifying those chemical substances shortly after that date.