

PP# 6E 4647
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PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAY 27, 1998

MEMORANDUM

SUBJECT: ID# 47870-1/PP#6E4647. Propylene Oxide on Nuts. Expiration of Time-Limited Tolerances. Chemical# 042501. DP Barcodes D245530, D245533. Case#'s 036221, 287234.

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Time-limited tolerances for residues of the fumigant propylene oxide in/on almonds, Brazil nuts, filberts, pecans, pistachio nuts, and walnuts expired on 5/20/98. The registrant (Aberco, Inc.) claims that the existing tolerance on processed nutmeats (except peanuts) (see 40 CFR 185.5150) covers the registered uses on the above nuts. We have been requested to comment on this matter.

The time-limited tolerances of 150 ppm for residues of propylene oxide on the above nuts were established in conjunction with PP#6E4647. For establishment of permanent tolerances various additional data were required such as off-gassing kinetics, time intervals for shipping and the retail shelf, residue data for propylene chlorohydrin and bromohydrin, and an independent laboratory validation for the analytical method (see 2/23/96 and 4/25/96 reviews by Steven Knizner for details). These data have not been submitted, although the registrant indicated at the 4/17/98 meeting that data are being generated to support the tolerance reassessment scheduled for 1999.

The directions for use on the label accepted in conjunction with the above petition stated "Also for the following nutmeats which are to be processed into a final form: almonds, brazil nuts, filberts (hazel nuts), pecans, pistachios, and walnuts." (Label stamped "ACCEPTED WITH COMMENTS in EPA Letter Dated: MAY 9, 1996"). The registrant claims this label is not in use. According to Aberco, the label being used specifies treatment of "processed nutmeats (except peanuts)" [label stamped "ACCEPTED OCT 31, 1995"]. A proposed label (dated 1/27/98) also has the use on "processed nutmeats (except peanuts)."

At the 4/17/98 meeting the registrant described the use on nuts and the regulatory history associated with it. Nuts are brought out of storage (still in the shell), rinsed with chlorinated water, shelled, cleaned, separated into different sized pieces and then sterilized by fumigation with propylene oxide. These nutmeats are then moved into the food processing industry for use in items such as cakes and candy.

At the meeting the registrant contended that the nutmeats being fumigated are processed commodities based on the steps (especially the shelling) that have been taken prior to propylene oxide treatment. In addition, the regulatory history was claimed to support that classification starting with FDA's amending the food additive regulation for propylene oxide at 21 CFR 121.1076 to include "processed nutmeats (except peanuts)" on May 4, 1965. Later amendments of the section 409 tolerance by EPA (including transfer from 21 CFR to 40 CFR) were similarly made by considering the nutmeats as processed commodities. Furthermore, the registrant correctly states that the section 409 tolerance for processed nutmeats was converted to a section 408 tolerance by FQPA. In the latest version of 40 CFR, this 300 ppm tolerance is still listed under 185.5150.

CONCLUSION

Although RAB2 does not necessarily agree with all of the arguments presented by the registrant, we do concur with the registrant that the 300 ppm tolerance for residues of propylene oxide in processed nutmeats (except peanuts) is in agreement with the use directions on the present (accepted 10/31/95) and proposed labels for the product (Reg. No. 47870-1). On that basis, RAB2 can agree that the time-limited tolerances for residues in/on almonds, Brazil nuts, filberts, pecans, pistachio nuts, and walnuts do not need to be renewed or extended at this time. The proper classification of these uses will be reexamined during the tolerance reassessment process. Any issues which arise concerning appropriate tolerance levels or commodities to be included in the tolerance will be addressed at that time. The registrant should be advised to generate the additional data specified in our 4/25/96 review of PP#6E4647 to support the tolerance reassessment process.

cc: RAB2 RF, Loranger, PP#6E4647
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