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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES

MEMORANDUM

Sept.4, 2006

SUBJECT: Review of the Technical Report: " The Reaction of Chlorite Ion With Raspberry Extract"

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DP Barcode: n/a
MRID#: 46944201

Background:

The premise of the study is that food/ fruits when treated (disinfected) with chlorine dioxide, convert to chlorite ion, and chlorite ion is not stable (degrades) in the matrix of fruits like raspberry or tomatoes. The rationale of the study was to help in the process of risk assessment for the chlorine dioxide and sodium chlorite RED and to show that the initial presence of chlorine dioxide and or chlorite pose no dietary concerns. The study, however, was submitted too late for consideration in the RED process. It is being reviewed now.

Study Methodology:

Fresh raspberry were purchased from a super market in California and its extracts were prepared in three concentration ranges: 0.1%, 0.5%, and 1%. Similarly analytical grade sodium chlorite solutions were prepared with nominal chlorite ion concentrations of: 100 ppb, 300 ppb and 500 ppb.

a. ***Instrumentation:*** Dionex Ion Chromatograph Model # 500 DX was used for the chlorite detection.

AS50 Dionex Autosampler
Dionex AD25 Detector Absorbance Detector operated at 450 nm wavelength
Dionex GS50 Gradient Pump set at flow rate of 1.0 ml/min
IonPac AS9-HC 4 mm Anion Exchange column, attached to an IonPac AG9-HC 4 mm Guard column
Software: Dionex PeakNet 6 was to measure the chromatographic peak height/width.
Sample vial: Dionex 2 mL sample vials with split septum were used.

b. ***Analytical Method***: EPA's Method 317 was modified for this experiment

c. ***Calibration Curve***: A calibration curve was generated in the range of 10 ppb to 500 ppb nominal concentration of sodium chlorite.

d. ***Sample Frequency***: Each sample was analyzed in duplicates. Each sample first run was carried within 67 minutes after preparation and the second run was performed in about 5 hours after the sample preparation.

e. ***Calculations***: Calculations were carried out with the measurement of the average peak area and then estimating the % remaining chlorite using the following equations:

1. Average peak area (at 100 ppb) = (Peak area for run 2 + peak area run 6)/2
2. % remaining chlorite = 100 x (peak area of unknown sample)/Average peak area(at 100ppb).

f. ***Results***: 1) Components in raspberry extract and chlorite reacted, and the amounts of chlorite was reduced at all three concentrations.
2) The reaction between these entities were time-and concentration dependent.
3) At 500 ppb nominal concentration of chlorite, the reaction was over 90% complete, i.e. chlorite concentration reduced to less than 10%.

g. ***Conclusions***: 1) Reactions proceed faster at higher concentrations of raspberry extract and chlorite nominal solutions. 2) At raspberry concentrations > 1 to 100%, the reaction is expected to be faster.

The **Agency** has noted the following **shortcomings** in the study:

1) According to the study, the raspberries were purchased in California, and the study was also conducted in California. However, no chain of command is indicated that how the purchased raspberry were transferred to the lab. In addition, what is the time-lapse between the purchase of commodity and the actual start of the experiments.
2) No attempt is made to estimate the recovery% in the study.
3) Ion chromatograms (retention times, peaks) are not provided with the study. These data should be provided by the registrants.
4) Agency encourages industry to conduct analytical studies with triplicate samples. The present study was conducted only with duplicate samples.
5) The study was not conducted according to GLP.
6) The study should be submitted through Agency's front-end office so that it can be assigned an MRID# and it becomes part of the permanent records of the Agency.

Agency Conclusions:

1) Although the study was not conducted according to the GLP, it is scientifically sound and is **acceptable** as supplement for future considerations in regards to new sodium chlorite/chlorine dioxide registrations.
2) The Agency is not convinced that at higher concentrations of raspberry, the reaction with chlorite will be necessarily a linear one (first order). Moreover,

the raspberry components may form some degradation products which are not formed at lower concentrations.

Cc: RMBII file room (NShamim)

APPENDIX

Following attachments are part of this review.

Copies of the:

1. Original data table from the study (page 4 of 28)
2. Table 1 on Page 14
3. Tables 2 and 3 from pages 15, and 16
4. Figure 1(Calibration Curve)
5. Figures 2, 3, and 4 (Percentages of residual chlorite concentration from nominal concentrations of 100, 300 and 500 ppb).