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March 24, 2000

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To Whom It May Concern:

Our company operated a generator for about 30 years based on the chemistry described by Eka Nobel. The process was originally known as the Solvay process for chlorine dioxide and reacted 12 normal sulfuric acid with sodium chlorate to form chloric acid at a pH of less than 1.0. This chloric acid was then reduced with hydrogen peroxide to form chlorine dioxide. This generating system is very sensitive to ClO_2 concentrations, and "puffs" (mini explosions) were commonplace. Early on, our plant was destroyed in an explosion, but it was rebuilt. The title of an early book on ClO_2 safety published in NY in 1949 was titled "Precautionary Fire and Explosion Safeguards in the Use of Chlorine Dioxide for Industrial Bleaching", distributed by the International Association of Fire Chiefs.

In disinfection with chlorine dioxide, it is more desirable to generate ClO_2 from chlorite solutions since the chlorite only required an easy oxidation with chlorine instead of a difficult reduction with hydrogen peroxide in a highly acid solution. The pH optimum for a chlorite generator is in the 3.5 - 4.0 range, leaving 7-8 times more unneutralized acid in the drinking water with a chlorate generator.

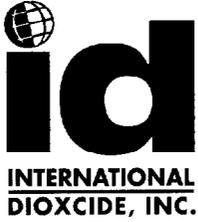
Environmentally, the process was very dirty, giving a large excess of a very acid solution which had to be neutralized. Also an excess of hydrogen peroxide had to be used to make sure all of the chlorate was reacted. If an excess was not used, unreacted chlorate or chloric acid would be in the product stream.

Another problem encountered with a chlorate generator is the possibility of perchlorate by-product formed in the presence of sulfuric acid which tends to oxidize chlorate to perchlorate in a H_2O_2 deficient reaction medium. There is no chance for a chlorite based ClO_2 generator to produce perchlorate, a serious drinking water contaminant. There are also three dangerous chemicals being brought on-site to generate chlorine dioxide from this method versus the chlorite method.

It would be highly undesirable to add this stream to food related systems, due to the extremely high acidity, or if neutralized to the high inorganic salt content of the stream as well as the possibility of residual chlorate, perchlorate or peroxide contamination of the product. In fact, the excess peroxide can

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reduce the chlorine dioxide back to chlorite when being applied to the application point reducing the residual fighting power of the initial chlorine dioxide dosage.

As you can see above, not all chlorine dioxide is the same. In fact, the FDA in the past has reviewed and approved different types of chlorine dioxide processes when supported by scientific data (acidified chlorite versus generated chlorine dioxide). This submittal needs to be looked at as a new compound, as the combined "soup" of chlorine dioxide generated from this system is not the same and I would think the FDA would not want this represented to potential users in this manner.

Sincerely,

A handwritten signature in cursive script that reads 'Joseph M. Kelley'.

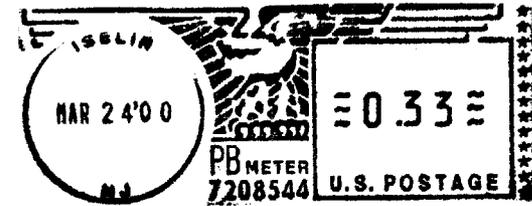
Joseph M. Kelley
Regulatory

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cc: T. Dwyer



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