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Address Reply To:
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January 20, 1987

Mrs. Sarah Cowman
Sparklets Drinking Water Corporation
Division of McKesson Corp.
45 York Blvd.
Los Angeles, California 90041

Re: Proposition 65 - PVC Bottles for Potable Water

Dear Mrs. Cowman:

This is in regard to our conversations about the effect of the labeling provisions of Proposition 65 on the use of polyvinyl chloride (PVC) bottles as containers for potable water. As we have discussed, the implications of Proposition 65 and how this law will be implemented are as yet unknown. Two of the basic problems with this legal masterpiece is a lack of definition of "any significant amount" [25249.9(b)(1)] and "no significant risk," [25249.10 (c)]. Unless some reasonable interpretation of these phrases is made, it could be possible that innumerable consumer products, including many common foods sold in California, would require cancer warning labels.

In spite of these unknowns, we believe we can assure you that potable water bottled in the recommended Geon PVC compounds will comply with the exemptions in sections 25249.9(b)(1) and 25249.10(c). Furthermore, we can make these assurances without the necessity of performing additional extractions. However, if necessary, we are prepared to perform additional tests so that we have hard data in hand to back up our assurances.

Our belief is based upon conversations I have had with Calvin Wilhite and Jack Shiniman of the California Department of Health Services and recent U.S. Food Drug Administration proposals for PVC food contact articles (FR. Vol. 51, No. 22, 4173-4188, Feb. 3, 1986) as well as current California Department of Health Services recommended action levels for water contaminants.

It was Mr. Wilhite's and Mr. Shiniman's belief that no warning label would be needed for PVC potable water bottles provided any introduced water contaminants are below the current California Department of Health Services recommended action levels. Although the recommended action levels are not now legally binding, they will be within the next year. The action level for vinyl chloride monomer (VCM) is 2 ppb. This level is based on a lifetime cancer risk of $1X10^{-6}$ (Water Quality Criteria, FR., Vol. 45, No. 231, Nov. 28, 1980).

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FDA has also used a $1X10^{-6}$ lifetime cancer risk level as a "de minimis" amount in approving several food and color additives containing carcinogenic contaminants. FDA's actions have been upheld in court challenges (Scot vs. FDA, 728 F2d 322-325 (6th Cir., 1984). Consequently, we believe a $1X10^{-6}$ lifetime cancer risk level meets the requirements of 25249.9(b)(1) (i.e., no significant amount) and 25249.10(c) (no significant risk).

Furthermore, Mr. Shiniman stated that there are currently mineral waters being sold in California in PVC bottles. He states that PVC bottles which meet the current requirements of the U.S. FDA for food contact applications are acceptable to the California Department of Health Services as potable water containers. I have reviewed the Geon compounds proposed for this purpose and find they are in compliance with current FDA requirements and in fact, will meet proposed FDA requirements for residual vinyl chloride monomer (RVCM).

The recent FDA proposals for vinyl chloride polymers would limit the RVCM content of rigid PVC food contact articles to 10 ppb RVCM. The FDA predicted that if all (100%) of the VCM at this level migrated from a typical 1.75 L PVC bottle weighing 105 grams, the contents would contain a level of 0.65 ppb VCM. In actuality not all of the RVCM is expected to migrate. This was shown by experimental migrations studies of bottles containing 0.9 ppm RVCM exposed for 9 months to 50% ethanol. Based on these experiments the FDA predicted a level of 0.036 ppb VCM would migrate into the contents. Since 50% ethanol is a very aggressive extraction solvent for RVCM from PVC, it is entirely unlikely that migration of VCM into potable water contained therein would approach the 0.036 ppb level. (The experiments in which you could not detect migration of VCM with a method sensitive to 0.25 ppb reflect these predictions.) With larger bottles, the VCM level in the contents would be expected to be even lower due to the increased volume-to-surface ratio.

Consequently, we are confident, we can assure you that bottles made from the recommended PVC compounds will comply with the exemption sections, 25249.9(b)(1) and 25249.10(c) of Proposition 65 without doing further extraction work. However, as I previously stated, we are prepared to perform extractions on production run bottles in order to have hard data in hand to back up our assurance.

The proposed studies would be performed in triplicate on 1.75 L capacity bottles. They would be extracted with water of a quality to duplicate your water. Extraction periods will be two weeks to six months to simulate minimum and maximum shelf life. At the end of the exposure period, the water contained therein will be analyzed for VCM by EPA method 601 (detection limit 0.25 ppb). These studies will be run by an independent laboratory located in California (National Food Labs, formerly McKesson Labs, has been suggested). If no VCM is detected, we feel the data will demonstrate our assurance that the recommended Geon compounds will meet the exemption requirements of Proposition 65 and are suitable for packaging potable water.

Before embarking on the proposed study, we need your concurrence that the described program will meet your needs.

Sincerely,

W. C. Bachtel
Toxicologist

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cc: R. Eiden
J. J. Salva
A. Olson

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