AN 4609
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CL-OTM-3

SUBJECT: GEONS 191 AND 198 - FDA STATUS

Geons 191 and 198 are homopolymer polyvinyl chloride (PVC) resins. Polyvinyl chloride is prior sanctioned for use in general food contact applications, both flexible and rigid. The prior sanction is based on an article by A. J. Lehman, from the FDA, published in the Journal of the Association of Food and Drug Officials, July, 1951. The current Good Manufacturing Practice (GMP) specifications for prior sanctioned PVC are a maximum volatility of 3.0% (1 hour at 105°C) and an inherent viscosity of not less than 0.35 by ASTM D-1243-79. Providing Geons 191 and 198 meet the GMP specifications for prior sanctioned PVC, they meet the current requirements of the FDA for general food contact applications including food wraps.

PVC is also listed as an acceptable ingredient of food contact articles under 21CFR:

175.105	177.1200
175.300	177.2250
176.180	179.45
177.1010	

21CFR Sections 300 to 400 cover drugs. There is no Section 477. Sections 461-499 are reserved for future use (see attached).

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potency of each diluted solution is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of micrograms of sulfamethoxazole that it is represented to contain. The pH of the solution containing 760 micrograms of sulfamethoxazole per milliliter is not less than 9.0 and not more than 12.5. The sulfamethoxazole used conforms to the standards prescribed by the National Formulary.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency and pH.

(ii) Samples required: A minimum of five frozen aliquots of each dilution of the concentrated stock solutions, each containing at least 10 milliliters.

(b) *Tests and methods of assay.* The sample solutions must be thawed and brought to room temperature before testing.

(1) *Potency.* Dilute aliquots of each sample in sufficient distilled water to make solutions containing 10 micrograms of sulfamethoxazole per milliliter. Place approximately 100 milligrams of the standard, accurately weighed, into a 100-milliliter volumetric flask and make to volume with 0.1*N* sodium hydroxide. Pipet 1.0 milliliter of this solution into a 100-milliliter volumetric flask and make to volume with distilled water. Using a suitable spectrophotometer equipped with 1.0 centimeter cells, and distilled water as the blank, determine the absorbance of sample and standard solutions at 257 nanometers. Calculate the potency of the sulfamethoxazole as follows:

$$\text{Micrograms of sulfamethoxazole per milliliter} = \frac{\text{sample absorbance} \times \text{weight of standard (in mcg)} \times f \times \text{purity of standard in percent}}{\text{standard absorbance} \times 100 \times 100}$$

where:

f = Dilution factor of each sample solution.

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the solution containing 760 micrograms of sulfamethoxazole per milliliter.

[43 FR 9793, Mar. 10, 1978; 43 FR 12859, Mar. 28, 1978]

PARTS 461—499 [RESERVED]