INFANT FORMULA AND ADULT NUTRITIONALS

Chloride in Milk, Milk Powder, Whey Powder, Infant Formula, and Adult Nutritionals Potentiometric Titration: Collaborative Study, Final Action 2016.03

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Background: **In September 2015, both AOAC *Official Methods* 2015.07 and 2015.08 single-laboratory validations (SLVs) were reviewed against *Standard Method Performance Requirements*® (SMPR) 2014.015 by the AOAC Stakeholder Panel for Infant Formula and Adult Nutritional (SPIFAN) Expert Review Panel (ERP). Looking at the similarity and uniqueness of the two methods, the authors agreed, as advised by the ERP, to work together to merge the two methods into one. This combined method was assigned Method 2016.03.** ***Objective:*** **In order to determine the repeatability and reproducibility of the AOAC First Action 2016.03 method, a collaborative study was organized. The study was divided in two parts: (Part 1) method set up and qualification of participants and (Part 2) collaborative study participation. During Part 1, each laboratory was asked to analyze two practice samples. The laboratories that provided results within a range of expected levels were qualified for Part 2, during which they analyzed 25 samples in blind duplicates.** ***Results:*** **The results were compared with SMPR 2014.015 established for chloride. The precision results (repeatability and reproducibility) were within the requirements stated in the SMPR. In general, the precision results (repeatability and reproducibility) were well within the limits stated in the SMPR. Repeatability ranged from 0.4 to 1.9%, in accordance with data obtained during SLV, with reported RSD of repeatability from 0.03 to 1.6%. Meanwhile, reproducibility ranged from 0.6 to 4.0%. Finally, the Horwitz ratio values were all below 1, from 0.2 to 0.9%.** ***Conclusions:*** **The ERP determined that the data presented met the SMPR and accordingly recommended the method to be granted Final Action status. In January 2018, the Official Methods Board approved the method as Final Action.**

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The method was approved by the AOAC Official Methods Board as Final Action. *See* "Standards News," (2018) *Inside Laboratory Management*, September/October issue.
The AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) invites method users to provide feedback on the Final Action methods. Feedback from method users will help verify that the methods are fit for purpose and is critical to gaining global recognition and acceptance of the methods. Comments can be sent directly to the corresponding author.
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Sodium chloride (salt) is the main source of chloride in food. On September 26, 1980, the Infant Formula Act of 1980 was signed into law. This bill, which was a result of 1979 reports stating that more than 100 infants became seriously ill as a consequence of using soybean-based formulas marketed with an insufficient amount of chloride, established a statutory requirement that formula manufacturers include chlorides as well as other essential elements in each infant formula preparation sold.

It also gives the Secretary of Health and Human Services authority to adjust nutritional standards to conform to the best available scientific knowledge. In addition, the bill requires manufacturers to test infant formulas on a periodic basis and to notify the Secretary promptly whenever formulas do not meet nutritional requirements.

On May 28, 2013, the World Health Assembly adopted the World Health Organization Action Plan for the Prevention and Control of Noncommunicable Diseases (Sixty-Sixth World Health Assembly, WHA66.10, Agenda Item 13.1, May 27, 2013). One of the measures involves product reformulation. The target is a 30% relative reduction in mean population intake of salt/sodium by reducing level of salt/sodium added to food.

Several *Official Methods* exist for the analysis of chloride in foods, and particularly in infant formula. A merger of *Official Methods* **2015.07** and **2015.08** (1, 2) was proposed to the Stakeholder Panel for Infant Formula and Adult Nutritional (SPIFAN) and was approved as a First Action Method **2016.03** in 2016, with a recommendation to advance to multilaboratory collaborative study. This paper presents the results of the collaborative study.

Samples

The study took place using SPIFAN matrixes, which represent most of the products in the scope of the project (infant formula