

Standard Method Performance RequirementsSM (SMPRs) for Sodium Fluoroacetate (“Compound 1080”) in Infant Formula

Intended Use: Surveillance and Monitoring of Infant Formula (and Possibly Adult/Pediatric) Formula by Trained Technicians

1 Purpose

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC stakeholder panels composed of representatives from industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC expert review panels (ERPs) in their evaluation of validation study data for methods being considered for *Performance Tested Methods*SM or *AOAC Official Methods of Analysis*SM, and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

Determination of total fluoroacetic acid and its salts in all forms of infant formula (powders, ready-to-feed liquids, and liquid concentrates).

3 Analytical Technique

Any analytical technique that meets the following method performance requirements is acceptable. High-throughput methods that can also determine total fluoroacetic acid and its salts in adult/pediatric formulas are preferable.

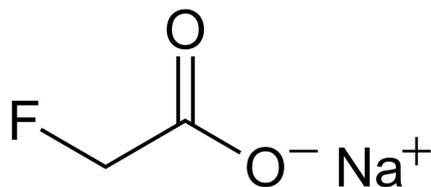
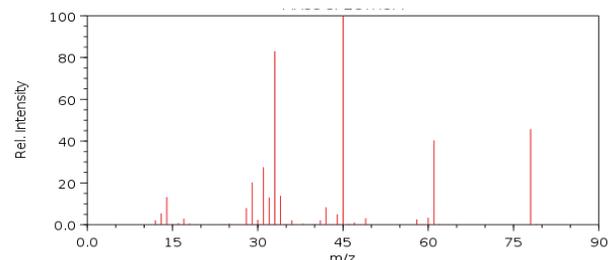


Figure 1. Chemical structure of sodium fluoroacetate (Compound 1080) molecular weight 100.24; molecular formula $C_2H_2FNaO_2$.



NIST Chemistry WebBook (<http://webbook.nist.gov/chemistry>)

Figure 2. Mass spectrum of fluoroacetic acid.

Table 1. Method performance requirements

Analytical range	4 ppb–100 ppm ^a
Limit of detection (LOD)	1 ppb ^a
Limit of quantitation (LOQ)	≤4 ppb ^a
Recovery	±20%
Repeatability (RSD _r)	≤14%
Reproducibility (RSD _R)	≤20%

^a Fluoroacetate expressed as μg of fluoroacetic acid/1000 g of solids.

4 Definitions

Accuracy (corresponds to the VIM definition for “trueness”).—The closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

Adult/pediatric formula.—Nutritionally complete, specially formulated food, consumed in liquid form, which may constitute the sole source of nourishment, made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Infant formula.—Breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding (Codex Standard 72-1981), made from any combination of milk, soy, rice, whey, hydrolyzed protein, starch, and amino acids, with and without intact protein.

Limit of detection (LOD).—The minimum concentration or mass of analyte that can be detected in a given matrix with no greater than 5% false-positive risk and 5% false-negative risk.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator, and repeating during a short time period. Expressed as the repeatability standard deviation (SD_r); or % repeatability relative standard deviation ($\%RSD_r$).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility relative standard deviation (SD_R); or % reproducibility relative standard deviation ($\%RSD_R$).

Sodium fluoroacetate.—The active ingredient in “Compound 1080,” a rodenticide. IUPAC name: Sodium 2-fluoroacetate. CAS No. 62-74-8. See Figure 1. See Figure 2 for a mass spectrograph of fluoroacetic acid.

5 Method Performance Requirements

See Table 1.

6 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the analytical range.

7 Reference Material(s)

Follow Annex F: Development and Use of In-House Reference Materials in Appendix F: Guidelines for *Standard Method Performance Requirements*SM in the *Official Method of Analysis of AOAC INTERNATIONAL*, 19th Ed. (2012).

8 Validation Guidance

Appendix L: AOAC Recommended Guidelines for Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN) Single-Laboratory Validation, *Official Methods of Analysis of AOAC INTERNATIONAL*, 19th Ed. (2012). Available at: http://www.eoma.aoc.org/app_l.pdf

9 Maximum Time-to-Result

No maximum time, but method should be suitable for high-throughput.

Approved by AOAC Stakeholder Panel on Infant Formula and Adult Nutritionals (SPIFAN). Final Version Date: March 17, 2015. Effective Date: March 17, 2015.