NSF/ANSI 61
Drinking Water System Components
Health Effects

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3 General requirements

3.1 General

3.1.1 Product and material information described in 3.2 shall be used to determine the specific section (4 through 9) under which a product or material shall be evaluated.

3.1.2 Products or materials whose intended uses fall under more than one section of this Standard shall be evaluated under the section with the most rigorous evaluation conditions.

NOTE – Rigorous conditions are typically associated with shorter conditioning periods, longer exposure periods, higher surface-area-to-volume ratios, and higher exposure temperatures.

3.2 Information and formulation requirements

The following information shall be reviewed to determine the appropriate analytical testing and to ensure that the potential health effects of products and materials are accurately and adequately identified:

– the product section(s) under which the product, component, or material is covered and the intended function or end use of the product or the material;

– for assembled products or components, a list of all of components and materials and their corresponding surface areas that come into direct contact with water;

– when appropriate, the total volume of water that the product can hold when filled to capacity;

– the expected service life of the product;

– the anticipated minimum, maximum, and average volumes of water that come into contact with the product, component, or material during a 24-h period;

– complete formulation information for each water contact material ~~as applicable~~;

~~NOTE – The complete formulation information may be omitted for a component material if the generic material type is contained in Table 3.1 and its diluted surface area in the application is less than or equal to 0.001 or 0.0001 for static or flowing conditions respectively.~~

The complete formulation information may be omitted for a component material if the generic material type is contained in Table 3.1 when used in a high flow device exclusively used at public water supply facilities. High flow devices are limited to chemical feeders, disinfection generators (chlorine dioxide, hypochlorite, ozone and ultraviolet), electrodialysis technologies, microfiltration technologies, reverse osmosis and ultrafiltration technologies.

Rationale: This replaces the existing note regarding diluted surface area. The desired net result of this proposal is that the products included in this evaluation requirement will not change. Instead, this change

simplifies the approach and increases transparency and consistancy of the products that can be considered for this approach.

No formulation information is required for activators, antioxidants, antimicrobials, co-solvents, fillers, curing agents, initiators, peroxides, inorganic pigments, polymers, plasticizers, process aids, solvents, surfactants, stabilizer and terminators or their impurities, degradation products and hydrolysis products when present at less than 0.10 % of the formulation. No testing is required for antimicrobials or organic pigments or their impurities, degradation products and hydrolysis products when present at less than 0.010 % of the formulation.

Rationale: To minimize the effort required in the information gathering phase of certification. It is important to set a practical level under which no formulation or testing is required where one can be assured that such testing, if done, would not result in a potential failure of the product.

– the composition of the formulation (e. g., percent or parts by weight for each chemical in the formulation or reference to a standardized material specification);

– a chemical abstract number (CAS no.), name, trade designation, and supplier for each chemical present in the formulation and a Material Safety Data Sheet (MSDS), when available; and

– an indication as to whether the chemical is an ingredient, reactant, or processing aid.

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3.3 Identification of analytes

For all products and materials, the formulation information required in 3.2 shall be reviewed for completeness (e. g., all formulations total 100%), and to determine whether a minimum test battery has been established for each water contact material (see table 3.1). The availability of an established minimum test battery shall not preclude performance of a formulation review to identify any formulation-dependent analytes (see 3.3.1).

3.3.1 Formulation-dependent analysis selection

For all water contact materials, the formulation information described in 3.2 shall be reviewed, and formulation-dependent analytes shall be identified for each water contact material. The criteria for selection of a formulation-dependent analyte shall include, but not be limited to, the following:

– known or suspected toxicity of the substance or its byproduct(s);

– high water solubility of the substance;

– monomer(s) of polymeric ingredients;

– high probability of extraction of a substance or its byproduct(s) at toxicologically significant concentrations; and

– extraction or migration information for the substance provided by the manufacturer.

3.3.2 Established minimum test batteries

– The materials listed in table 3.1 shall be tested for the indicated analyses and any formulation-dependent analyses identified during the formulation-dependent analyte selection. ~~Products, components, or materials shall not require testing if their diluted surface area in the application is less than or equal to 0.001 or 0.0001 for static or flowing conditions respectively.~~

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~~NOTE – The complete formulation information may be omitted for a component material if the generic material type is contained in Table 3.1 and its diluted surface area in the application is less than or equal to 0.001 or 0.0001 for static or flowing conditions respectively.~~

No testing is required for a component material if the generic material type is contained in Table 3.1 when used in a high flow device exclusively used at public water supply facilities. High flow devices are limited to

chemical feeders, disinfection generators (chlorine dioxide, hypochlorite, ozone and ultraviolet), electrodialysis technologies, microfiltration technologies, reverse osmosis and ultrafiltration technologies.

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Rationale: It is important to set a practical level under which no testing is required where one can be assured that such testing, if done, would not result in a potential failure of the product.

3.4 Products manufactured from annex C acceptable materials

Products manufactured entirely from annex C materials shall not be required to undergo extraction testing for material-specific analytes of interest. However, extraction testing for contaminants contributed by processes specific to a production site shall be considered formulation-dependent analytes. Annex C contains the evaluation requirements for qualification as an acceptable material.