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 obtained and reviewed for all materials with a water contact surface 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~~ assemblies, sub-assemblies, 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 (equal to 100.0%) for each water contact material. This shall include: ~~as applicable~~

NOTE – A material is defined as a combination of ingredients used to: manufacture (mold, extrude, stamp, cast, machine, mix etc.) a part or component used in the assembly of a device. To include but not be limited to plastics, elastomers, metallic components, media, lubricants, adhesives, process aid, preservatives, coatings and surface treatments.

– a complete formulation shall result in the identity by CAS# or chemical name of each component of the formulation including but not limited to the activators, antioxidants, antimicrobials, co-solvents, fillers, initiators, peroxides, pigments, plasticizers, process aids, solvents, stabilizer, surfactants and terminators;

– percent or parts by weight for each chemical in the formulation or reference to a national or international standardized material specification for metallic materials (e.g. UNS copper alloy specifications);

– when the chemical composition of an ingredient or component cannot be determined based on the information submitted by the material supplier, the information shall be obtained by the certifier from the ingredient supplier prior to determining all formulation dependant analytes;

– the composition of the materials ingredients and their components shall be known to determine the identity of formulation specific analytes.

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 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 a Material Safety Data Sheet (MSDS), when available; and~~

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

– the maximum temperature to which the product, component, or material is exposed during its intended end use;

– a description/classification of the manner in which the product or material is manufactured (including any process parameters that affect product surface areas in direct contact with water), handled, and packaged. The manufacturing process variability shall be verified by the manufacturer as to its effect on contaminant leachate levels, and the manufacturer shall establish and demonstrate appropriate ongoing process controls to ensure ongoing product conformance with this Standard;

NOTE – The methods used to alter the water contact surfaces of product components during manufacturing, either mechanically (e. g., metal cutting, molding, stamping) or chemically (e. g., washing, coating, plating, brite-dip cleaning), may have a significant effect upon contaminant leachate performance.

– when available, a list of the known or suspected impurities within the product or material and the maximum percent or parts by weight of each impurity;

– when available, the solubility, hydrolysis products, and extraction rates of chemicals within the product or material; and

– when available, a list of published and unpublished toxicological studies relevant to the chemicals and impurities present in the product, component, or material.

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 100.0%), and to determine whether a minimum test battery has been established for each water contact material (see table 3.1). In addition to selecting the minimum testing parameters decribed in 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 shall be performed for all water contact materials (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;

– solvents and co-solvents used in the polymerization process or those used in the material formulation;

– antioxidants, antimicrobials, curing agents, initiators, peroxides, pigments, plasticizers, process aids, stabilizer and terminators and their impurities, degradation and hydrolysis products;

– 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 or that present in the public literature.

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