Powders/Solids/Non-Aqueous Liquids Annex (to be added to GS-8, GS-37, GS-44, GS-52, and GS-53)

Products as Powders/Solids/Non-Aqueous Liquids. Powder/solid/non-aqueous liquid products that meet all of the following requirements may be exempt from the skin and eye corrosion criterion (reference section number in specific standard) and may have an alternate threshold of 300 mg/kg for oral acute mammalian toxicity (reference section number in specific standard) herein. They shall also be exempt from pH declaration (reference section number in specific standard) for the undiluted product. [the last sentence only applies to industrial and institutional standards]

A. Packaging Requirements. The product shall meet the requirements under either A(1) Child-Resistant Packaging Requirements or A(2) Packaging Durability Requirements.

1. Child-Resistant Packaging. The product shall be packaged in child-resistant packaging following the ASTM D3475 classification. Child-resistant packaging must be tested per ISO 8317 or European Standard (EN) 862.

2. Packaging Durability. The product shall meet the following requirements to be considered durable.

   i. Drop Test. The primary package, including any lid, shall be durable as demonstrated by passing the following drop test: drop the product from a height of 48 inches with 4 drops scenarios: flat-on-bottom, flat-on-top, flat-on-side, and corner; with passing results including that the packages must not leak, contents must be retained, and no damage to the outer package likely to adversely affect safety must be sustained.

   ii. Spill Resistant. The primary package shall not spill when tipped over, turned upside down or shaken and shall not leak when exposed to water.

   iii. Practically Inaccessible. The primary package shall not allow for easy access/exposure of the product during routine handling of the package, such as while transferring from shipping cartons, during storage, or after opening (e.g. the user still cannot get at the contents, or the contents are protected or wrapped).

B. Dispensing Exposure Requirements. Documentation shall be provided to demonstrate that expected dispensing situations will not result in incidental contact exposure to oral consumption/toxicity, skin corrosion, or eye corrosion.

C. Labeling Requirements. The product label shall include the following in a conspicuous location:
The signal word “WARNING” or “CAUTION” on products which cause skin corrosion, cause serious eye damage, or have an acute mammalian toxicity greater than or equal to 300 mg/kg and less than or equal to 5,000 mg/kg, with the applicable precautionary measures:
- May cause skin corrosion, do not get on skin
- May cause serious eye damage, do not get in eyes
- Harmful if swallowed, do not ingest

Instruction, when necessary or appropriate, for first-aid treatment

The statement “KEEP OUT OF REACH OF CHILDREN” or its practical equivalent in capitalized text

Definitions (to be added to the standards for the Products as Powders/Solids/Non-Aqueous Liquids Annex)

Child-Resistant Packaging. Child-resistant packaging, as defined by the Poison Prevention Packaging Act, is packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time. Code of Federal Regulations, Title 16, Part 1700 and Title 40, Part 157.

Powders/Solids/Non-Aqueous Liquids. Products that cannot be formulated with additional water due to the form of the product, including, but not limited to: powdered detergents, solid bar soaps, detergents in tablet form, detergents as extruded or cast solids, non-aqueous liquid products in a dissolvable shell.

Primary Package. Package material that physically contains and contacts the product, not including the cap or lid. For products that meet the annex requirements for Products as Powders/Solids/Non-Aqueous Liquids, the primary package is the material that holds the individually packaged product units or the entire product.

Serious Eye Damage. The production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application. This includes substances identified under Category 1 for Serious Eye Damage/Eye Irritation (H318) under the GHS.

Skin Corrosion. The production of irreversible damage to the skin, namely visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. This includes substances designated as Category 1A, 1B or 1C for Skin Corrosion/Irritation (H314) under the GHS.
Alternate Statement of Basis for Certification: (to be added to the standards for the Products as Powders/Solids/Non-Aqueous Liquids Annex)

If the powder/solid/non-aqueous liquid product was evaluated in accordance with Annex __ (reference annex number in specific standard for products as powders/solids/non-aqueous liquids), the description shall read as follows:

"(Statement of basis for certification for the specific standard), with alternate thresholds for skin and eye corrosion and acute toxicity due to added packaging and labeling requirements". [whichever health criteria apply to the product]

Products Containing Enzymes Annex (to be added to GS-8 and GS-37, to be updated in GS-52 and GS-53)

Products Containing Enzymes. Products that contain enzymes shall meet all of the following:

A. Enzyme Form. Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. Enzyme Source. The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. Enzyme Source Microorganisms. For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in (reference annex number in specific standard) herein.

D. Sensitization and Asthma. Enzymes are exempted from the requirements for Asthmagens (reference section number in specific standard) and Respiratory Sensitization (reference section number in specific standard) herein. [if no section included in standard, reference terms as defined only]

E. Spray Packaging. Enzyme products in spray packaging, or designed for use in spray packaging shall demonstrate airborne enzyme exposure for users below 1 ng/m³ when sampling is conducted according to the protocol described in the international Association for Soaps, Detergents and Maintenance Products (AISE) document “Exposure measurements of enzymes of risk assessment of spray products.”

F. Labeling Requirements. Products containing enzymes shall include the following on the product label:
A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line

A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application to these products and instruction, when necessary or appropriate, for follow-up treatment

G. Industrial Hygiene. Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.

Definitions (to be added to the standards for the Products Containing Enzymes Annex)

Asthmagen. A substance designated as an asthma causing agent by the Association of Occupational and Environmental Clinics (AOEC), which after review by AOEC have met the AOEC sensitization criteria.

Enzyme. A protein that acts as a catalyst in biochemical reactions. Each enzyme is specific to a particular reaction or group of similar reactions.

Microorganism. An organism that cannot be seen by the naked eye (microscopic organisms) including, but not limited to, bacteria, fungi, archaea, and protists. Also included in this category are viruses or virus-like particles, although they are generally regarded as non-living.

Respiratory Sensitizer. A substance designated as leading to hypersensitivity of the airways following inhalation of the substance and meeting the classification criteria of Category 1 respiratory sensitization (H334) in accordance with the GHS.

Spray Packaging. A package that dispenses the product through a nozzle and the product is in small droplets (i.e., a spray). It does not require a pressurized propellant to dispense the product.

Products Containing Microorganisms Annex (to be added to GS-8 and GS-37, to be updated in GS-52 and GS-53)

Products Containing Microorganisms. Products that contain microorganisms shall meet all of the following with any specified testing conducted with an objective,
scientifically-validated method under controlled and reproducible laboratory conditions (and appropriate testing details provided to the certification program):

A. Genetically Modified Microorganisms in Microbial Products. The presence of \textit{GMM} as components in finished products [or use “a deliberate addition or as a contaminant above 0.01% in the finished product” if component term not used in standard] is prohibited.

B. Microorganism Biosafety. All \textit{microorganisms} shall be classified as \textit{WHO Risk Group 1} or equivalent biosafety designation. For strains that do not appear on any international biosafety designation lists, alternative means may be acceptable; consultation with the certifying organization may be required.

C. Microorganism Strain Identification. \textit{Microorganism} strains shall be identified through a taxonomic review (e.g., genetic or phenotypic analysis) that is provided by a full-service culture collection listed with the World Federation of Culture Collections, whether or not the strain is part of the collection.

D. Absence of Contaminants. \textit{Pathogenic microorganisms} shall not be present in the microbial strain, finished product, or at the end of the product’s intended shelf life. Testing for the presence of \textit{pathogenic microorganisms} shall be conducted according to the Joint Food and Agriculture Organization of the United Nations/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications standard microbiological analytical methods or comparable method and a Certificate of Analysis shall be provided to the certification program.

E. Effective Prevention Measures and Treatment. All \textit{microorganisms} shall be demonstrated to be susceptible to the following prevention and treatment measures:

- \textit{Antimicrobial agents}, as demonstrated by testing the microbial strain against an acceptable substance (i.e., an EPA general disinfectant, Center for Disease Control low-level disinfectant, or a registered \textit{antimicrobial agent} by Health Canada) in accordance with the EPA/Office of Pesticide Programs Standard Operating Procedure (SOP) or the AOAC International Use Dilution Method for Testing Disinfectants, SOP Number: MB-05-04
- Each of the five major antibiotic classes (aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones), as demonstrated by testing the microbial strain in accordance with Beckman Dickinson BBL antimicrobial susceptibility disc method.

F. Microbial Count. A \textit{microorganism} used to serve the primary cleaning function in the \textit{undiluted product} shall have a plate count that is greater than or equal to $1 \times 10^7$ \textit{CFU} per milliliter for liquid products and $1 \times 10^9$ \textit{CFU} per gram for solid products. A total plate count shall be conducted in accordance with the methods for microbiological analyses listed in the JECFA Combined Compendium of Food Additive Specifications or
comparable method. An exception shall be made for microorganisms used to serve a secondary function in the undiluted product.

G. Spray Packaging. Products containing microorganisms in spray packaging, or designed for use in spray packaging shall demonstrate airborne enzyme exposure for users below 1 ng/m³ when sampling is conducted according to the protocol described in the international AISE document “Exposure measurements of enzymes of risk assessment of spray products.” Products containing microorganisms in aerosol packaging shall not be in particle form.

H. Labeling Requirements. Products containing microorganisms shall include the following on the label:

- A declaration that the product contains microorganisms
- A statement that the product should not be used in patient areas of hospitals [first part of sentence only applies to industrial and institutional standards] and that immune-compromised individuals should avoid exposure to products containing microorganisms from both direct use and incidental contact during or shortly after application to these products, especially when the treated areas are still wet
- Contact with open cuts or sores should be avoided
- Users should wash their hands after using the product
- Instructions that microorganisms may not be effective in the presence of antimicrobial agents such as chlorine bleach
- Instructions that the product shall not be used on food-contact surfaces
- Instructions that products containing microorganisms should not be sprayed directly into the air.

Definitions (to be added to the standards for the Products Containing Microorganisms Annex)

Aerosol Packaging. A package that requires a pressurized propellant to dispense product through a nozzle.

Antimicrobial Agent. A substance intended to disinfect, sanitize, reduce, or mitigate growth or development of microorganisms and protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

Colony Forming Unit (CFU). A measure of bacteria concentration assuming that each bacterium is capable of forming a colony.

Genetically Modified Microorganism (GMM). A microorganism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination. The methods or techniques by which GMM are produced are listed by the

Microorganism. An organism that cannot be seen by the naked eye (microscopic organisms) including, but not limited to, bacteria, fungi, archaea, and protists. Also included in this category are viruses or virus-like particles, although they are generally regarded as non-living.

Package. This includes the primary package used for the product.

Pathogenic Microorganism. For the purposes of this standard this includes microorganisms that cause disease and can be classified as WHO Risk Group 2, 3, or 4, including, but not limited to: coliforms, Escherichia coli, Salmonella, Staphylococcus aureus, Pseudomonas aeruginosa, and some yeasts and molds.

Primary Cleaning Function. For the purposes of this standard, a cleaning product’s primary function is to remove soil.

Secondary Function. For the purposes of this standard, the secondary function of a cleaning product may be to enhance the primary cleaning function through bubble or foam formation or to provide some other added functional enhancement (e.g. longer-term cleaning effect).

Spray Packaging. A package that dispenses the product through a nozzle and the product is in small droplets (i.e., a spray). It does not require a pressurized propellant to dispense the product.

World Health Organization (WHO) Risk Group 1. Microorganisms that are unlikely to cause human or animal disease under the basis for classification defined by the World Health Organization in the Laboratory Biosafety Manual. In the case that a particular strain has conflicting risk group designations on various international lists, the most hazardous (highest level) designation will be utilized. The biosafety designation lists that will be consulted include:

- Australia/New Zealand
- Belgium
- Switzerland
- United Kingdom
- Germany
- United States Department of Health and Human Services, National Institutes of Health (NIH)
- European Commission
- Singapore
- Japan