EPA's Safer Choice Criteria for Processing Aids and Additives

A large set of chemicals that play supporting roles in product formulations, Safer Choice will now group processing aids and additives as a class, with tailored criteria for each subclass. These chemicals (often considered commodity or generic ingredients) are diverse in structure and function, but have in common, beyond their formulary supporting roles, that their chemical characteristics and long-standing safe use make them a low hazard concern. For example, physical-chemical properties (like simple acids, when controlled for product pH) or essential functionality in humans (like polysaccharides) can indicate low hazard. Like colorants, polymers and related chemicals, processing aids and additives are often data-poor. Yet, they are very common ingredients in cleaning and other products and frequently provide multiple functional attributes.

In this document, Safer Choice has sets out parameters and explanations for qualifying processing aids and additives, organized into eleven subgroups, for use in Safer Choice products. At a minimum, they must meet the specific criteria for their subgroup and comply with the baseline requirements in section 5.2 of the Safer Choice Standard.

Inorganic spectator ions

Conditions: Must be an inorganic salt with ions that pose a low concern for human and environmental health.

Rationale. Salts containing these ions are expected to dissociate in aqueous environments. Ions like calcium, potassium, magnesium, sodium, and chloride are essential nutrients for biological processes. Available experimental data suggests there is no hazard concern for these chemicals.

Qualifying chemicals: sodium chloride, potasssium chloride, magnesium chloride, magnesium chloride hexahydrate, calcium chloride, and calcium chloride dihydrate.

Simple acids and bases

Conditions: Are not used at concentrations that alter the permitted product pH range—2 to 11.5. Do not demonstrate potential for protein-binding (as with NH4). Must have acceptable counter ions (see spectator ions).

Rationale. Simple acids and bases provide a pH-adjustment functionality to product formulations. Potential health effects are associated with their corrosive nature when used at high concentrations outside Safer Choice's acceptable pH range.

Qualifying chemicals: potassium hydroxide; sodium hydroxide; sulfuric acid; hydrochloric acid (aqueous); sulfurous acid, monosodium salt (aqueous); and disulfurous acid,

disodium salt (aqueous).

Silicates

Conditions: Are not used at concentrations that alter the permitted product pH range—2 to 11.5. Must have a molar ratio of SiO2 to [M]2O of equal to or greater than 2, where M is sodium (Na) or potassium (K), and acceptable counter ions (see spectator ions).

Rationale. Potential health effects are associated with the alkalinity from high molar ratios of sodium or potassium, outside Safer Choice's acceptable pH range. Provide necessary builder functionalities in products and pose a low concern when the amount of silicate to counter ion is in the specified range.

Qualifying chemicals: sodium silicate, sodium metasilicate, disodium disilicate, calcium silicate, sodium metasilicate pentahydrate, sodium metasilicate nonahydrate, and potassium silicate.

Simple sugars

Conditions: Must be non-derivatized, monosaccharides with the general molecular formula of [CH2O] n, where n is equal to or greater than 3. Or, disaccharides, oligosaccharides, or mixtures of these comprised of the following sugars: glucose, fructose, and sucrose, lactose, galactose, mannose, or maltose.

Rationale. Simple sugars are naturally occurring chemicals that are rapidly metabolized and used as an energy source. Available information suggests there is no hazard concern for these chemicals.

Qualifying chemicals: glucose, sucrose, molasses, blackstrap, dextrin, and corn syrup.

Polysaccharides

Conditions: Must be comprised of repeating units of one or more of the acceptable sugars and have a molecular weight great than 1,000 Daltons (i.e., typically not bioavailable). If the qualifying polysaccharide is bioavailable (e.g., starch), then it must metabolize to simple sugars.

Rationale. Polysaccharides made up of qualifying simple sugars (low concern) are themselves of low concern. Available test data confirms a low-concern for these chemicals (e.g., data set on xanthan gum). Also, polysaccharides with low water solubility are expected to have limited bioavailability and thus low hazard concern.

Qualifying chemicals: xanthan gum, guar gum, cellulose, maltodextrin, starch, carrageenan, and cellulose (regenerated).

Polysaccharide derivatives

Conditions: Sugar components must meet the requirements of the "polysaccharides" group. Saturated aliphatic (linear or branched) derivates must only contain: hydroxyl groups; carboxylic acids, esters, or salts (with qualifying counter ions); and ethers. Further, acceptable derivatives should have a molecular weight greater than 1000 and no surfactant properties.

Rationale. Polysaccharide derivatives made up of qualifying simple sugars (low concern) are themselves of low concern. They are neutral or anionic substances with non-reactive functional groups. Available information suggests there is no hazard concern for these chemicals.

Qualifying chemicals: carboxymethyl cellulose (sodium salts), hydroxyethylcellulose, 2-hydroxypropyl methyl ether cellulose, methyl ether cellulose, hydroxybutyl methyl cellulose, starch (2-hydroxyethyl ether), starch (2-hydroxypropyl ether), cellulose (2-hydroxypropyl ether),and inulin (carboxymethyl ether, sodium salt).

Mineral ions

Conditions: Group does not include phosphorus-based or other mineral ions implicated in the nutrient loading and eventual eutrophication of water bodies. Cannot contain non-qualifying ions (see inorganic spectator ions above).

Rationale: Available data indicates there is no hazard concern for these chemicals; some class members, like sodium sulfate, have complete data sets that meet the Safer Choice criteria. They freely dissociate in water to their component moieties and qualifying counter ions. They are common components in minerals and ubiquitous in nature.

Qualifying chemicals: sodium carbonate, potassium carbonate, sodium bicarbonate, potassium bicarbonate, sodium sesquicarbonate, potassium sesquicarbonate, sodium sulfate, sodium metabisulfate, potassium sulfate, calcium carbonate, magnesium sulfate and heptahydrate, and sodium thiosulfate.

Non-crystalline clays, silicates and alumino-silicates

Conditions: Limited to minerals containing oxides of silicon, aluminum, calcium, sodium, potassium, or magnesium. Must be amorphous or rounded in shape and not contain any crystalline morphology (candidates with crystalline structures that do not contain needles or fibrous components will be evaluated on a case-by-case basis). Must not be

nano-sized. If added to a product that is a powder or in dry form, the distribution of particles below 10 microns (the inhalation threshold) must be less than 1 percent and below 3.5 microns (the deep-lung respirability threshold) must be at 0 percent, as demonstrated by a generally accepted method for measuring particle size.

Rationale: Evidence only of potential adverse human health and environmental effects from crystalline structures (which pose concerns for lung overload and respiratory effects, like silicosis). Otherwise, available data indicates there is no hazard concern for these chemicals (and none is anticipated based on current and projected use levels).

Qualifying chemicals: calcined kaolin, kaolin, fuller's earth, silica, silica (amorphous, fumed, crystalline-free), amorphous silicon dioxide, kieselguhr (calcined), silica gel, uncalcined diatomaceous earth, bentonite, pumice, smectite clay, perlite (expanded), nepheline syenite, and zeolite A and zeolite (based on data set; is crystalline, but not fibrous or needle-like).

Hydroxy carboxylic acids and salts

Conditions: Structures must contain at least one short-chin (C3 to C6) aliphatic (branched or linear, with one or more hydroxyl groups) carboxylic acid and associated salts must be from the group of qualified counter ions (see above).

Rationale. Some class members, like citric acid and lactic acid, have complete data sets that meet the Safer Choice criteria. In general, extensive anecdotal evidence indicates low hazard concerns for the class. Class members are present in biological processes, e.g., products of fermentation, sugar derivatives, and reactants or products in metabolic pathways (like Kreb's cycle anaerobic glycosis).

Qualifying chemicals: gluconic acid, sodium gluconate, sodium citrate, potassium citrate, citric acid, lactic acid, and sodium lactate.

Alkyl carboxylic acids and salts

Conditions: Scope of class is limited to short-chain, non-functionalized alkyl groups (eliminates chemicals with mild surfactant properties). Class members must contain at least one carboxylic acid functional group and a non-functionalized linear alkyl chain, less than C6 in length; salts must be one of the qualified counter ions (see above).

Rationale: Available data for chemicals in this class indicates low potential for human health and ecological hazards and low persistence. Extensive anecdotal evidence indicates low hazard concerns in general.

Qualifying chemicals: acetic acid, propionic acid, calcium propionate, sodium proprionate, sodium acetate, potassium acetate, calcium magnesium acetate, and

sodium formate.

Triglycerides

Conditions: Chemical in this class must consist of the following general molecular structure: (COOR)CH2CH(COOR)CH2(COOR), where R is a non-polar, unsaturated, aliphatic chain. Also, they must not exhibit surfactant properties nor contain reactive functional groups (e.g., epoxides).

Rationale. Triglycerides are natural biological substances that rapidly metabolized and are used as an energy source in the human body. Available data indicate there is no hazard concern for these chemicals.

Qualifying chemicals: soybean oil, olive oil, linseed oil, corn oil, coconut oil, hydrogenated castor oil, palm oil, and hydrogenated soybean oil.