

EPA's Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals

The Safer Choice approach to product review and labeling focuses on identifying the safest possible chemical ingredients, within a functional class context, that are necessary for a product to perform well. The general requirements in the [Safer Choice Master Criteria for Safer Chemical Ingredients](#) serve as the reference set of benchmarks on which Safer Choice bases its chemical ingredient-specific criteria. The criteria also constitute a baseline set of toxicity parameters, with functionality-driven tailoring, that all ingredients without component-specific criteria must address to be considered for use in Safer Choice products.

While EPA has used the stringent and comprehensive elements of the Master Criteria to evaluate ingredient classes, its experience in implementing the Safer Choice Program has demonstrated that most functional classes require a tailored approach. For example, colorants, polymers, and certain preservatives have as part of their functionality the ability to resist degradation. They also typically lack a complete set of measured toxicity data, for which Safer Choice substitutes data based on predictive models, estimation techniques, and expert judgment. EPA has therefore adapted its criteria for colorants, polymers, preservatives, and related chemicals (e.g., defoamers) to accommodate specific functional-class characteristics, like persistence, permitting the listing of the safest chemicals in those classes.

Although modifying the Master Criteria to some extent, the provisions serve largely to clarify, elaborate on, and make more transparent the technical considerations involved in evaluating chemicals in the functional classes without tailored criteria. The approach Safer Choice has adopted retains the human health safety thresholds from the Master Criteria, but allows flexibility in environmental toxicity and fate endpoints, as appropriate to chemicals that persist as part of their functionality. To address the lack of data common to many of these chemicals, Safer Choice relies on a mix of estimated, measured and authoritative list-based data elements. (Please note that any modifications to the component-class criteria will not alter the prohibition on the use of listed carcinogens, mutagens or reproductive or developmental toxicants, or persistent, bioaccumulative and toxic chemicals in Safer Choice products.)

Colorants, Polymers, Preservatives, and Related Chemicals (extract from the [Safer Choice Standard](#), section 5.8)

Colorants (including pigments and optical brighteners), polymers, and certain preservatives (including antioxidants) (and other chemicals referenced in section 5.14) include as part of their functionality the ability to resist degradation and be effective over long periods. They also can be complex molecules and mixtures and often lack

measured toxicity data. To identify the safest available chemicals in each class given their functional characteristics, the toxicity thresholds in the Master Criteria will be used to evaluate human health endpoints, and the thresholds in section 5.8.3 will be used for environmental endpoints. Data on these chemicals will be required as per 5.8.3, unless noted otherwise.

5.1 Polymers

To be acceptable for labeled products, polymers must have low-concern characteristics.¹ Also, the requirements of this section apply to the low molecular weight components of polymers (typically less than 1,000 daltons). Safer Choice encourages the use of degradable polymers whenever possible; only those that do not degrade into CMRs or PBTs will be allowed.

Special conditions for certain categories of polymer: In addition to the requirements in 5.8.3, polymers that are respirable or water-absorbing must be in solution. Anionic polymers used as chelating agents must meet the requirements in the Safer Choice Criteria for Chelating Agents, except section 5.9, Environmental Toxicity and Fate, which must be addressed as per 5.8.3. Perfluoroalkyl polymers, allowed only in floor finishes, must, at a minimum, be limited to fluorinated carbon-chain lengths of less than eight atoms.

5.2 Preservatives

Preservatives have biocidal properties and time-sensitive functionality. Safer Choice will allow use only at the lowest effective level. In addition to the CMR and PBT prohibitions in 5.2, preservatives that release CMRs or PBTs or whose reaction byproducts are CMRs or PBTs will not be allowed.

5.8.3 Special requirements

For colorants, polymers, and preservatives, the toxicological endpoints in the Master Criteria will be addressed as follows:

- 1) *For Acute Mammalian Toxicity (section 5.1 of the Master Criteria), Neurotoxicity (5.4), Repeated Dose Toxicity (5.5), and Skin Sensitization (5.8), the following apply:*

Data requirements: Screen Authoritative Lists. Chemicals with new measured data not yet reviewed by authoritative bodies may be subject to review.

- 2) *For Carcinogenicity (section 5.2 of the Master Criteria), Genetic Toxicity (5.3),*

¹ Described in the Sustainable Futures' Interpretive Assistance Document for Assessment of Polymers (http://www.epa.gov/oppt/sf/pubs/iad_polymers_june2013.pdf).

and Reproductive and Developmental Toxicity (5.6), and Respiratory Sensitization (5.7), the following apply:

Data requirements: Screen specified R-Phrases and Authoritative Lists. Available data, measured and/or estimated, for the chemical and/or a suitable analog may be reviewed against the criteria using a weight-of-evidence approach.

3) *Environmental Toxicity and Fate*

Limitation on Persistent, Bioaccumulative and Toxic chemicals: Acceptable chemicals must not be persistent (half-life \geq 60 days), bioaccumulative (BCF/BAF \geq 1,000), and aquatically toxic* (LC/EC50 \leq 10 mg/L or NOEC/LOEC \leq 1 mg/L).

Limitation on very Persistent and very Bioaccumulative chemicals: Acceptable chemicals must not be very persistent (half-life > 180 days or recalcitrant) and very bioaccumulative (> 5,000).

Limitation on very Persistent and very Toxic chemicals: Acceptable chemicals must not be very persistent (half-life > 180 days or recalcitrant) and very aquatically toxic* (LC/EC50 < 1.0 mg/L or NOEC/LOEC < 0.1 mg/L).

Data requirements: Screen Authoritative Lists. Available data, measured and/or estimated, for the chemical and/or a suitable analog may be reviewed against the criteria using a weight-of-evidence approach.

*Excludes the algal shading effects of colorants.