

EPA's Safer Choice Criteria for Fragrances

The Safer Choice Criteria for Fragrances do not allow listed carcinogens, mutagens, or reproductive toxicants (CMRs), persistent, bioaccumulative, and toxic chemicals (PBTs), and known respiratory sensitizers to be used as discrete fragrance chemicals in Safer Choice-certified products. (Natural Complex Substances [NCSs], including essential oils and extracts, are chemical mixtures subject to special requirements that allow only very low levels of listed chemicals, as discussed below.) If used, European Union (EU)-restricted dermal sensitizers must be listed on product packaging (as described under "Sensitizers," below).

Listed CMRs and PBTs:

Under the Safer Choice Criteria for Fragrances, each fragrance material¹ Chemical Abstracts Service Registry Number (CAS Number) is checked against authoritative lists of CMRs, PBTs, and relevant EU risk or hazard phrases. If a fragrance material (CAS Number) is included on one of the authoritative lists below, it is not allowed to be added to a fragrance formulation as a discrete fragrance material, regardless of its use level in the final product. (Please see the NCS section below for information on how the criteria treats listed chemicals in NCSs.)

For CMRs:

- International Agency for Research on Cancer (IARC). [Agents Classified by the IARC Monographs](#), Designated Group 1, 2A, or 2B.
- US EPA. [Integrated Risk Information System \(IRIS\)](#), Chemicals carcinogenic to humans, likely to be carcinogenic to humans, or suggestive evidence of carcinogenic potential (2005 Guidelines).
- California Office of Environmental Health Hazard Assessment (OEHHA). [Proposition 65 List of Chemicals Known to the State to Cause Cancer or Reproductive Toxicity](#).
- European Commission Hazard Phrases ([Annex VI to the Classification, Labelling, and Packaging \(CLP\) Regulation](#)) indicating possible carcinogenic, mutagenic, or reproductive toxicity: H350, H350i, H351, H340, H341, H360, H361, H362, and H373.

For PBTs:

- US EPA. [Toxic Release Inventory \(TRI\)](#). Designated PBT.
- EU REACH. [Substances of Very High Concern due to PBT, vPvB, or vPvT](#).
- Stockholm Convention [Persistent Organic Pollutants \(POPs\)](#).
- OSPAR List of Substances of Possible Concern. [Hazardous Substances List - Sections A-D](#).
- Chemicals determined to exceed the [Safer Choice thresholds for persistence, bioaccumulation, and aquatic toxicity](#) when addressed through the TSCA Work Plan Chemical process.

(Note that Safer Choice makes a limited exception for some chemicals on PBT lists based on new data.)

¹ For the purposes of the Safer Choice Criteria for Fragrances, fragrance materials are discrete substances, obtained by chemical synthesis or derived from a natural source, present in a fragrance at any level. Fragrance materials are materials whose primary function is to impart or mask a scent. This definition does not include auxiliary materials such as solvents and preservatives (covered under "Non-Fragrance Materials" below).

Sensitizers:

If a fragrance material CAS Number is included on the list below, it is not allowed under the Safer Choice Criteria for Fragrances, regardless of its use level in the final product.

- European Commission Hazard Phrases ([Annex VI to the CLP Regulation](#)) or Risk Phrases ([Annex VI to the DSD Regulation](#)) indicating possible respiratory sensitization: H334, R42.

Fragrance materials from another authoritative source referenced below – a list of 26 dermal sensitizers from Annex III of the EU Cosmetics Regulation – are allowed but must be disclosed in accordance with the Safer Choice Standard, section 5.5.1. These provisions, as previously proposed and finalized through public comment, address sensitizers in Safer Choice-certified products and will be part of the Safer Choice Criteria for Fragrances. Please note: When a product contains a listed dermal sensitizer, Safer Choice will treat industrial and institutional products the same as consumer products and require disclosure. Manufacturers should list any of the 26 dermal sensitizers in a product on the product label. Safer Choice will not require on-pack listing at the time of partnership or at audit but asks manufacturers to include the listing on-pack as soon as practicable. In the meantime, the presence of any of the listed dermal sensitizers must be disclosed—preferably on the company’s website—as part of the Safer Choice ingredient disclosure requirements at section 3.8 of the [Safer Choice Standard](#).²

- [Dermal Sensitizers from Annex III of the EU Cosmetics Regulation](#)

Lists of Banned Fragrance Materials:

Further, under the Safer Choice Criteria for Fragrances, fragrance materials banned by the EU, Canada and the International Fragrance Association (IFRA) are not allowed:

- [European Union \(EU\) Annex II](#) (EU Cosmetics Regulation).
- [Health Canada Cosmetic Ingredient Hotlist](#) – prohibited chemicals.
- [International Fragrances Association \(IFRA\) Standards](#) – prohibited chemicals.

Non-Fragrance Materials in Fragrance Formulations:

Fragrance houses should separately indicate any non-fragrance materials when submitting fragrance formulations.

- Carriers: Carriers act as solubilizers in the fragrance formulation and may include solvents or surfactants. Safer Choice evaluates carriers against the appropriate criteria (e.g., the Safer Choice [Criteria for Solvents](#) or [Criteria for Surfactants](#)).
- Odor Eliminators: Odor eliminators will be evaluated against the Safer Choice [Master Criteria](#).
- Preservatives: Preservatives will be evaluated against the Safer Choice [Criteria for Colorants, Polymers, Preservatives, and Related Chemicals](#).

² To implement ingredient disclosure, Safer Choice will ensure that product manufacturers are aware of the sensitizing fragrance chemicals in their products.

Natural Complex Substances (NCSs) Including Essential Oils (EOs) and Extracts:

Authoritative lists do not typically include NCSs. Some NCSs contain components that are listed CMR/PBTs. NCSs that contain listed CMRs or PBTs totaling 10% or more of the NCS are not allowed under the Safer Choice Criteria for Fragrances.

- 1) To be considered under the Safer Choice Criteria for Fragrances, NCS component information must be available from at least one of the following sources:
 - a. IFRA Labeling Manual;
 - b. EO University Database; or
 - c. Fragrance house analytical data.

The NCS CAS Number must also be listed on TSCA inventory.

- 2) From one of the three sources referenced above, Safer Choice must be able to confirm that there are no listed CMR/PBTs present at or above 10% (individually or in aggregate) in the NCS. If the IFRA Labeling Manual and/or EO University analysis indicates that CMR/PBTs are present at or above 10% in the NCS, fragrance houses have the option to provide batch-specific analytical data demonstrating that their NCS meets this threshold.

Questions?

Please contact saferchoice@epa.gov.