



DfE Quick Guide

Version 1.0

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DfE Safer Product Labeling Program Criteria: Quick Reference

Endpoint	Master (V.2.0: 2010)	Fragrance (V.1.0 Effective to 12/30/11) (V.2.0: Effective from 12/31/11)	Solvent (02/2009)	Surfactant (2010)	Chelant (V.1.0: 2010)	Direct Release (2010)
Acute Mammalian Toxicity	<p>Oral LD50 >2,000 mg/kg; Dermal LD50 >2,000 mg/kg; Inhalation LC50 (gas) >20,000 ppmV; Inhalation LC50 (vapor) >20 mg/L; Inhalation LC50 (dust/mist/fume) >5 mg/L</p>	<p>V. 1 Oral LD50 >50 mg/kg; Dermal LD50 >200 mg/kg; Inhalation LC50 (gas) >500 ppmV; Inhalation LC50 (vapor) >2 mg/L; Inhalation LC50 (dust/mist/fume) >0.5 mg/L</p> <hr/> <p>V. 2 Oral LD50 >50 mg/kg; Dermal LD50 >200 mg/kg; Inhalation LC50 (gas) >500 ppmV; Inhalation LC50 (vapor) >2 mg/L; Inhalation LC50 (dust/mist/fume) >0.5 mg/L</p>	<p>Oral LD50 >2,000 mg/kg; Dermal LD50 >2,000 mg/kg; Inhalation LC50 (gas) >5,000 ppm; Inhalation LC50 (vapor) >20 mg/L; Inhalation LC50 (dust/mist/fume) >5 mg/L</p>	<p>Oral LD50 >2,000 mg/kg; Dermal LD50 >2,000 mg/kg; Inhalation LC50 (gas) >5,000 ppm; Inhalation LC50 (vapor) >20 mg/L; Inhalation LC50 (dust/mist/fume) >5 mg/L</p>	<p>Oral LD50 >2,000 mg/kg; Dermal LD50 >2,000 mg/kg; Inhalation LC50 (gas) >20,000 ppmV; Inhalation LC50 (vapor) >20 mg/L; Inhalation LC50 (dust/mist/fume) >5 mg/L</p>	<p>Oral LD50 >2,000 mg/kg; Dermal LD50 >2,000 mg/kg; Inhalation LC50 (gas) >5,000 ppm; Inhalation LC50 (vapor) >20 mg/L; Inhalation LC50 (dust/mist/fume) >5 mg/L</p>
Carcinogenicity	<p>Not listed by NTP, U.S. EPA, IARC, EU CMR, GHS per DfE criteria; Not EU R45, R49 or R40</p>	<p>V.1 Not listed by NTP, U.S. EPA, IARC, EU CMR per DfE criteria; Not EU R45, R49 or R40</p> <hr/> <p>V. 2 Not listed by NTP, U.S. EPA, IARC, EU CMR per DfE criteria; Not EU R45, R49 or R40</p>	<p>Not listed by NTP, U.S. EPA, IARC, EU CMR per DfE criteria</p>	N/A	<p>Not listed by NTP, U.S. EPA, IARC, EU CMR, GHS per DfE criteria</p>	N/A

Endpoint	Master (V.2.0: 2010)	Fragrance (V.1.0 Effective to 12/30/11) (V.2.0: Effective from 12/31/11)	Solvent (02/2009)	Surfactant (2010)	Chelant (V.1.0: 2010)	Direct Release (2010)
Mutagenicity and Genotoxicity	Not classified as GHS category 1A, 1B, or 2; Not EU CMR List category 1, 2, or 3; Not EU R46 or R68	V. 1 Not classified EU CMR category 1, 2, or 3; Not EU R46 or R68 <hr/> V. 2 Not classified EU CMR category 1, 2, or 3; Not EU R46 or R68	Not classified as GHS category 1A, 1B, or 2; No other demonstrated mutagenic/genotoxic effects	N/A	Not classified as GHS category 1A, 1B, or 2; Not EU CMR List category 1, 2, or 3; Not EU R46 or R68	N/A
Reproductive and Developmental Toxicity	Oral >250 mg/kg-bw/day; Dermal >500 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >2.5 mg/L/6h/day; Inhalation (dust/mist/fume) >0.5 mg/L/6h/day; Not EU CRM category 1, 2 or 3; Not EU R60, R61, R62, R63 or R64; Not EU category 1 or 2 for endocrine disruption; Not U.S. EPA prioritized testing for endocrine disruption	V. Oral >250 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 ppm/6hr/day Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day; Not EU CRM category 1, 2 or 3; Not EU R60, R61, R62, R63 or R64 <hr/> V. 2 Oral >250 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 ppm/6hr/day Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day; Not EU CRM category 1, 2 or 3; Not EU R60, R61, R62, R63 or R64	Oral >250 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day	N/A	Oral >250 mg/kg-bw/day; Dermal >500 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >2.5 mg/L/6h/day; Inhalation (dust/mist/fume) >0.5 mg/L/6h/day	N/A

Endpoint	Master (V.2.0: 2010)	Fragrance (V.1.0 Effective to 12/30/11) (V.2.0:Effective from 12/31/11)	Solvent (02/2009)	Surfactant (2010)	Chelant (V.1.0: 2010)	Direct Release (2010)
Repeated Dose Toxicity	<p>Oral >100 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day; Not EU R33, R39, R48 or R68; Not EU category 1 or 2 for endocrine disruption; Not U.S. EPA prioritized testing for endocrine disruption</p>	<p>V. 1 <u>If a fragrance ingredient meets any of the conditions below, it must be reviewed based on GHS Criteria:</u></p> <ul style="list-style-type: none"> • Appears on list of substances prioritized for EU endocrine disruption testing • EU R33, R39, R48 or R68 <p>If a fragrance ingredient meets GHS criteria for Category 1 or 2, then the fragrance compound must be evaluated per GHS mixing rules to limit the amount of material in the overall formulation.</p> <p><u>GHS Category 1- Repeated:</u> Oral <10 mg/kg-bw/day; Dermal <20 mg/kg-bw/day; Inhalation (gas) <50 ppm/6h/day; Inhalation (vapor) <0.2 mg/L/6h/day; Inhalation (dust/mist/fume) <0.02 mg/L/6h/day</p> <p><u>GHS Category 2- Repeated:</u> Oral 10-100 mg/kg/day; Dermal 20-200 mg/kg/day; Inhalation (gas) 50-250 ppm/6h/day; Inhalation (vapor) 0.2-1 mg/L/6h/day; Inhalation (dust/mist/fume) 0.02-0.2 mg/L/6h/day</p>	<p>Oral >100 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day</p>	N/A	<p>Oral >100 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day</p>	N/A

		<p>V. 2</p> <p><u>If a fragrance ingredient meets any of the conditions below, it must be reviewed based on GHS Criteria:</u></p> <ul style="list-style-type: none"> • Appears on the list of substances prioritized for testing for endocrine disruption by EU • EU R33, R39, R48 or R68 <p>If a fragrance ingredient meets GHS criteria for Category 1 or 2, then the fragrance compound must be evaluated per GHS mixing rules to limit the amount of material in the overall formulation.</p> <p><u>GHS Category 1- Repeated:</u> Oral <10 mg/kg-bw/day; Dermal <20 mg/kg-bw/day; Inhalation (gas) <50 ppm/6h/day; Inhalation (vapor) <0.2 mg/L/6h/day; Inhalation (dust/mist/fume) <0.02 mg/L/6h/day</p> <p><u>GHS Category 2- Repeated:</u> Oral 10-100 mg/kg/day; Dermal 20-200 mg/kg/day; Inhalation (gas) 50-250 ppm/6h/day; Inhalation (vapor) 0.2-1 mg/L/6h/day; Inhalation (dust/mist/fume) 0.02-0.2 mg/L/6h/day</p>				
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Endpoint	Master (V.2.0: 2010)	Fragrance (V.1.0 Effective to 12/30/11) (V.2.0: Effective from 12/31/11)	Solvent (02/2009)	Surfactant (2010)	Chelant (V.1.0: 2010)	Direct Release (2010)
Neurotoxicity	Oral >100 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day	Versions 1 and 2 Refer to Repeated Dose Toxicity data	Oral >100 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day	N/A	Oral >100 mg/kg-bw/day; Dermal >200 mg/kg-bw/day; Inhalation (gas) >250 mg/kg-bw/day; Inhalation (vapor) >1 mg/L/6h/day; Inhalation (dust/mist/fume) >0.2 mg/L/6h/day	N/A
Sensitization	Not a known dermal or respiratory sensitizer; Not classified EU R42 or R43; Not classified GHS category 1A or 1B; Not present on AOEC Code List sensitizer-induced asthmagen	V. 1 Not IFRA classified as a photo sensitizer; Not a known respiratory or dermal sensitizer; Not EU R42 or R43; Not GHS category 1; Not present on AOEC Code List sensitizer-induced asthmagen; Not present on EU 26 Allergens List V. 2 Not IFRA classified as a photo sensitizer; Not a known respiratory or dermal sensitizer; Not EU R42 or R43; Not GHS category 1; Not present on AOEC Code List sensitizer-induced asthmagen; Not present on EU 26 Allergens List	Not a known dermal or respiratory sensitizer; Not classified EU R42; Not classified GHS category 1	Not a known dermal or respiratory sensitizer; Not classified EU R42; Not classified GHS category 1	Not a known dermal or respiratory sensitizer; Not classified EU R42; Not classified GHS category 1A or 1B; Not present on AOEC Code List sensitizer-induced asthmagen	Not a known dermal or respiratory sensitizer; Not classified EU R42; Not classified GHS category 1
Eutrophication	Total phosphorus in cleaning product limited to 0.5 weight %; Inorganic phosphate is not present	N/A	N/A	N/A	Total phosphorus in cleaning product limited to 0.5 weight %; Inorganic phosphate is not present	N/A

Endpoint	Master (V.2.0: 2010)	Fragrance (V.1.0 Effective to 12/30/11) (V.2.0: Effective from 12/31/11)	Solvent (02/2009)	Surfactant (2010)	Chelant (V.1.0: 2010)	Direct Release (2010)
Environmental Toxicity and Fate	<p>Acute Aquatic Toxicity (L/E/IC50): -If ≤1 ppm: may be acceptable if meets 10-day biodegradation window and BCF/BAF < 1000; -If >1 ppm and ≤10 ppm: must meet 10-day biodegradation window and BCF/BAF < 1000; If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF/BAF < 1000; -If ≥100 ppm: need not pass 28-day biodegradation test if its half-life <60 days and BCF/BAF <1000</p>	<p>V. 1 Acute Aquatic Toxicity (L/E/IC50): Not Acceptable: -If ≤0.1 ppm</p> <p>Pass: - If ≤1 ppm: may be acceptable if meets 10-day biodegradation window and BCF/BAF < 1000; -If >1 ppm and ≤10 ppm: must meet 10-day biodegradation window and BCF/BAF < 1000; -If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF/BAF < 1000; -If ≥100 ppm: need not pass 28-day biodegradation test if its half-life <180 days and BCF/BAF <1000</p> <p>Could be improved: - If ≤1 ppm: must meet 28-day biodegradation test and BCF/BAF < 1000; -If >1 ppm and ≤10 ppm: must meet 28-day biodegradation test and BCF/BAF < 1000; -If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF/BAF < 1000; -If ≥100 ppm: need not pass 28-day biodegradation test if its half-life <180 days and BCF/BAF <1000</p>	<p>Acute Aquatic Toxicity (L/E/IC50): -If ≤1 ppm: may be acceptable if meets 10-day biodegradation window and BCF < 1000; -If >1 ppm and ≤10 ppm: must meet 10-day biodegradation window and BCF < 1000; If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF < 1000; -If ≥100 ppm: need not pass 28-day biodegradation test if its half-life <180 days and BCF <1000</p>	<p>Acute Aquatic Toxicity (L/E/IC50): -If ≤1 ppm: may be acceptable if meets 10-day biodegradation window and BCF < 1000; -If >1 ppm and ≤10 ppm: must meet 10-day biodegradation window and BCF < 1000; If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF < 1000; -If ≥100 ppm: need not pass 28-day biodegradation test if its half-life <180 days and BCF <1000</p>	<p>Acute Aquatic Toxicity (L/E/IC50): -If ≤1 ppm: may be acceptable if meets 10-day biodegradation window and BCF/BAF < 1000; -If >1 ppm and ≤10 ppm: must meet 10-day biodegradation window and BCF/BAF < 1000; If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF/BAF < 1000; -If ≥100 ppm: need not pass 28-day biodegradation test if its half-life <60 days and BCF/BAF <1000</p>	<p>Acute Aquatic Toxicity (L/E/IC50): -If ≤1 ppm: not acceptable; -If >1 ppm and ≤10 ppm: must meet 10-day biodegradation window = could be improved If >10 ppm and <100 ppm: 28-day biodegradation = could be improved; 10 day biodegradation = acceptable; -If ≥100 ppm: 28-day biodegradation = acceptable</p>

V. 2
If the fragrance ingredient is present at or above 0.1% as applied it must meet the following criteria unless it is a substantive¹ chemical, essential oil, or constituent of an essential oil:

Acute Aquatic Toxicity (L/E/IC50):

-If ≤ 1 ppm: may be acceptable if meets 10-day biodegradation window and BCF/BAF < 1000;

-If >1 ppm and ≤ 10 ppm: must meet 10-day biodegradation window and BCF/BAF < 1000;

If >10 ppm and <100 ppm: must pass 28-day biodegradation test and BCF/BAF < 1000;

-If ≥ 100 ppm: need not pass 28-day biodegradation test if its half-life <60 days and BCF/BAF <1000

If the chemical is a substantive chemical,¹ essential oil or constituent of an essential oil it must meet the criteria above or demonstrate a high capacity for ultimate biodegradation per the test methods in Appendix 2 of the Fragrance v2.0 criteria.

Fragrance raw materials present in the cleaning product as applied below 0.01% and in the fragrance above 0.01% will be reviewed using the most recent version of EPI Suite™ models. No constituent is allowed in

	the product that is classifiable as P2¹ (or higher) and B2² (or higher) and T2³ (or higher) as defined by the USEPA New Chemicals Program (Appendix 3).			
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¹ A substantive chemical is a chemical substance, derived synthetically or present as a constituent of an essential oil, with the function to provide slow release aroma characteristics; typically has an experimental log Kow > 3.0

² P2 is classified as having a half life in soil, water and sediment of ≥ 60 days. Based on dominant compartment from fugacity modeling within EPI Suite software

³ B2 is classified as having a Bioconcentration factor (BCF) or Bioaccumulation factor (BAF) of ≥ 1000

⁴ T2 is classified as having a chronic aquatic toxicity of ≤ 10 mg/L or an acute aquatic toxicity of ≤ 100 mg/L

REFERENCES

All references can be found on the DfE website. The first place to start is: <http://www.epa.gov/dfe/index.htm>

Design for the Environment (DfE). 2009a. Design for the Environment Safer Product Recognition Program Elements: A Discriminating and Protective Approach to Product Review and Recognition. Dated June 2009. Available: http://www.epa.gov/dfe/pubs/formulat/formulator_review1.pdf

Design for the Environment (DfE). 2009b. DfE Screen for Solvents in Cleaning Products. Dated February 2009. Available: http://www.epa.gov/dfe/pubs/projects/gfcp/dfe_screen_for_solvents_in_cleaning_products_february2009.pdf

Design for the Environment (DfE). 2009c. DfE Screen for Fragrances Human Health Criteria. Version 1.0. Dated July 2009. Available: http://www.epa.gov/dfe/pubs/projects/gfcp/dfe_screen_for_fragrances_human_health_criteria_version_1.pdf (Effective until 12/30/2011)

Design for the Environment (DfE). 2010a. DfE's Standard and Criteria for Safer Chemical Ingredients. Available: <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Standard>

Design for the Environment (DfE). 2010b. EPA's DfE Standard for Safer Cleaning Products (SSCP). June 2009, Revised March 2010. Available: http://www.epa.gov/dfe/pubs/projects/gfcp/standard_for_safer_cleaning_products.pdf

Design for the Environment (DfE). 2010c. Design for the Environment Program Master Criteria for Safer Ingredients. Version 2.0. Dated July 2010. Available: http://www.epa.gov/dfe/pubs/projects/gfcp/dfe_master_criteria_safer_ingredients.pdf

Design for the Environment (DfE). 2010d. Design for the Environment Program Criteria for Chelating and Sequestering Agents. Version 1.0. Dated July 2010. Available: http://www.epa.gov/dfe/pubs/projects/gfcp/dfe_criteria_for_chelating_agents.pdf

Design for the Environment (DfE). 2010e. Design for the Environment Program Criteria for Fragrances. Version 2.0. Dated July 2010. Available: http://www.epa.gov/dfe/pubs/projects/gfcp/dfe_screen_criteria_for_fragrances.pdf (effective on 12/31/2011)

Design for the Environment (DfE). 2010f. DfE Criteria for Surfactants. Available: <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Surfactants>

Design for the Environment (DfE). 2010g. Criteria for Environmental Toxicity and Fate for Chemicals in Direct Release Products. Available: <http://www.epa.gov/dfe/pubs/projects/gfcp/index.htm#Toxicity>