



# GreenScreen® for Safer Chemicals Hazard Assessment Guidance

## Version 1.4 (December 2017) – Revision List

This revision release of **GreenScreen® for Safer Chemicals Hazard Assessment Guidance** (Guidance) v1.4 (December 2017) features a new organization with chemicals addressed in Section I, polymers in Section II and products in Section III. There are new GreenScreen Hazard Criteria specific to polymers and new GreenScreen Assessment Reporting Templates specific to polymers and products. Clarifications and updates were also made to the GreenScreen Hazard Criteria for chemicals and to the GreenScreen® List Translator. The following provides a list of revisions made between GreenScreen Guidance v1.3 2(e) and v1.4:

### GreenScreen Guidance Revisions:

1. Added Overview section which includes the following sub-sections:
  - a. Introduction (new)
  - b. Normative References (previously V1.3 Section 3)
  - c. General Requirements (previously V1.3 Section 5)
  - d. General Reporting Requirements (previously V1.3 Section 14)
  - e. Making Informed Decisions (previously V1.3 Section 15)
  - f. Records (previously V1.3 Section 16)
  - g. Terms and Definitions (previously V1.3 Section 4)
2. Made following key changes to Terms and Definitions:
  - a. Chemical Substance (Substance) changed to Chemical Compound (Chemical) and redefined.
  - b. New definition of Chemical Substance added.
  - c. Following Terms and Definitions relevant to polymers revised or added: Additivity, Bioavailability, Component, Constituent, Dalton, Monomer, Number Average Molecular Weight (Mn), Oligomer, Polymer Species, Polymeric Material, Polymeric Material Impurities, Polymer Mixture, Polymer Substance, Reactive Functional Group (RFG), Residual Monomer, Stabilizer, Thermoplastic Polymer, Thermoset Polymer, Unreacted Monomer.
  - d. Following Terms and Definitions relevant to products added: Article, Product, Substance Impurity.
  - e. Revisions to definitions of Functional Additive and Impurity.
3. Moved Disclosure and Assessment Rules and Best Practice to Section III Products (previously V1.3 Section 7).
4. Added Section I – Assessing Chemicals which includes Sections 1,2, 6- 13 of V1.3 with the following key changes:
  - a. Revisions to Purpose and Scope.
  - b. The Hazard Endpoints (previously V1.3 Section 8) moved to Annex 2 – GreenScreen Hazard Endpoint Classification Guidance. Clarifications made to assessing and classifying effects via lactation under Reproductive and Developmental Toxicity (Sub-section A2.1.1).

- Clarifications made to assigning Low hazards to Endocrine Activity (Sub-section A.2.12). Clarifications made to assessing hazards for Systemic Toxicity/Organ Effects and Neurotoxicity based on single versus repeat exposure data and addition of aspiration hazards (Sub-section A2.1.3).
- c. Re-organized V1.3 Sections 9-13 as follows: sub-section 11 addresses assessment of organic chemicals, while sub-section 12 addresses assessment of inorganic chemicals, with each sub-section including guidance for hazard assessment and assigning a GreenScreen Benchmark Score.
  - d. GreenScreen Hazard Criteria was retitled as GreenScreen Chemical Hazard Criteria and included as Annex 1.
  - e. Clarified guidance regarding assigning High versus Low confidence to hazard levels (Sub-section 11.3.2).
  - f. Clarified guidance regarding documenting hazard classifications (Sub-section 11.3.4).
  - g. Moved guidance on hazard assessment of Feasible and Relevant Environmental Transformation Products (previously V1.3 Section 12.3) to fall after hazard assessment of the parent chemical (Sub-section 11.4).
  - h. Created separate GreenScreen Benchmark Criteria for Organic and Inorganic chemicals and included them as Annexes 3 and 4, respectively.
  - i. Moved procedure for determining whether a preliminary Benchmark score should be modified due to lack of sufficient data (previously V1.3 Sections 11.2.1-11.2.4) to Annex 5 - GreenScreen Benchmark Data Requirements.
  - j. Clarified guidance regarding modifying a preliminary Benchmark score based on scores for Feasible and Relevant Transformation Products (Sub-section 11.6.5.1).
  - k. Added guidance on documenting Benchmark scores (Sub-section 11.6.6).
5. Added Section II – Assessing Polymers – this is an entirely new section within the Guidance and includes revised and in-depth procedures for assessing polymer hazards. The following Annexes and GreenScreen Assessment Reporting Templates were added as part of Section II:
    - a. Annex 7 – GreenScreen Polymer Hazard Criteria
    - b. Annex 8 – GreenScreen Qualifying Constituent/Component Hazard Criteria.
    - c. Template 2 – GreenScreen Polymer Substance Assessment Report Template.
    - d. Template 3 – GreenScreen Polymer Mixture Assessment Report Template.
  6. Added Section III – Assessing Products – this section incorporates V1.3 Section 7 Disclosure and Assessment Rules and Best Practice, V1.3 Annex II—Assessing and Benchmarking Mixtures, and V1.3 Annex III—Assessing and Benchmarking Polymeric Materials, but with substantial revisions and clarifications. Revised

reporting requirements include the addition of the following GreenScreen Assessment Reporting Templates:

- a. Template 4 – GreenScreen Non-Polymeric Product Assessment Report Template
  - b. Template 5 – GreenScreen Polymeric Material Assessment Report Template
7. Added Section IV – GreenScreen List Translator which was previously Annex I in V1.3.

### **GreenScreen Chemical Hazard Criteria (previously Chemical Hazard Criteria in V1.3):**

1. The GreenScreen Chemical Hazard Criteria are now included as Annex 1 of the Guidance.
2. Revised language for assigning Low hazards for all endpoints; removed text regarding structural alerts as that is now addressed in the Guidance (Sub-section 11.3).
3. Added EU REACH Substances of Very High Concern Candidate List and Prioritization List to GreenScreen (Authoritative).
4. For all endpoints, clarified that country-specific GHS classifications may refer to GHS Categories or EU H-Statements. Provided separate listing for New Zealand GHS classifications which use a unique numbering system.
5. Revised OSPAR listing: Chemicals for Priority Action list is Authoritative, while Substances of Possible Concern list is Screening.
6. Systemic Toxicity/Organ Effects Single Exposure – added clarifying language to remind users neurotoxic effects are evaluated separately under GreenScreen. Moved EU H-Statements, EU R-Phrases and GHS-Country Lists to Multiple Endpoints, as these designations may include neurotoxic effects. Added EU H-Statement H335 and EU R-Phrase R37 as these are specific (non-neurotoxic) effects.
7. Systemic Toxicity/Organ Effects Single Exposure – added Aspiration Hazards.
8. Systemic Toxicity/Organ Effects Repeated Exposure – added clarifying language to remind users neurotoxic effects are evaluated separately under GreenScreen. Moved EU H-Statements, EU R-Phrases and GHS-Country Lists to Multiple Endpoints, as these designations may include neurotoxic effects.
9. Neurotoxicity Single Exposure – added clarifying language that neurotoxic effects are evaluated separately under GreenScreen. Added GHS Guidance Values. Moved EU H-Statements, EU R-Phrases and GHS-Country Lists to Multiple Endpoints (except H336 and R67), as these designations may include non-neurotoxic effects.
10. Neurotoxicity Repeated Exposure – added clarifying language that neurotoxic effects are evaluated separately under GreenScreen. Added GHS Guidance Values. Moved EU H-Statements, EU R-Phrases and GHS-Country Lists to Multiple Endpoints, as these designations may include non-neurotoxic effects.
11. Skin and Respiratory Sensitization – MAK listing changed from Authoritative A to Authoritative B (spanning High to Moderate Hazard Level).

12. Skin and Respiratory Sensitization – Added a footnote to the GHS-[Country] Lists stating: “If a country does not designate between Category 1A and Category 1B for evaluating Skin or Respiratory Sensitization, then the list should be treated as a Screening B list, with a High to Moderate hazard level in GreenScreen for GHS Category 1 classifications.”
13. Acute Aquatic Toxicity and Chronic Aquatic Toxicity – Moved EC – CEPA DSL listing to Multiple Endpoints, as listing could be based on either acute or chronic aquatic toxicity.
14. Acute Aquatic Toxicity – Moved R51/R53 and R52/53 listing to Multiple Endpoints, as listing could be based on either acute or chronic aquatic toxicity.
15. Chronic Aquatic Toxicity – Moved EU H-Statement H413, EU R-Phrase R53 and GHS Country-Listing Category 4 to Multiple Endpoints.
16. Reactivity – Added Desensitized Explosives per latest GHS Rev 7 (2017). Added EU-H029, EU-H031, and EU-H032 Statements and EU R-Phrase R29, R30 and R32.
17. Flammability – Revised guidance for flammable gases and EU H-Statements H220, H221 and H230 per latest GHS Rev 7 (2017). Added H231.
18. Removed US EPA - Priority PBTs (PPT) as GreenScreen Specified List.
19. Changed EU - ESIS PBT from Authoritative to Screening List.

### **GreenScreen List Translator:**

1. List Translator document is now Annex 11 of the Guidance.
2. All of the changes to the GreenScreen Chemical Hazard Criteria listed above were incorporated into the List Translator.