

## Section II — Assessing Polymers

### 13. PURPOSE

Section II outlines the procedure to be used to assess and classify hazards of polymers.

Follow the procedure in Section III, sub-section 20 for evaluating polymeric materials.

### 14. SCOPE

The scope of assessment described in Section II includes the multiple molecular species that make up a polymer. Within GreenScreen, two polymer types have been defined: polymer substance and polymer mixture (see Terms and Definitions). It is noted that most thermoplastic polymers will be polymer substances, while thermoset polymers may be polymer substances or polymer mixtures, depending on the stage in the manufacturing process at which they are being evaluated. In general, if the polymer contains unreacted monomer by intention (i.e., it is being evaluated at a stage where it is not fully reacted), then it should be evaluated following the steps provided for polymer mixtures. If the polymer is fully reacted and any monomer present is considered residual (an impurity), then it should be evaluated following the steps provided for polymer substances.

### 15. POLYMER ASSESSMENT PROCEDURE

Figure 3 provides an overview of the assessment process for polymer substances and polymer mixtures.

#### 15.1 Step 1 – Identify Polymer Type and Inventory Constituents and/or Components

Determine whether the assessment is for a polymer substance or polymer mixture.

See Term & Definitions.

Within GreenScreen, hazard classification for endpoints is based on consideration of constituents in polymer substances or components in polymer mixtures if toxicological data are not available for the polymer substances or mixtures themselves. The constituents in polymer substances and components in polymer mixtures which must be evaluated have been outlined in Section 15.1.1 and Section 15.1.2, respectively.

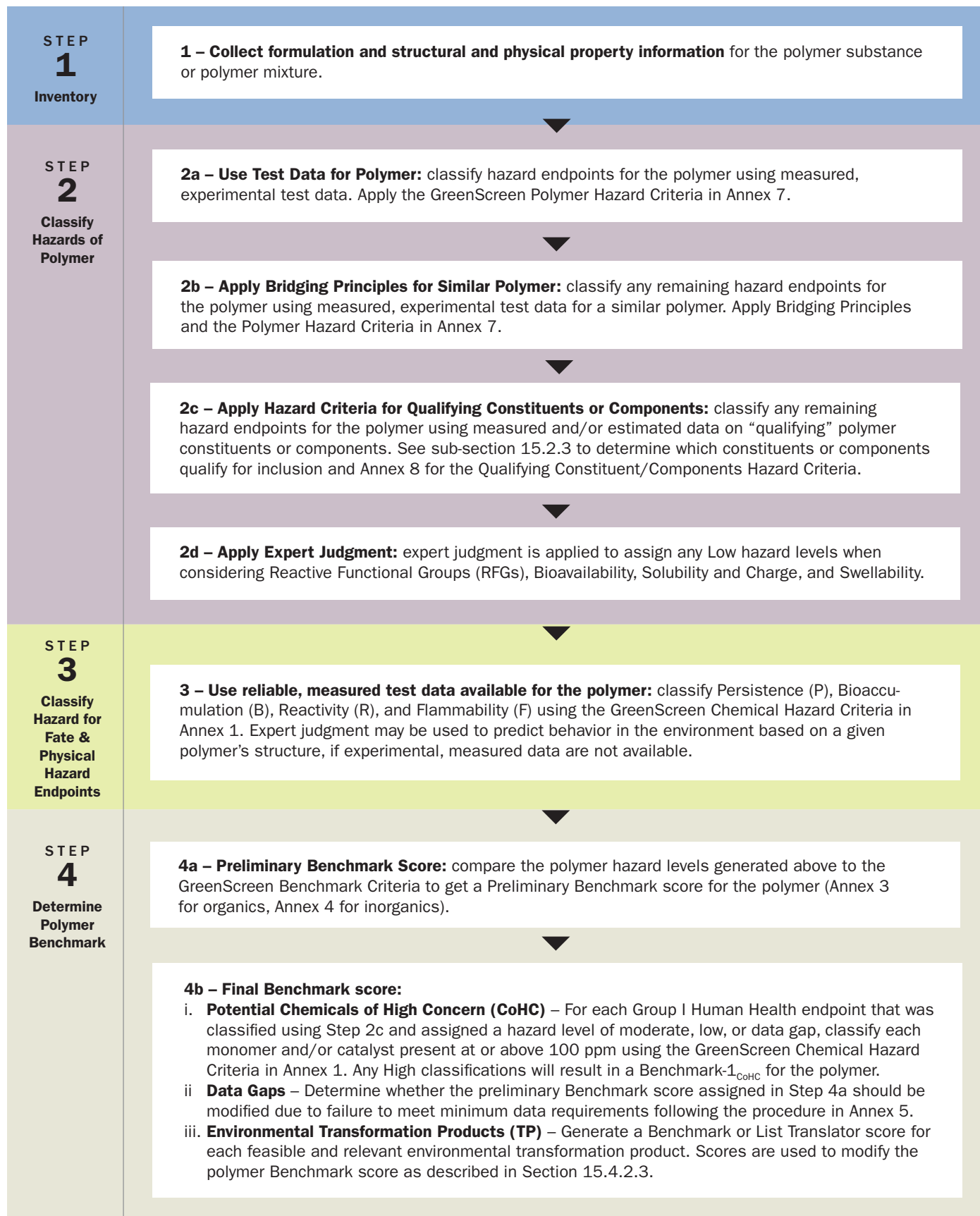
For the inventory of constituents within the polymer substance or components within the polymer mixture, the assessor must provide a description of the method used to determine compliance with the thresholds listed below (i.e., analytical testing, supplier attestations, and/or supply chain research). If analytical testing is used, it is recommended to include test method and detection limit.

##### 15.1.1 Polymer substance

A polymer substance inventory includes the constituents depicted in Figure 4 below. Collect information regarding physical and chemical characteristics of the polymer substance. Record all information in the GreenScreen Polymer Substance Assessment Report Template (Section VI, Template 2).

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FIGURE 3. GreenScreen Polymer Assessment Process



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**FIGURE 4. Inventory Constituents of a Polymer Substance**

**POLYMER SUBSTANCE**

- Polymer species of varying lengths
- Residual monomer(s)  $\geq 100$  ppm
- Oligomers
- Stabilizer(s)  $\geq 100$  ppm
- Substance impurities  $\geq 100$  ppm
- Special Case impurities  $< 100$  ppm\*

\* Special case impurities  $< 100$  ppm (0.01%) are scored and reported separately using the GreenScreen List Translator.

**15.1.2 Polymer mixture**

A polymer mixture inventory includes the components depicted in Figure 5 below. Collect information regarding physical and chemical characteristics of the polymer mixture. Record all information in the GreenScreen Polymer Mixture Assessment Report Template (Section VI, Template 3).

For polymer mixtures, it is necessary to specify the life cycle stage being assessed in the GreenScreen assessment report, which will be 1) “as placed on the market” (liquid or low molecular weight solid with significant intentionally added unreacted monomer); or 2) “semi-cured” (what is known in the composites sector as “pre-preg”). Because there are differing levels of unreacted monomers at different stages, a polymer mixture may have a different Benchmark score depending on the life-cycle stage being considered. A “fully cured” polymer (high molecular weight, fully cross-linked matrix) is considered a polymer substance and the constituents are inventoried as described in 15.1.1.

**FIGURE 5. Inventory Components of a Polymer Mixture**

**POLYMER MIXTURE**

- Unreacted monomer(s)  $\geq 100$  ppm

**POLYMER SUBSTANCE**

- Polymer species of varying lengths
- Oligomers
- Stabilizer(s)  $\geq 100$  ppm
- Substance impurities  $\geq 100$  ppm
- Special case impurities  $< 100$  ppm\*

\* Special case impurities  $< 100$  ppm (0.01%) are scored and reported separately using the GreenScreen List Translator.

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### 15.2 Step 2 – Classify Human Health and Ecotoxicity Hazards of Polymer

The stepwise process of classifying the human health and ecotoxicity hazard endpoints for a polymer substance or mixture is outlined in this Section 15.2. Document hazard levels in the Polymer Hazard Summary Table located in the GreenScreen Polymer Substance Assessment Report Template or the GreenScreen Polymer Mixture Assessment Report Template, as appropriate (See Section VI for templates).

#### 15.2.1 Step 2a – Use test data for the polymer

In classifying human health and ecotoxicity hazards, highest preference is given to reliable measured test data on the polymer substance or mixture of interest (i.e., specific to the manufacturer and trade name, representative of number average molecular weight (Mn), and the type and level of residual or unreacted monomers and oligomers present). Review available polymer substance or mixture test data against the GreenScreen Polymer Hazard Criteria in Annex 7 to classify hazard endpoints and record in the Polymer Hazard Summary Table.

#### 15.2.2 Step 2b – Apply bridging principles for a similar polymer

For any unclassified hazard endpoint(s) from Step 2a above, collect measured test data on a similar polymer substance or mixture. For a polymer to be considered similar, the level of residual or unreacted monomers and other impurities must be equal to or greater than the concentration of the same monomer or impurity in the original polymer. Hazard classification is accomplished by applying Bridging Principles and the GreenScreen Polymer Hazard Criteria in Annex 7. Guidance on applying the Bridging Principles can be found in Section 3.2.3.2 in GHS Rev.7.<sup>5</sup>

#### 15.2.3 Step 2c – Apply hazard criteria for qualifying constituents or components

Where reliable measured test data on the polymer substance or mixture itself (Step 2a) or Bridging Principles on a similarly tested polymer substance or mixture (Step 2b) cannot assist in classifying hazard endpoints, data on individual qualifying constituents of the polymer substance or components of the polymer mixture are used to classify any remaining human health and ecotoxicity hazard endpoints.

Proceed through the steps below.

- 1) Identify Qualifying Constituents or Components
  - a. For polymers substances with  $Mn \geq 1000 \text{ Da}$ <sup>6</sup>:
    - i. Include residual monomers, stabilizers and other substance impurities present at  $\geq 1000 \text{ ppm}$  (0.1%) in the classification of the polymer substance following the GreenScreen Polymer Qualifying Constituent/Component Hazard Criteria in Annex 8;<sup>7</sup> If the number average molecular weight of the polymer substance is  $\geq 1000$  and  $< 10,000 \text{ Da}$  and if oligomers with molecular weight  $< 500 \text{ Da}$  are present at  $\geq 10\%$ ; and/or oligomers with molecular weight

5 [https://www.unece.org/trans/danger/publi/ghs/ghs\\_rev07/07files\\_e0.html](https://www.unece.org/trans/danger/publi/ghs/ghs_rev07/07files_e0.html), accessed 9/20/17

6 In the case of a polymer substance with a number average molecular weight of  $< 1000 \text{ Da}$ , models such as the U.S. Environmental Protection Agency's EPI Suite™ (version 4.1) (as documented in the Sustainable Futures/P2 Framework Manual) may be used to estimate key chemical properties, where test data are not available (i.e., polymer substance hazards are not classified based on separate consideration of polymer substance constituents). As is always the case, predictions from modeling software should not be used if acceptable measured data are available, but measured data can be entered into EPI Suite™ to replace conservative default assumptions to improve the estimations of the other properties. All model limitations must be observed.

7 The Polymer Qualifying Constituent/Component Hazard Criteria are based on GHS mixture rules with adaptations for some hazard endpoints.

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- <1,000 Da are present at  $\geq 25\%$ , then also include their hazards in the classification of the polymer substance following the GreenScreen Polymer Qualifying Constituent/Component Hazard Criteria in Annex 8.
- ii. If the number average molecular weight of the polymer substance is  $\geq 10,000$  Da and if oligomers with molecular weight <500 Da are present at  $\geq 2\%$ ; and/or oligomers with molecular weight <1,000 Da are present at  $\geq 5\%$ , then also include their hazards in the classification of the polymer substance following the GreenScreen Polymer Qualifying Constituent/Component Hazard Criteria in Annex 8.
  - iii. If conditions above are not met, oligomers are not considered qualifying constituents of the polymer substance and do not need to be assessed.
- b. For polymer mixture components:
    - i. Evaluate the polymer substance first. Include stabilizers and other substance impurities present at  $\geq 1000$  ppm (0.1%) and qualifying oligomer species as determined above in the classification of the polymer substance following the GreenScreen Qualifying Constituent/Component Hazard Criteria in Annex 8.
    - ii. Evaluate the polymer mixture second. Include unreacted monomers, stabilizers and substance impurities present at  $\geq 1000$  ppm (0.1%) and qualifying oligomer species as determined above in the classification of the polymer mixture following the GreenScreen Qualifying Constituent/Component Hazard Criteria in Annex 8.
- 2) Assess Qualifying Constituents or Components and Record Results
- a. Polymer Substance Constituents: Determine the hazard level for each human health and ecotoxicity hazard endpoint not classified in Steps 2a and 2b above based on the GreenScreen Qualifying Constituent/Component Hazard Criteria in Annex 8. Record results in the appropriate Polymer Hazard Summary Table.
  - b. Polymer Mixture Components: For polymer mixtures, the evaluation is first conducted for the polymer substance and second for the polymer mixture. For the polymer substance, determine the hazard level for each human health and ecotoxicity hazard endpoint not classified in Steps 2a and 2b above based on the GreenScreen Qualifying Constituent/Component Hazard Criteria in Annex 8 (excluding unreacted monomers) and record results in the appropriate Polymer Hazard Summary Table. Repeat the process for polymer mixtures, including unreacted monomer(s) as qualifying components and record results in the appropriate Polymer Hazard Summary Table.

### 15.2.4 Step 2d – Apply expert judgment

Apply expert judgment if there are no qualifying constituents or components, or if the assessment of qualifying constituent(s) or component(s) does not meet the criteria for vH, H, or M hazard level. Expert judgment is applied to determine if an L hazard level can be assigned. In addition, in some cases, it may be warranted to replace a hazard level assigned based on qualifying components or constituents with a higher hazard level due to certain characteristics of the polymer substance or mixture as discussed below. The assessor should apply expert judgment in these cases and document all rationale for final hazard levels in the GreenScreen assessment report.

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Polymers that are “exempt” from the premanufacture notification (PMN) regulations for new chemical substances under §5 of the Toxic Substances Control Act (TSCA) are required to meet a variety of criteria outlined in the USEPA Polymer Exemption Guidance Manual (<https://www.epa.gov/sites/production/files/2015-03/documents/polyguid.pdf>, accessed 11/27/17).

Criteria for EPA polymer exemption do not necessarily directly translate and align with GreenScreen hazard criteria for all hazard endpoints; therefore, an EPA-exempted polymer is not automatically assumed to have “Low” hazard for any GreenScreen hazard endpoint. However, assessors can use key chemical and physical characteristics of the exempted polymer as lines of evidence to support a hazard classification based on expert judgment.

### 1) Reactive Functional Groups (RFGs)

The classification should take into consideration the presence of reactive functional groups on the polymer side chains. A key consideration is whether these side chain functional groups have the potential for biological functions and/or adverse effects. The USEPA Polymer Exemption Guidance Manual assigns key reactive functional groups a High, Moderate, or Low designation, and discusses how the RFGs might influence hazard classification for certain endpoints. This authoritative reference should be used as the main resource for applying expert judgment when assigning a hazard level based on RFG data.

### 2) Bioavailability

To assign a Low hazard level to any GreenScreen hazard endpoint based on “lack of bioavailability,” supporting evidence must show lack of bioavailability for all routes of exposure (i.e., inhalation, skin absorption, and oral). Following CLP Guidance, “conclusive scientific experimental data [must] show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable” (CLP; [https://echa.europa.eu/documents/10162/23036412/clp\\_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5](https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5), accessed 9/20/17). Any evaluation of the bioavailability of a polymer should take into account measured data for all relevant constituents or components and their potential to interact that might influence bioavailability. In general, any Low hazard level assigned based on bioavailability arguments must be supported by adequate analysis using strong scientific evidence, and a strength of evidence determination using expert judgment must be applied. Conclusions may be based on considerations of the physical properties of a substance or derived from Structural Activity Relationships (SAR) (CLP; [https://echa.europa.eu/documents/10162/23036412/clp\\_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5](https://echa.europa.eu/documents/10162/23036412/clp_en.pdf/58b5dc6d-ac2a-4910-9702-e9e1f5051cc5), accessed 9/20/17).

### 3) Solubility and Charge

Water solubility is used to estimate how a chemical will distribute between environmental compartments (i.e., air, soil, or water/sediment). The scale for water solubility is provided below in Table 2 (EPA Sustainable Futures/P2 Manual, Section 5: Estimating Physical / Chemical and Environmental Fate Properties with EPI Suite; <https://www.epa.gov/sites/production/files/2015-05/documents/05.pdf>, accessed 9/20/17).

The US EPA Interpretive Assistance Document for Assessment of Polymers provides guidance on assigning a Low hazard level for Acute Aquatic Toxicity based on solubility and charge (nonionic, anionic, cationic, and amphoteric) (USEPA Interpretive Assistance

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Document for Assessment of Polymers—Sustainable Futures Summary Assessment (June 2013); [https://www.epa.gov/sites/production/files/2015-05/documents/06-iaad\\_polymers\\_june2013.pdf](https://www.epa.gov/sites/production/files/2015-05/documents/06-iaad_polymers_june2013.pdf), accessed 12/15/17).

TABLE 2. Water Solubility Classifications

Water Solubility (mg/L water @ 25 degrees C)	Classification
> 10,000	Very soluble
> 1,000 - 10,000	Soluble
> 100 - 1,000	Moderate solubility
> 0.1 – 100	Slightly soluble
< 0.1	Negligible solubility

## 4) Swellability

Per the USEPA Polymer Exemption Guidance Manual (<https://www.epa.gov/sites/production/files/2015-03/documents/polyguid.pdf>, accessed 11/21/17), assessment of Carcinogenicity should take into account the water absorption properties (i.e., swellability) of the polymer. EPA makes the “may present an unreasonable risk” determination with concerns for fibrosis and cancer, based upon water absorption properties. Data show that cancer was observed in a two-year inhalation study in rats on a high molecular weight water-absorbing polyacrylate polymer (TSCA 8(e)-1795). Therefore, expert judgment should be used to classify Carcinogenicity for swellable polymers >70,000 Da.

Also per US EPA Polymer Exemption Guidance Manual, insoluble, non-swellable polymers >70,000 Da are expected to show irreversible lung damage linked with inhalation of highly respirable particles <10 microns and lack absorption potential are expected to show irreversible lung damage linked with inhalation of highly respirable particles. This is based on a study of toner used in copy machines, designated TSCA 8(e)-0668. The physical hazard is based on deposition to the deep lung and inability to dislodge the particles. Expert judgment should be used to classify Repeated Dose Systemic Toxicity for insoluble, non-swellable polymers with molecular weights >70,000 Da that are respirable (<10 micron).

**15.3 Step 3 – Classify Environmental Fate and Physical Hazards of Polymer**

Since the process outlined in Step 2 is based on GHS mixture rules with some adaptations, and GHS mixture rules do not apply to the environmental fate and physical hazard endpoints in GreenScreen, this section outlines the process to be used to classify these hazards.

**15.3.1 Environmental fate endpoints – Persistence (P) and Bioaccumulation (B)**

First determine whether reliable measured test data are available for the polymer substance or mixture itself to evaluate the Persistence (P) and Bioaccumulation (B) endpoints. If yes, use these data to classify the hazards of these endpoints based on the GreenScreen Chemical Hazard Criteria in Annex 1. In the absence of test data for the polymer substance or mixture, and where modeling software may not provide reliable estimates for polymers ≥ 1000 Da, expert judgment may be used to predict behavior in the environment based on

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chemical and physical properties. The U.S. EPA Sustainable Futures Interpretive Assistance Document for Assessment of Polymers can be used to support hazard classification in these cases (USEPA Interpretive Assistance Document for Assessment of Polymers—Sustainable Futures Summary Assessment (June 2013); [https://www.epa.gov/sites/production/files/2015-05/documents/O6-iad\\_polymers\\_june2013.pdf](https://www.epa.gov/sites/production/files/2015-05/documents/O6-iad_polymers_june2013.pdf), accessed 12/15/17). Assessors should document the values listed in the correct Polymer Assessment Report Template for parameters used to derive hazard levels based on the GreenScreen Chemical Hazard Criteria, even if they are estimated and/or based on expert judgment.

### 15.3.2 Physical hazard endpoints – Reactivity (R) and Flammability (F)

If reliable measured test data are available for the polymer substance or mixture itself, these data should be used to classify hazards for the Reactivity (R), and Flammability (F) endpoints based on the GreenScreen Chemical Hazard Criteria in Annex 1. If such data are not available, expert judgment may be used to assign hazard levels based on polymer physical and chemical characteristics.

## 15.4 Step 4 – Determine Polymer Benchmark Score

For polymer substances, perform the following steps to determine the GreenScreen Benchmark score.

For polymer mixtures, first perform the following steps to determine the GreenScreen Benchmark score for the polymer substance, and second for the polymer mixture including unreacted monomer(s) as qualifying components.

The order of steps below determines the final Benchmark score (i.e., the Benchmark score from each subsequent step will replace the Benchmark score of the previous step, if it is lower). Any change to Benchmark scores per Step 4b, 4c, and 4d should be designated by including the subscripts “DG,” “CoHC,” or “TP,” respectively.

### 15.4.1 Step 4a – Generate a preliminary Benchmark score

Compare the polymer substance and/or polymer mixture hazard levels in the Polymer Hazard Summary Table generated in Steps 2 and 3 above to the GreenScreen Benchmark Criteria in Annex 3 to obtain a Preliminary Benchmark score. If the preliminary Benchmark score is Benchmark-1, skip step 4b and assign a final score of Benchmark-1.

### 15.4.2 Step 4b – Determine the final Benchmark score

#### 1) Conduct Potential Chemical of High Concern (CoHC) Analysis

Identify each **Group I Human Health Endpoint** requiring potential CoHC analysis. A Group I Human Health endpoint requires potential CoHC analysis if the endpoint was classified using Step 2c and was assigned a hazard level of moderate, low, or data gap for the polymer substance or polymer mixture. Perform the following steps for each Group I Human Health hazard endpoint that requires potential CoHC analysis.

#### **For polymer substances:**

Determine the hazard level for each residual monomer and/or catalyst present at or above 100 ppm using the GreenScreen Chemical Hazard Criteria in Annex 1 and record results in the Polymer Hazard Summary Table (see example in Table 3 below). If one or more residual monomer(s) and/or catalyst(s) assessed are assigned a high hazard level for any one or more Group I Human Health hazard endpoints, modify the polymer's final Benchmark score to a Benchmark-1<sub>CoHC</sub>.



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### For polymer mixtures:

Determine the hazard level for each unreacted monomer and/or catalyst present at or above 100 ppm using the GreenScreen Chemical Hazard Criteria in Annex 1 and record results in the Polymer Hazard Summary Table. If one or more unreacted monomer(s) and/or catalyst(s) assessed are assigned a high hazard level for any one or more Group I Human Health hazard endpoints, modify the polymer's final Benchmark score to a Benchmark-1<sub>CoHC</sub>.

Report the modified Benchmark score and the rationale for the modified Benchmark score in the Benchmark and hazard summary section of the GreenScreen assessment report. To ensure transparency, hazard levels for residual/unreacted monomers and/or catalysts  $\geq 100$  ppm are reported separately from the polymer substance or polymer mixture as shown in Table 3.

Any data gaps for Group 1 Human Health hazard endpoints for residual or unreacted monomer and/or catalyst present at or above 100 ppm should be reported, however they do not impact the polymer's final Benchmark score when conducting a potential CoHC analysis.

#### 2) Conduct a Data Gap Analysis

Follow the procedure outlined for chemicals in Section I, sub-section 11.6.2.1 and Annex 5 to perform a data gap analysis and determine whether the GreenScreen Benchmark score for the polymer substance or polymer mixture must be modified due to data gaps.

#### 3) Evaluate Environmental Transformation Products

Follow the procedure outlined for chemicals in Section I, sub-section 11.6.2.2 and determine if the Benchmark score must be modified. Feasible and relevant environmental transformation products may result from chemical changes in which a polymer breaks down as the result of oxidation, hydrolysis, heat, sunlight, attack by solvents, microbial action, etc. (USEPA Polymer Exemption Guidance Manual; <https://www.epa.gov/sites/production/files/2015-03/documents/polyguid.pdf>, accessed 11/21/17).

## 16. DOCUMENT HAZARD LEVELS

**16.1** Record the hazard levels for a polymer substance in the Hazard Summary Table of Template 2 – Polymer Substance Assessment Report Template (See Section VI). An example for a polymer substance is shown in Table 3.

Hazard levels for the Group I Human Health Endpoints are included for residual monomers and/or catalysts  $\geq 100$  ppm (0.01%) if one or more of these hazard levels were used to determine the final Benchmark score of the polymer substance.

**16.2** Record the hazard levels for a polymer mixture in the Hazard Summary Table of Template 3 – Polymer Mixture Assessment Report Template.

Hazard levels for the Group I Human Health Endpoints are included for unreacted monomers and/or catalysts  $\geq 100$  ppm (0.01%) in the polymer mixture if one or more of these hazard levels were used to determine the final Benchmark score of the polymer mixture.

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TABLE 3. Example Polymer Hazard Summary Table for a Polymer Substance with a Residual Monomer > 100 ppm

GreenScreen Polymer Hazard Summary Table																					
Group I Human					Group II and II* Human								Ecotox		Fate		Physical				
Polymer Substance	Carcinogenicity	Genotoxicity/Mutagenicity	Reproductive Toxicity	Developmental Toxicity	Endocrine Activity	Acute Toxicity	Systemic Toxicity		Neurotoxicity		Skin Sensitization*	Respiratory Sensitization*	Skin Irritation	Eye Irritation	Acute Aquatic Toxicity	Chronic Aquatic Toxicity	Persistence	Bioaccumulation	Reactivity	Flammability	BM
							SINGLE	REPEAT*	SINGLE	REPEAT*											
Polymer Substance	DG	M	M	M	DG	H	M	M	VH	H	H	DG	H	H	VH	VH	H	L	M	L	1 <sub>COHC</sub>
Residual Monomer at 250 ppm	H	M			M																

Assume the assessor conducted the following steps to obtain the hazard summary table above:

- Assessor identified which Group I Human Health endpoints required potential CoHC analysis:
  - Carcinogenicity – YES because assigned a data gap in step 2c
  - Mutagenicity – YES because assigned a moderate hazard level in in step 2c
  - Reproductive Toxicity – NO because assessed in step 2a
  - Developmental Toxicity – NO because assessed in step 2b
  - Endocrine Activity – Yes because assigned a data gap in step 2c
- Assessor identified all monomer(s) and catalyst(s) present above 100 ppm:
  - Identified only one: Residual Monomer at 250 ppm
- Assessor classified Carcinogenicity, Mutagenicity, and Endocrine Activity for the residual monomer using GreenScreen Chemical Hazard Criteria in Annex 1:
  - Carcinogenicity – HIGH
  - Mutagenicity – MODERATE
  - Endocrine Activity – MODERATE
- Assessor assigned final score of Benchmark-1<sub>COHC</sub> to polymer substance due to high carcinogenicity for residual monomer present at 250 ppm in the polymer substance.