# SECTION V — ANNEX 8

# GreenScreen Qualifying Polymer Constituent/ Component Hazard Criteria

# GreenScreen Qualifying Polymer Constituent/Component Hazard Criteria

## GROUP I HUMAN HEALTH EFFECTS (GROUP I HUMAN)

**TABLE A8.1: Carcinogenicity (C) — Non-Additive**

| | Hazard Levels | | | |
|---|---|---|---|---|
| | High (H) | Moderate (M) | Low (L) | Data Gap (DG) |
| **Polymer Chain** | GHS Cat. 1A or 1B | GHS Cat. 2 | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1A or 1B and present at >0.1% | GHS Cat. 2 and present at ≥ 1% | • Adequate data available and negative studies; and • GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

**TABLE A8.2: Mutagenicity & Genotoxicity (M) — Non-Additive**

| | Hazard Levels | | | |
|---|---|---|---|---|
| | High (H) | Moderate (M) | Low (L) | Data Gap (DG) |
| **Polymer Chain** | GHS Cat. 1A or 1B | GHS Cat. 2 | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1A or 1B and present at >0.1% | GHS Cat. 2 and present at ≥ 1% | • Adequate data available and negative studies for both chromosomal aberrations and gene mutations; and • GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

TABLE A8.3: **Endocrine Activity (EA) — Non-Additive**

| | Hazard Levels | | | |
|---|---|---|---|---|
| | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | Evidence of endocrine activity and related human health effect. | Evidence of endocrine activity. | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/ component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | Evidence of endocrine activity and related human health effect and present at >0.1% | Evidence of endocrine activity and present at ≥ 1% | Adequate data available and negative studies | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

TABLE A8.4: **Reproductive Toxicity (R) and Developmental (D) Toxicity — Non-Additive**

| | Hazard Levels | | | |
|---|---|---|---|---|
| | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1A or 1B | GHS Cat. 2 | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/ component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1A or 1B and present at > 0.3% | GHS Cat. 2 and present at ≥ 3% | · Adequate data available and negative studies; and · GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

# GreenScreen Qualifying Polymer Constituent/Component Hazard Criteria

## GROUP II AND II* HUMAN HEALTH EFFECTS (GROUP II AND II* HUMAN)

TABLE A8.5: **Acute Mammalian Toxicity (AT) — Additive**

| | | Hazard Levels | | | | |
|---|---|---|---|---|---|---|
| | | **Very High (vH)** | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | | GHS Category 1 or 2 for any route of exposure | GHS Category 3 for any route of exposure | GHS Category 4 for any route of exposure | · GHS Category 5; or<br>· Adequate data available and negative studies; and<br>· GHS not classified | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain.<br><br>OR<br><br>There is insufficient information to classify one or more qualifying constituent(s)/component(s). |
| **GreenScreen Guidance**<br><br>**Values for Calculated ATE$_{mixture}$** | **Oral ATE (mg/kg)** | ≤ 50 | >50-300 | > 300-2000 | > 2000 | N/A |
| | **Dermal ATE (mg/kg)** | ≤ 200 | >200-1000 | > 1000-2000 | > 2000 | |
| | **Inhalation-Gas or Vapor ATE (mg/L)** | ≤ 2 | >2-10 | > 10-20 | > 20 | |
| | **Inhalation-Dust/ Mist/Fumes ATE (mg/L)** | ≤ 0.5 | >0.5-1.0 | > 1-5 | > 5 | |

The Acute Toxicity Estimate for the mixture (ATE$_{mixture}$) needs to be calculated and then compared against the GreenScreen Hazard Criteria to assign the corresponding hazard level as shown in Table A8.5.

The concentration limits in Table A8.5 are expressed as Acute Toxicity Estimate (ATE) values. The ATE$_{mixture}$ value represents the expected LD50/LC50 of the mixture and is calculated from the LD$_{50}$/LC$_{50}$ values for all qualifying constituents according to the following formula for oral, dermal or inhalation toxicity.

$$\frac{100}{ATE_{mixture}} = \sum_n \frac{\% \text{ ingredient is in formulation}}{LD_{50} \text{ or } LC_{50} \text{ for ingredient}}$$

Use the above equation if data are available for all ingredients in the mixture as per GHS Rev. 6 Section 3.1.3.6.1 (or equivalent section in future GHS versions). If data are not available for one or more ingredients in the mixture, follow the procedures in GHS Rev. 6 Section 3.1.3.6.2 (or equivalent section in future GHS versions).

**SECTION V — ANNEX 8**
**GreenScreen Qualifying Polymer Constituent/Component Hazard Criteria**

TABLE A8.6: **Systemic Toxicity & Organ Effects (ST-single) and Neurotoxicity (N-single) — Non-Additive except for Cat.3**

| | Hazard Levels | | | | |
|---|---|---|---|---|---|
| | **Very High (vH)** | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1 | GHS Cat. 2 | GHS Cat. 3 | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1 and present at ≥ 10% | GHS Cat. 1 and present at ≥ 1% and < 10% <br> Or <br> GHS Cat. 2 and present at ≥10% | Sum of all GHS Cat. 3 qualifying constituents present at ≥ 1% is ≥ 20% | · Adequate data available and negative studies; and <br> · GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

TABLE A8.7: **Systemic Toxicity & Organ Effects (ST-repeated) and Neurotoxicity (N-repeated) — Non-Additive**

| | Hazard Levels | | | |
|---|---|---|---|---|
| | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1 | GHS Cat. 2 | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1 and present at ≥ 10% | GHS Cat. 1 and present at ≥ 1% and < 10% <br> Or <br> GHS Cat. 2 and present at ≥10% | · Adequate data available and negative studies; and <br> · GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

TABLE A8.8: **Skin Sensitization (SnS) — Non-Additive**

| | Hazard Levels | | | |
| --- | --- | --- | --- | --- |
| | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1A | GHS Cat. 1B | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1A and present at >0.1% | GHS Cat. 1B and present at ≥ 1% | · Adequate data available and negative studies; and · GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

TABLE A8.9: **Respiratory Sensitization (SnR) — Non-Additive**

| | Hazard Levels | | | |
| --- | --- | --- | --- | --- |
| | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1 or 1A | GHS Cat. 1B | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | GHS Cat. 1 or 1A and present at >0.1% | GHS Cat. 1B and present at ≥ 1% (solid/liquid) or present at ≥ 0.2% (gas) | · Adequate data available and negative studies; and · GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

**GreenScreen Qualifying Polymer Constituent/Component Hazard Criteria**

TABLE A8.10: **Skin Irritation (IrS) — Additive**

| | Hazard Levels | | | | |
|---|---|---|---|---|---|
| | **Very High (vH)** | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1 (corrosive) | GHS Cat. 2 | GHS Cat. 3 | Expert judgment review (See Section 15.2.4 of guidance) | There are no qualifying constituent(s)/ component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | Sum of all GHS Cat. 1 qualifying constituents present at ≥ 1% is ≥ 5% | Sum of all GHS Cat. 1 qualifying constituents present at ≥ 1% is <5% OR Sum of all GHS Cat. 2 qualifying constituents present at ≥ 1% is ≥ 10% OR [(10 X Sum of all GHS Cat. 1 qualifying constituents present at < 1%) + (Sum of all GHS Cat. 2 qualifying constituents present at ≥ 1%)] ≥ 10% | Sum of all GHS Cat. 2 qualifying constituents present at ≥ 1% is <10% OR Sum of all GHS Cat. 3 qualifying constituents present at ≥ 1% is ≥ 10% OR [(10 X Sum of all GHS Cat. 1 qualifying constituents present at < 1%) + (Sum of all GHS Cat. 2 qualifying constituents present at ≥ 1%)] < 10% | • Adequate data available and negative studies; and • GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

**SECTION V — ANNEX 8**
**GreenScreen Qualifying Polymer Constituent/Component Hazard Criteria**

TABLE A8.11: **Eye Irritation (IrE) — Additive**

| | Hazard Levels | | | | |
|---|---|---|---|---|---|
| | Very High (vH) | High (H) | Moderate (M) | Low (L) | Data Gap (DG) |
| **Polymer Chain** | GHS Cat. 1 | GHS Cat. 2A | GHS Cat. 2B | Expert judgment review (see Section 15.2.4) | There are no qualifying constituent(s)/ component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | Sum of all GHS Cat. 1 qualifying constituents present at ≥ 1% is ≥ 3% | Sum of all GHS Cat. 1 qualifying constituents present at ≥1% is <3% OR Sum of all GHS Cat. 2A qualifying constituents present at ≥ 1% is ≥ 10% OR [(10 X Sum of all GHS Cat. 1 qualifying constituents present at < 1%) + (Sum of all GHS Cat. 2A qualifying constituents present at ≥ 1%)] ≥ 10% | Sum of all GHS Cat. 2B qualifying constituents present at ≥ 1% is ≥ 10% | · Adequate data available and negative studies; and · GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

## ECOTOXICITY (ECOTOX)

Note: For Acute Aquatic Toxicity (Table A8.12) and Chronic Aquatic Toxicity (Table A8.13):

· Obtain Multiplying factors (M-factors) from GHS Rev. 7, Table 4.1.5
  (https://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev07/English/ST_SG_AC10_30_Rev7e.pdf,
  accessed 1/8/18)

· CTV = Chronic Toxicity Value

TABLE A8.12: **Acute Aquatic Toxicity (AA) — Additive**

| | Hazard Levels | | | | |
|---|---|---|---|---|---|
| | **Very High (vH)** | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | GHS Cat. 1 | GHS Cat. 2 | GHS Cat. 3 | Expert judgment review (see Section 15.2.4) | There are no qualifying constituent(s)/ component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | Sum of all GHS Cat. 1 qualifying constituents present at ≥ 0.1% multiplied by M-factor is ≥ 25% | [(10 X Sum of all GHS Cat. 1 qualifying constituents present at ≥ 0.1%) X M-factor) + (Sum of all GHS Cat. 2 qualifying constituents present at ≥ 1%)] ≥ 25% | [(100 x Sum of GHS Cat. 1 qualifying constituents present at ≥ 0.1% x M-factor) + (10 x Sum of GHS Cat. 2 qualifying constituents present at ≥ 1%) + (Sum of GHS Cat. 3 qualifying constituents present at ≥ 1%)] ≥ 25% | · Adequate data available and negative studies; and<br>· GHS not classified | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |

TABLE A8.13: **Chronic Aquatic Toxicity (CA) — Additive**

| | Hazard Levels | | | | |
|---|---|---|---|---|---|
| | **Very High (vH)** | **High (H)** | **Moderate (M)** | **Low (L)** | **Data Gap (DG)** |
| **Polymer Chain** | CTV ≤ 0.1 mg/L | CTV >0.1 to 1.0 | CTV >1.0 to 10.0 or GHS Cat. 4 | CTV > 10 mg/L | There are no qualifying constituent(s)/ component(s) and there is insufficient information to classify polymer chain. |
| | OR | OR | OR | AND | OR |
| **Qualifying constituent(s)/ component(s)** | Sum of all qualifying constituents with CTV ≤ 0.1 mg/L and present at ≥ 0.1% multiplied by M-factor is ≥ 25% | [(10 x Sum of all qualifying constituents with CTV ≤ 0.1 mg/L and present at ≥ 0.1% x M-factor) + [(sum of all qualifying constituents with 0.1 < CTV <1 mg/L and present at ≥ 1%)] ≥ 25% | [(100 x Sum of all qualifying constituents with CTV ≤ 0.1 mg/L and present at ≥ 0.1% x M-factor) + (10 x Sum of all qualifying constituents with 0.1< CTV < 1 mg/L and present at ≥ 1%) + (sum of all qualifying constituents with 1.0< CTV <10 mg/L and present at ≥ 1%)] ≥ 25% | Sufficient data available and does not meet criteria for vH, H or M | There is insufficient information to classify one or more qualifying constituent(s)/ component(s). |