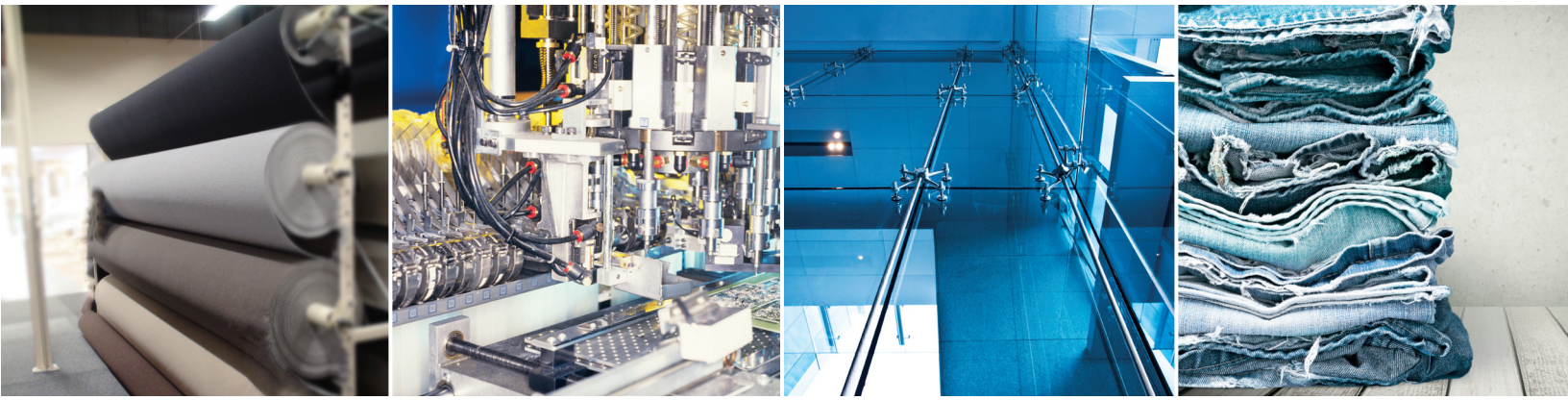
GreenScreen® for Safer Chemicals Hazard Assessment Guidance

VERSION 1.3 (1e) • JUNE 2016



CLEAN PRODUCTION ACTION

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Clean Production Action designs and delivers strategic solutions for green chemicals, sustainable materials and environmentally preferable products.

Contents

Tables & Figures

Acknowledgements

Clean Production Action is committed to maintaining clear and transparent guidance for producing comprehensive GreenScreen assessments and accurate Benchmark scores. As a result of increasingly widespread implementation of GreenScreen for Safer Chemicals, clarifications and additional guidance revisions are conducted on a regular basis in order to uphold its scientific rigor and alignment with other global programs. This is accomplished by in-depth technical discussions with GreenScreen advisory groups, who provide valuable feedback and recommendations for improving the method resources. We would like to extend distinguished acknowledgement to the scientists and industry professionals who have donated significant time and expertise toward the development and continued upkeep of GreenScreen for Safer Chemicals.

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Preface

Clean Production Action developed GreenScreen® for Safer Chemicals as a publicly available and transparent chemical hazard assessment method to help move our society quickly and effectively toward the use of greener and safer chemicals. It is used by a wide range of professionals, governmental bodies, non-profits, businesses, formulators, and product developers—anybody interested in assessing the inherent hazards of chemicals and their potential effect on human health and the environment. The guidance provided in this publication clearly outlines every step for performing GreenScreen assessments, including how to assess and classify hazards, apply Benchmarks™, and make informed decisions. In addition, extensive guidance has been developed on using GreenScreen List Translator to identify priority chemicals of high concern.

GreenScreen® for Safer Chemicals is a method for comparative chemical hazard assessment that builds on the U.S. Environmental Protection Agency's Design for Environment (DfE) approach and other national and international precedents including but not limited to the Organisation for Economic Cooperation and Development (OECD), Canada Domestic Substances List Methodology, the International Joint Commission, the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Classification, Labeling and Packaging (CLP) Regulations, the Stockholm Convention on Persistent Organic Pollutants and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). It is freely and publicly accessible, transparent and peer-reviewed.

Regulatory requirements and toxicology continue to evolve rapidly, and new hazard classifications, test data and science continue to emerge. This Guidance will be regularly revised and updated, particularly as new versions of important foundational pieces, such as the GHS, are released.

Hazard Assessment Guidance v1.3

1. PURPOSE

1.1 This document outlines the procedural guidance for performing GreenScreen assessments, including how to assess and classify hazards, apply benchmarks, and make informed decisions.

1.1.1 GreenScreen assessment of a given chemical includes a comprehensive review of all available information including 1) measured data from toxicological studies in the scientific literature, 2) estimated data from suitable analogs and models, and 3) hazard lists.

1.1.2 The hazard lists required for GreenScreen assessments are called GreenScreen Specified Lists and are included in GreenScreen Hazard Criteria. They are also included in GreenScreen List Translator (List Translator), which maps GreenScreen Specified Lists to hazard classifications. GreenScreen List Translator assessment is not equivalent to GreenScreen assessment; however, it can help to identify chemicals with known hazard attributes. GreenScreen List Translator is available through automated software to facilitate ease of use. (See Annex I for detailed GreenScreen List Translator guidance).

2. SCOPE

2.1 This document includes requirements for Licensed GreenScreen Profilers and Authorized GreenScreen Practitioners. This document is also intended to serve as guidance for general users seeking to generate comprehensive and high quality GreenScreen assessments.

3. NORMATIVE REFERENCES

3.1 Familiarity with the documents listed below are part of the competency requirements for Licensed GreenScreen Profilers and Authorized GreenScreen Practitioners:

3.1.1 Globally Harmonized System of Classification and Labelling of Chemicals (GHS), United Nations, New York and Geneva,[1] and

3.1.2 Design for the Environment (DfE) Program Alternatives Assessment Criteria for Hazard Evaluation, Office of Pollution Prevention & Toxics, U.S. Environmental Protection Agency.[2]

3.2 Apply the latest editions of references with unspecified dates or version numbers.

1 http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

2 https://www.epa.gov/saferchoice/alternatives-assessment-criteria-hazard-evaluation

4. TERMS AND DEFINITIONS

TERM	DEFINITION
100 ppm	A threshold used for inventorying substances in a product or material. One hundred (100 ppm) is equivalent to 0.01% by weight.
1000 ppm	A threshold used for inventorying substances in a product or material. One thousand (1000 ppm) is equivalent to 0.1% by weight.
Acute Aquatic Toxicity (AA)	The intrinsic property of a substance to be injurious to an organism in a short-term, aquatic exposure to that substance (GHS, Chapter 4.1: Hazards to the Aquatic Environment. 2009, United Nations).
Acute Mammalian Toxicity (AT)	Refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours (GHS, Chapter 3.1: Acute Toxicity. 2009, United Nations).
Analog	See Suitable Analog.
Assessment Report Template	A report template used to document all findings gathered during a GreenScreen assessment.
Authoritative Secondary Sources	A compilation of research studies that have been reviewed and analyzed by a group that is not the author of the original study(ies) but that is a group of recognized authorities such as health profession organizations, accredited institutions and universities, and governmental entities.
Authoritative Toxicology Databases	Database information that is reviewed, approved, and regularly updated by a group of recognized authorities such as health profession organizations, accredited institutions and universities, and governmental entities.
Authorized GreenScreen Practitioner	An individual who has completed advanced GreenScreen training, has demonstrated scientific expertise and capacity to perform high quality GreenScreen assessments, and is licensed by Clean Production Action to conduct GreenScreen assessments for his or her registered organization.
Bioaccumulation (B)	A process in which a chemical substance is absorbed in an organism by all routes of exposure as occurs in the natural environment (e.g., dietary and ambient environment sources). Bioaccumulation is the net result of competing processes of chemical uptake into the organism at the respiratory surface and from the diet and chemical elimination from the organism including respiratory exchange, fecal egestion, metabolic biotransformation of the parent compound and growth dilution (Arnot, J.A. and F.A. Gobas, A review of bioconcentration factor (BCF) and bioaccumulation factor (BAF) assessments for organic chemicals in aquatic organisms. Environmental Reviews, 2006. 14: p. 257-297).
Carcinogenicity (C)	Capable of increasing the incidence of malignant neoplasms, reducing their latency, or increasing their severity or multiplicity (IARC. Preamble to the IARC Monographs: A. General Principles And Procedures: 2. Objective and scope. 2006 [cited 2011 June 20]; Available from: http://monographs.iarc.fr/ENG/Preamble/currenta2objective0706.php).
CASRN	Chemical Abstracts Service Registry Number (also known as “CAS#”)
Catalyst	By definition, catalysts are substances that modify or increase the rates of reactions but are typically not consumed. However, they may be inhibited, deactivated, or destroyed by secondary processes.

TERM	DEFINITION
Chemical Substance ("Substance")	A substance of fixed composition, characterized by its molecular structure(s), which typically has an associated CASRN (and may also have synonym CASRNs). Synonyms include "constituent"; "ingredient"; "chemical"; "compound"; "component".
Chronic Aquatic Toxicity (CA)	The intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which are determined in relation to the life-cycle of the organism (GHS, Chapter 4.1: Hazards to the Aquatic Environment. 2009, United Nations).
Data Gap (DG)	A Data Gap indicates that measured data and authoritative and screening lists have been reviewed, and expert judgment and estimation such as modeling and analog data have been applied, and there is still insufficient information to assign a hazard level to an endpoint. When generating a final GreenScreen Benchmark score, the presence and number of Data Gaps in different hazard categories can result in downgrading the Benchmark. This can result in a final GreenScreen Benchmark "U" or the addition of a subscript DG (e.g., GreenScreen Benchmark-2_{DG} or -3_{DG}).
Developmental Toxicity (D)	Adverse effects in the developing organism that may result from exposure prior to conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Adverse developmental effects may be detected at any point in the lifespan of the organism. The major manifestations of developmental toxicity include: (1) death of the developing organism, (2) structural abnormality, (3) altered growth, and (4) functional deficiency (USEPA, Guidelines for Developmental Toxicity Risk Assessment. Federal Register, 1991. 56(234): p. 63798-63826).
DfE	Design for Environment
Endocrine Activity (E) (Endocrine Active Substance)	An endocrine active substance is a substance having the inherent ability to interact or interfere with one or more components of the endocrine system resulting in a biological effect, but need not necessarily cause adverse effects. Endocrine activity is considered as a collection of modes of action, potentially leading to adverse outcomes, rather than a (eco)toxicological hazard in itself (http://www.efsa.europa.eu/en/efsajournal/pub/3132.htm).
Endocrine Disruption (Endocrine Disruptor)	An endocrine disrupter is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations (http://ec.europa.eu/environment/chemicals/endocrine/definitions/endodis_en.htm).
Eye Irritation (IrE)	Eye irritation is the production of changes in the eye following the application of a test substance to the anterior surface of the eye, which are fully reversible within 21 days of application (http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/03e_part3.pdf).
Feasible Environmental Transformation Product (TP)	An environmental transformation product that is likely to form/occur under natural or artificial conditions because the chemical structure of the parent chemical allows for certain types of transformations (e.g., hydrolysis) and because those transformations are likely to occur based on the functional use of the chemical across its life cycle (e.g., discharged to water). When generating a final GreenScreen Benchmark score, the hazards of any feasible and relevant transformation products are considered and can change the final Benchmark score. If the final Benchmark is altered due to a transformation product, the subscript "TP" is added (i.e., GreenScreen Benchmark-1_{TP}, -2_{TP} or -3_{TP}).

TERM	DEFINITION
Functional Additives	Chemicals or mixtures added to impart desired physical characteristics of a polymeric material or mixture.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
GreenScreen Assessment	A GreenScreen assessment is a comprehensive chemical hazard assessment that is conducted using this GreenScreen for Safer Chemicals Hazard Assessment Guidance (http://www.greenscreenchemicals.org/method/method-documents) and results in one GreenScreen Benchmark score (Benchmark-1, -2, -3, -4, or -U).
GreenScreen Benchmark™ Criteria	A set of algorithms or decision logic used to assign a GreenScreen Benchmark score to a chemical based on the hazard profile of the chemical. The Benchmark criteria include a combination or combinations of GreenScreen Hazard Endpoints and hazard classifications.
GreenScreen List Translator (LT)	A streamlined chemical hazard assessment developed by Clean Production Action that produces GreenScreen List Translator scores.
GreenScreen List Translator (LT) scores	List Translator scores are based upon screening chemicals against GreenScreen Specified Lists using GreenScreen List Translator guidance. "LT-1" means "Likely GreenScreen Benchmark-1". If GreenScreen assessment was performed on the chemical, it would likely result in a Benchmark-1 score. "LT-P1" means "Possible GreenScreen Benchmark-1". Frequently this means that the chemical appears on a list that does not translate directly to a single Benchmark score and Benchmark-1 is included in the range of possible Benchmark scores. "LT-UNK" ("unknown") indicates that a chemical is present on a GreenScreen Specified List, but that there is insufficient information to classify the hazard as LT-1 or LT-P1. The LT-UNK score or the absence of a chemical on hazard lists does not mean it is safe. It may mean the chemical has not been reviewed by the body publishing the list or that the chemical has not yet been well tested. For complete details on List Translator see Annex I.
GreenScreen Software Provider—Pharos	The Pharos Chemical and Material Library is a fee-based database that provides online access to chemical hazard information for over 30,000 CASRN identified substances and reports GreenScreen hazard classifications and GreenScreen List Translator scores for chemicals by applying GreenScreen List Translator methodology. Developed and maintained by the Healthy Building Network, the Pharos Chemical and Material Library (CML) is available at http://www.pharosproject.net.
GreenScreen Specified Lists	GreenScreen Specified Lists are chemical lists generated by state, national, or international governments, authoritative bodies, and expert organizations. These lists are recommended for use in identifying and classifying chemical hazards using GreenScreen Hazard Criteria. GreenScreen List Translator relies on these lists to generate preliminary hazard scores.

TERM	DEFINITION
GreenScreen Specified Lists—Authoritative and Screening Lists	Authoritative Lists are generated by recognized experts, often as part of a government regulatory process to identify chemicals and known associated hazards. These lists are considered to be of high reliability and should only be changed when new data or special circumstances clearly indicate that a new level-of-concern is warranted. Intervention of a Licensed GreenScreen® Profiler or Clean Production Action's consulting toxicologist would be required to validate such a change. Screening Lists result in a classification with a lower level of confidence because at least one of the following is true of the list. It was: a. developed using a less comprehensive review, b. compiled by an organization that is not considered to be authoritative, c. developed using predominantly or exclusively estimated data, or d. developed to identify chemicals for further review and/or testing.
Hazard Endpoint	A specific type of adverse health outcome or physical property that can cause harm. GreenScreen guidance specifies 18 Hazard Endpoints that must be evaluated. A few examples include: Carcinogenicity, Acute Aquatic Toxicity, Bioaccumulation, and Flammability.
Hazard Summary Table	A table provided in the GreenScreen Assessment Report Template used to document and present the hazard classifications for all 18 Hazard Endpoints. The template can be downloaded at: http://www.greenscreenchemicals.org/method/method-documents.
Homogeneous Material ("Material")	A uniform solid, liquid, or gas composed of one or more substances that cannot be mechanically disjointed, in principle. It may be a chemical formulation or compound; a substance of unknown or variable composition, complex reaction product, or biological material (UVCB); or a combination of the two. Coatings and finishes such as plating, powder coats, enamels, etc., are considered unique homogeneous materials.
Impurity	Residuals from prior manufacturing processes or contaminants from raw materials (i.e., residual output or by-product from a prior process is a contaminant input to the next process).
Intentionally Added Substance	A chemical in a product that is added at any concentration to provide an intended function in a product.
Licensed GreenScreen Profiler	A company with expertise in toxicology and comparative chemical hazard assessment that is licensed by Clean Production Action to provide GreenScreen assessments on a fee-for-service basis to any individual or organization who seeks to commission one.[3]
Mixture	A chemical and its impurities; a formulated mixture of single chemicals; a combination of formulated mixtures, polymeric materials and/or single chemicals (e.g., liquid cleaning product, fragrances, lotions, and printing ink).
Monomer	A molecule, typically small and of low molecular weight, that can be bonded to other molecules to form a polymer.

3 http://greenscreenchemicals.org/professionals/profilers

TERM	DEFINITION
Mutagenicity & Genotoxicity (M)	The more general terms genotoxic and genotoxicity apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication (from http://www.epa.gov/sites/production/files/2014-01/documents/aa_criteria_v2.pdf).
Neurotoxicity (N)	An adverse change in the structure or function of the central and/or peripheral nervous system following exposure to a chemical, or a physical or biological agent (USEPA, Guidelines for Neurotoxicity Risk Assessment. Federal Register, 1998. 63(93): p. 26926-26954).
Oligomer	A polymer or polymer intermediate containing up to five monomers.
Persistence (P)	The length of time the chemical can exist in the environment before being destroyed (i.e., transformed) by natural processes (http://www.who.int/ceh/publications/endocrine/en/index.html).
Polymer	A compound comprised of chains of repeating units called monomers.
Polymeric Material	A special kind of formulated mixture made of repeating units called monomers (e.g., compounded plastics, adhesives, foams, resins).
Processing Aids	Chemicals that are used to provide a technological effect in processing but no technical or functional effect in the product and may remain in small amounts in finished product (e.g., lubricants, mold release agent).
Proprietary Ingredient	Ingredients in products that are confidential to the manufacturer or producer.
Relevant Transformation Product	An environmental transformation product that is: 1) persistent enough to be encountered after use or release of the parent chemical and 2) NOT a substance necessary for life or commonly formed in the ambient environment.
Reproductive Toxicity (R)	The occurrence of biologically adverse effects on the reproductive systems of females or males that may result from exposure to environmental agents. The toxicity may be expressed as alterations to the female or male reproductive organs, the related endocrine system, or pregnancy outcomes. The manifestation of such toxicity may include, but not be limited to, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, gestation, parturition, lactation, developmental toxicity, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems (USEPA, Guidelines for Reproductive Toxicity Risk Assessment. Federal Register, 1996. 61(212): p. 56274-56322).
Respiratory Sensitization (SnR)	Hypersensitivity of the airways following inhalation of the substance (GHS, Chapter 3.4: Respiratory or Skin Sensitization. 2009, United Nations).
Skin Sensitization (SnS)	A skin sensitizer is a substance that will lead to an allergic response following skin contact (http://www.unece.org/fileadmin/DAM/trans/danger/publi/ghs/ghs_rev04/English/03e_part3.pdf).
Skin Irritation (IrS)	The production of reversible damage to the skin following the application of a test substance for up to 4 hours (GHS, Chapter 3.2: Skin Corrosion/Irritation. 2009, United Nations).
Special Case Impurity	Chemicals of high concern typically found in a chemical or material and identified based on life cycle knowledge, particularly of feedstock or upstream manufacturing processes.

TERM	DEFINITION
Strength of Evidence	A qualitative evaluation that considers the results of a clinical trial or research study. The strength of the evidence will take into consideration how well a study was designed, conducted, and analyzed, and evaluate the overall strength of that body of evidence.
Suitable Analog	A chemical that can be used to estimate the hazard of the chemical of interest when data on the chemical of interest are not available. A suitable analog is chemically (e.g., based on chemical structure) and/or biologically (e.g., based on metabolic breakdown, or likely mechanistic/mode of action considerations) similar to the chemical of interest. Guidance for identifying a suitable analog can be found in OECD Series on Testing and Assessment No. 80 Guidance on Grouping of Chemicals. The suitable analog used must be appropriate for the attribute being evaluated.[4]
Systemic Toxicity & Organ Effects (including Immunotoxicity) (ST)	Includes all significant non-lethal effects in a single organ that can impair function, both reversible and irreversible, immediate and/or delayed, not otherwise covered by any other endpoint; or generalized changes of a less severe nature involving several organs.
Transient Transformation Products	A transformation product that has a very short half-life and is typically an intermediate along a degradation pathway.
Valid GreenScreen Assessment	GreenScreen assessment reports are considered valid for three years after which time they expire and should be updated to restore validity.

4 http://www.oecd.org/env/ehs/testing/seriesontestingandassessmentpublicationsbynumber.htm

5. GENERAL REQUIREMENTS

5.1 In order to keep GreenScreen assessments up-to-date and to ensure clarity about GreenScreen versions used and the extent to which assessments are current:

5.1.1 The version number of GreenScreen documentation used for an assessment shall always be identified in the assessment report along with the date.

5.2.2 Results shall not be directly compared between different versions where changes are categorized as major changes according to the GreenScreen Version Control Policy. To compare assessments between 1.0 and 2.0 level changes, the older assessment shall be revised to meet the criteria of the most recent guidance version.

5.2 GreenScreen assessments shall be revised at a minimum of every three (3) years to ensure that the hazard profiles remain up to date and valid.

5.3 Refer to GreenScreen Terms of Use.[5]

6. PROCESS OVERVIEW

6.1 GreenScreen resources[6] necessary to effectively implement this Guidance are:

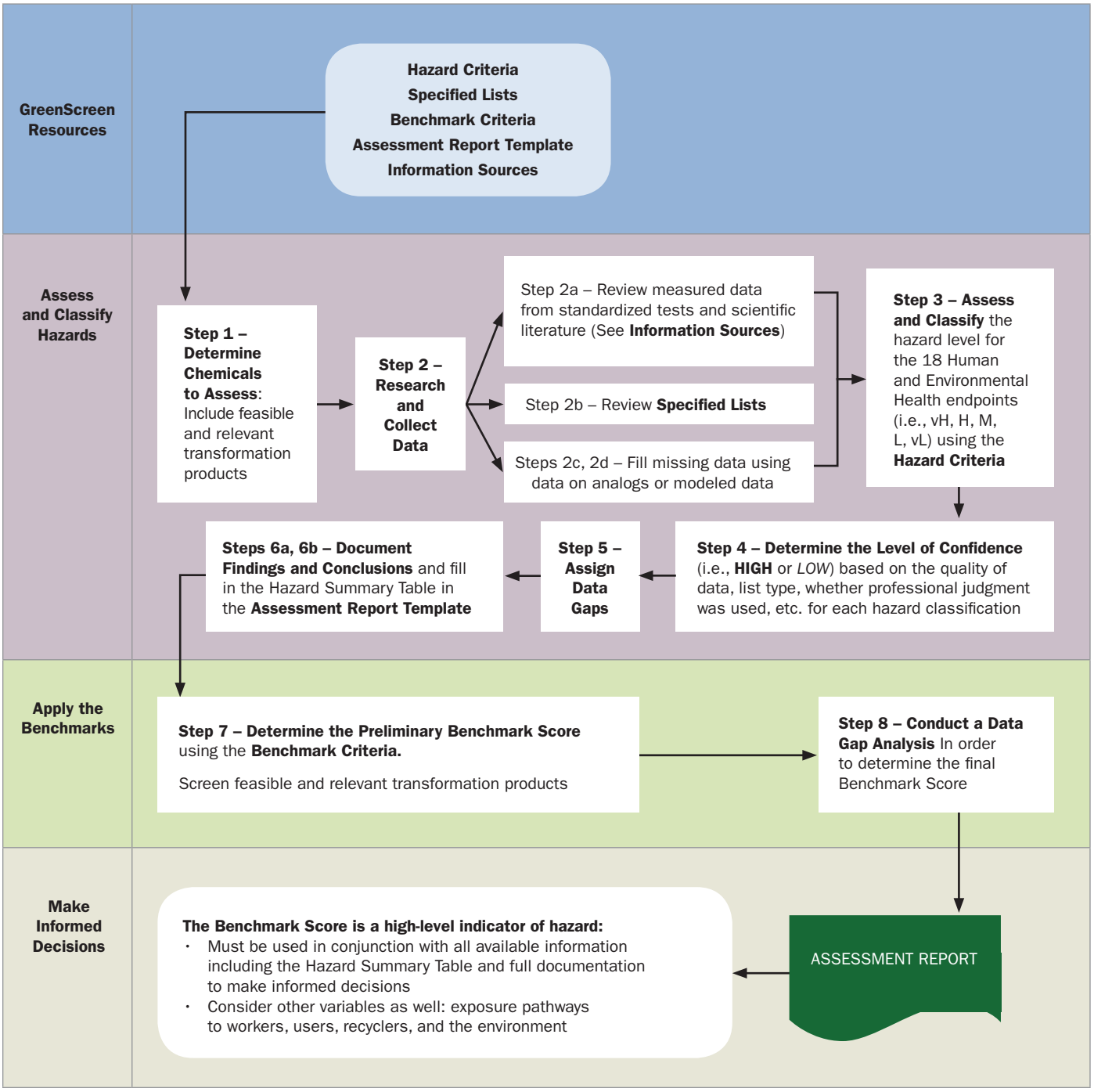
1) GreenScreen Hazard Criteria
2) GreenScreen Benchmark™ Criteria
3) GreenScreen Assessment Report Template
4) GreenScreen Specified Lists
5) GreenScreen Information Sources
6) GreenScreen List Translator

5 http://greenscreenchemicals.org/about/greenscreen-terms-of-use

6 Download GreenScreen resources: http://greenscreenchemicals.org/method/method-documents

The following figure illustrates the relationship between GreenScreen resources and the various steps performed in conducting GreenScreen assessments. The order of steps may vary based on individual preference.

FIGURE 1. **Performing GreenScreen Assessments**



7. DISCLOSURE AND ASSESSMENT RULES AND BEST PRACTICE

7.1 Every chemical intentionally added to the material, formulation, or article by the manufacturer should be assessed. Every impurity present in the material, formulation, or article at greater than or equal to 100 ppm (0.01%) should be assessed.

7.1.1 An intentionally added chemical in a product means a chemical in a product that serves an intended function in the product component.[7] Any other chemical in the product is therefore an impurity.

7.1.2 Special case impurities are chemicals of concern typically found in a chemical or material and identified based on life cycle knowledge, particularly of feedstock or upstream manufacturing processes. On a case-by-case basis, special case impurities below 100 ppm (0.01%) may be reported along with their concentration in the formula. For polymeric materials, monomers and catalysts shall be treated as special case impurities if present below 100 ppm (0.01%).

7.1.3 Special case impurities below 100 ppm shall be screened using GreenScreen List Translator[8] to determine whether they are LT-1 or LT-P1. (See Annex I).

7.2 Where 100 ppm (0.01%) is not feasible or practicable (i.e., supply chain will not/cannot disclose all chemicals), a value of 1000 ppm (0.1%) may be used, however:

7.2.1 Where GreenScreen Disclosure and Assessment requirements are not applied and a different disclosure level is used, it is mandatory that the disclosure level is provided, as well as the reasoning, in the assessment report for every intentionally added chemical and impurity. This will allow for the equivalent comparison of alternatives.

7.2.2 Referencing GreenScreen in other standards or metrics must specify the disclosure level applied (both for intentionally added chemicals and impurities).

7.3 The following table shows where to apply GreenScreen Benchmarks versus instances where it is sufficient to screen using GreenScreen List Translator only.

TABLE 1. **GreenScreen Disclosure and Assessment Best Practice**

Type of Ingredient	Assessment Requirement
Intentionally added ingredients ≥ 0 ppm	GREENSCREEN ASSESSMENT
Any known impurity ≥ 100 ppm	
Special case impurities ≤ 100 ppm	LIST TRANSLATOR
Other known impurities ≤ 100 ppm (best practice, not mandatory)	
Oligomers as a constituent of a polymeric material (See Annex III for guidance on polymeric materials)	NO SCREENING

7 http://apps.leg.wa.gov/WAC/default.aspx?cite=173-334-040

8 Note: It is best practice (but not mandatory) to provide the identity and CAS # of all known impurities, even if they are below 100 ppm and to screen them using the List Translator.

8. THE HAZARD ENDPOINTS

There are 18 Human Health, Environmental Toxicity, Fate, and Physical Hazard Endpoints that must be evaluated for each chemical. The endpoints are grouped as shown in the table below:

TABLE 2. **Groupings of GreenScreen Hazard Endpoints**

Human Health Group I	Human Health Group II	Human Health Group II*	Environmental Toxicity & Fate	Physical Hazards
Carcinogenicity (C)	Acute Mammalian Toxicity (AT)	Systemic Toxicity & Organ Effects* Repeated Exposure sub-endpoint (ST-repeated)	Acute Aquatic Toxicity (AA)	Reactivity (Rx)
Mutagenicity & Genotoxicity (M)	Systemic Toxicity & Organ Effects (ST-single)	Neurotoxicity – Repeated Exposure sub-endpoint (N-repeated)	Chronic Aquatic Toxicity (CA)	Flammability (F)
Reproductive Toxicity (R)	Neurotoxicity (N-single)	Skin Sensitization (SnS)	Other Ecotoxicity studies when available	
		Respiratory Sensitization (SnR)		
Developmental Toxicity including Neurodevelopmental Toxicity (D)	Skin Irritation (IrS)		Persistence (P)	
	Eye Irritation (IrE)		Bioaccumulation (B)	
Endocrine Activity (E)				

8.1 Group I Human Health

These endpoints reflect priorities that are consistent with national and international governmental regulations, and cover hazards that can lead to chronic or life-threatening effects or adverse impacts that are potentially induced at low doses and transferred between generations.

8.1.1 Endocrine Activity

A preliminary hazard level or range is assigned by determining whether the substance is endocrine active. This is done by searching all Specified Lists and available data. For chemicals that are endocrine active, determine whether there is a plausibly related adverse human health effect, and identify the associated level of hazard. Assigning the final hazard level for Endocrine Activity will use expert judgement and a strength of evidence approach.[9]

1. Low Hazard
   a. Low hazard classification requires data for multiple endocrine pathways (e.g., androgenicity, anti-androgenicity, thyroid effects, estrogenicity, and anti-estrogenicity).
2. Moderate Hazard
   a. Endocrine Activity is classified as Moderate if there is indication of Endocrine Activity in the scientific literature.
   b. All chemicals with data suggesting Endocrine Activity associated with adverse effects

9 The science associated with testing for endocrine activity and associated adverse effects continues to evolve rapidly and will be incorporated into future revisions of GreenScreen.

are initially assigned as Moderate. It is also acceptable to assign a range (Moderate or High) to indicate preliminary classification.

c. For substances listed on Specified Lists for Endocrine Activity, other than EU – SVHC Authorisation List, classify them initially as Moderate. It is also acceptable to assign a range (Moderate or High) to indicate preliminary classification.

d. Chemicals initially classified as Moderate using Specified Lists should be further reviewed using the scientific literature to confirm classification.

3. High Hazard

a. For substances listed on the EU – SVHC Authorization List for Endocrine Activity, classify those substances as High.

b. Where there is a High (or very High) plausibly[10] related adverse effect for Carcinogenicity, Reproductive Toxicity, Developmental Toxicity and/or Systemic Toxicity (Repeated dose, typically, thyroid), modify the hazard level for Endocrine Activity from Moderate to High. Where the adverse effect is not plausibly related, do not modify the Endocrine Activity level. See Table 3.

TABLE 3. **Modified Endocrine Activity Classifications for Select Endpoints**

Endpoint	Initial Endocrine Activity Classification	Plausibly Related Hazard Endpoint Classification	Modified Endocrine Activity Classification
Carcinogenicity	M	H	H
Carcinogenicity	M	M	M
Reproductive Toxicity	M	H	H
Reproductive Toxicity	M	M	M
Developmental Toxicity	M	H	H
Developmental Toxicity	M	M	M
Systemic Toxicity—repeated dose (Thyroid)	M	vH	H
Systemic Toxicity—repeated dose (Thyroid)	M	H	H
Systemic Toxicity—single dose (Thyroid)	M	M	M

4. Data Gaps

a. A chemical that is not listed on Specified Lists for Endocrine Activity and for which test data do not exist shall be assigned Data Gap.

b. Data Gaps are assigned using expert judgment: 1) if there is no evidence of Endocrine Activity, but data are incomplete for any endocrine mediated pathway, and 2) when a study demonstrating Endocrine Activity is judged to be inadequate.

10 Plausibly related means that the adverse effect is likely to be due to the endocrine mode of action. For example, an increase in T3 along with thyroid tumors would be plausibly related, but an increase in T3 would have no obvious connection to a skin cancer.

8.2 Group II and II* Human Health

These endpoints reflect hazards that are also important for understanding and classifying chemicals. Typically, Group II hazards may be mitigated. Group II and II* are differentiated from one another in the Benchmarking system because Group II endpoints have 4 hazard levels (i.e., vH, H, M and L) while Group II* endpoints have 3 hazard levels (i.e., H, M and L) and are evaluated based on repeated exposure.

8.2.1 Systemic Toxicity/Organ Effects and Neurotoxicity

These endpoints can belong in either Group II or Group II* depending on whether the data are generated from single exposure (acute) or repeated exposure (sub-chronic or chronic) studies. Results from single and repeated exposures are not considered as separate endpoints but rather sub-endpoints.

1. When classifying hazard for Systemic Toxicity/Organ Effects and Neurotoxicity endpoints, repeated exposure results are required and preferred. Lacking repeated exposure results in a Data Gap.
2. If data from both single and repeated exposure studies are available, then both may be included and the more conservative value will drive the hazard classification. If the less conservative value is used, include the rationale for why it was chosen in the assessment report.

8.3 Environmental Toxicity and Fate

Environmental Toxicity and Fate includes Acute and Chronic Aquatic Toxicity, Persistence and Bioaccumulation potential. Additional Ecotoxicity endpoints such as Avian or Bee Toxicity may be included when available and relevant.[11]

8.4 Physical Hazards

Physical hazards include Flammability and Reactivity and are based on GHS criteria.

11 Refer to EPA's Design for the Environment (DfE) Program Alternatives Assessment Criteria for Hazard Evaluation, Office of Pollution Prevention & Toxics, U.S. Environmental Protection Agency (Version 2.0, August 2011); http://www.epa.gov/sites/production/files/2014-01/documents/aa_criteria_v2.pdf

9. PROCEDURE FOR ASSESSING HAZARDS (USE OF HAZARD LISTS, ANALOGS, AND MODELS)

9.1 Step 1 – Determine chemicals to assess

9.1.1 Identify the parent chemical along with all feasible and relevant environmental transformation products. See Section 12.

9.1.2 Guidance for determining what chemicals to assess for mixtures and polymeric materials can be found in Annex II and Annex III, respectively.

9.2 Step 2 – Research and collect data

Assessing chemicals is accomplished by examining comprehensive toxicological data, checking GreenScreen Specified Lists, and using estimated data from suitable analogs or modeled data where measured data are lacking for the parent chemical. A strength of evidence approach may be used and the rationale behind the hazard classification should be clearly stated, particularly in the case where multiple studies are available that measure the same endpoint. The order of steps may vary based on individual preference (e.g., reviewing Specified Lists prior to conducting a toxicological review).

9.2.1 Step 2a – Conduct a comprehensive data review

Review measured data from standardized tests and scientific literature:

1. Primary literature sources, authoritative secondary sources that are peer reviewed, and authoritative sources are preferred. Examples of peer reviewed authoritative secondary sources include IARC Monographs, government risk assessments, and authoritative toxicology databases.
2. Other high quality secondary sources are acceptable.
   a. If a study is cited from a secondary source, it must be referenced as a secondary source.
   b. Publicly available primary data for Flammability and Reactivity may not be available. Secondary sources such as Safety Data Sheets (SDS) may be used for Flammability and Reactivity when there are no other options.

9.2.2 Step 2b – Review Specified Lists

1. When conducting GreenScreen assessments, it is mandatory to search all GreenScreen Specified Lists and report the results. Automated software has been developed to assist with searching (See Annex I).
2. Use the information contained within the Specified Lists in combination with the literature review and expert judgment to classify hazards.
3. See Annex I for a description of how GreenScreen Specified Lists are categorized (i.e., Authoritative A or B, and Screening A or B).

9.2.3 Step 2c – Use measured data from suitable analogs to fill missing data

Measured data on suitable analogs may be used to fill missing data.

1. Provide information on whether and why a suitable analog(s) was used to evaluate one or more Hazard Endpoints that were missing measured data. If a suitable analog(s) was not used, include rationale for not using the analog in the final report. A suitable analog is a chemical that shares similarities in structure, function and mechanism of action with the chemical being assessed. In some cases, the analog may be a metabolite or transformation product. Examples of resources to identify analogs and guidance for using analogs are provided in number 3 (a-g) below.

2. Provide the name and chemical structure for each suitable analog used. Suitable analog selection is hazard endpoint/parameter dependent, and the choice can be different for different endpoints and chemicals.
3. Profilers shall make a good faith effort to review at least one readily available suitable analog for each hazard endpoint missing data for the parent chemical and consult at least one of the following publicly accessible tools. Additional suitable analog identification and assessment may be performed; however, this is beyond the minimum scope and may lead to additional cost.
    a. Analog Identification Methodology (AIM) – http://www.epa.gov/tsca-screening-tools/analog-identification-methodology-aim-tool (accessed 1/14/16)
    b. ChemIDplus database – http://chem.sis.nlm.nih.gov/chemidplus/documentation/help/chemidfs2webAdvanced.jsp (accessed 1/14/16)
    c. REACH dossiers (Registration, Evaluation Authorisation and Restriction of Chemicals) – http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances (accessed 1/14/16)
    d. High Production Volume Information System (HPVIS) – https://ofmext.epa.gov/hpvis/HPVISlogon (accessed 1/14/16)
    e. Organisation for Economic Co-operation and Development (OECD) Guidance on the Grouping of Chemicals. Series on Testing and Assessment, Number 80[12]
    f. Environmental Protection Agency (EPA) chemical categories (from New Chemicals program) – www.epa.gov/oppt/newchems/ (accessed 1/14/16)
    g. Other Risk assessment/risk management regulatory or government documents

9.2.4 Step 2d – Use modeled data to fill in for missing measured data

1. At a minimum, use the Sustainable Futures suite of models (a-c below). These models use quantitative structure activity relationship (QSAR) methods to apply statistical tools correlating biological activity of chemicals with descriptors representative of molecular structure and/or properties.
    a. EPISUITE: Software containing physical/chemical property and environmental fate estimation programs. (http://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface)
    b. ECOSAR: The Ecological Structure Activity Relationships (ECOSAR) Class Program estimates the acute and chronic aquatic toxicity of industrial chemicals. (http://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model)
    c. ONCOLOGIC: A computer program that estimates the carcinogenic potential of chemicals. (http://www.epa.gov/tsca-screening-tools/oncologictm-computer-system-evaluate-carcinogenic-potential-chemicals)
    d. Additional models may also be useful and are beyond the minimum scope and may require additional cost (e.g., OECD Toolbox[13]).

12 http://www.oecd.org/env/ehs/testing/seriesontestingandassessmentpublicationsbynumber.htm
13 http://www.oecd.org/env/ehs/risk-assessment/theoecdqsartoolbox.htm

10. PROCEDURE FOR CLASSIFYING HAZARDS

10.1 Step 3 – Classify hazard level for each hazard endpoint (e.g., vH, H, M, L, vL)

The Hazard Criteria are used to classify the hazard level as very High (vH), High (H), Moderate (M), Low (L) or in some cases very Low (vL) for each hazard endpoint. Figure 2 below depicts the Hazard Criteria for 2 Hazard Endpoints.

FIGURE 2. **Hazard Criteria for Carcinogenicity and Mutagenicity**

	Information Type	Information Source	List Type	High (H)	Moderate (M)	Low (L)
Carcinogenicity (C)	Data	GHS Criteria & Guidance		GHS Category 1A (Known) or 1B (Presumed) for any route of exposure	GHS Category 2 (Suspected) for any route of exposure or limited or marginal evidence of carcinogenicity in animals (See Guidance)	Adequate data available, and negative studies, no structural alerts, and GHS not classified.
	A Lists	US EPA – IRIS Carcinogens (1986)	Authoritative	Group A, B1 or B2	Group C	Group E
		US EPA – IRIS Carcinogens (1996, 1999, 2005)	Authoritative	Known or Likely		Not Likely
		EU – REACH Annex XVII CMRs	Authoritative	Category 1 or 2	Category 3	
		EU – Annex VI CMRs	Authoritative	Carc 1A or 1B	Carc 2	
		EU – GHS (H-Statements)	Authoritative	H350 or H350i	H351	
		EU – R-Phrases	Authoritative	R45 or R49	R40	
		EU – SVHC Authorisation List	Authoritative	Carcinogenic – Banned unless Authorised		
		"GHS – [COUNTRY]* Lists (*Australia, the European Union, Indonesia, Japan, Korea, Malaysia, New Zealand, Taiwan and Thailand)"	Screening	Category 1A or 1B	Category 2	Not Classified
		IARC	Authoritative	Group 1 or 2a	Group 2b	Group 4
		MAK	Authoritative	Carcinogen Group 1 or 2	Carcinogen Group 3A or 3B, 4, or 5	
		US CDC – Occupational Carcinogens	Authoritative	Occupational Carcinogen		
		US NIH – Report on Carcinogens	Authoritative	Known or Reasonably Anticipated		
		CA EPA -- Prop 65	Authoritative	Carcinogen		
	B Lists	US EPA – IRIS Carcinogens (1986)	Authoritative	Group D		
		US EPA – IRIS Carcinogens (1999)	Authoritative	Suggestive Evidence, but not sufficient to assess human carcinogenic potential		
		US EPA – IRIS Carcinogens (2005)	Authoritative	Suggestive evidence of carcinogenic potential		
		IARC	Authoritative	Group 3		
		CA EPA – Prop 65 (with qualifications)*	Authoritative	Carcinogen – specific to chemical form or exposure route		
Mutagenicity/Genotoxicity (M)	Data	GHS Criteria & Guidance		GHS Category 1A (Known) or 1B (Presumed) for any route of exposure	GHS Category 2 (Suspected) for any route of exposure or limited or marginal evidence of mutagenicity in animals (See Guidance)	Adequate data available, and negative studies for both chromosomal aberrations and gene mutations, no structural alerts, and GHS not classified.
	A Lists	EU – REACH Annex XVII CMRs	Authoritative	Category 1 or 2	Category 3	
		EU – Annex VI CMRs	Authoritative	Mutagen 1A or 1B	Mutagen 2	
		EU – GHS (H-Statements)	Authoritative	H340	H341	
		EU – R-Phrases	Authoritative	R46	R68	
		EU – SVHC Authorisation List	Authoritative	Mutagenic – Banned unless Authorised		
		"GHS – [COUNTRY]* Lists (*Australia, the European Union, Indonesia, Japan, Korea, Malaysia, New Zealand, Taiwan and Thailand)"	Screening	Category 1A or 1B	Category 2	Not Classified
	B Lists	MAK	Authoritative	Germ Cell Mutagen 1, 2, or 3a		
		MAK	Authoritative	Germ Cell Mutagen 3b or 5		

10.2 Step 4 – Determine level of confidence (HIGH or *LOW*) for each hazard level assigned

Level of confidence is determined by data source(s) and expert judgment of the overall strength of the evidence. The rationale behind the assigned level of confidence shall be provided for each hazard endpoint.

10.2.1 Indicate the level of confidence for each designated hazard classification level using specified fonts (i.e., **BOLD** versus *ITALICS*).

1. Hazard classifications shall be represented in **BOLD** capital letters for high confidence (e.g., **H** for High).
2. Hazard classifications shall be represented in *ITALIC* capital letters for low confidence (e.g., *H* for High).

10.2.2 Classify an endpoint as high confidence if the hazard level was determined primarily based on one or more high confidence data sources such as Authoritative A lists or high quality measured data for the chemical being assessed, or a strong analog.

10.2.3 Classify an endpoint as low confidence if the hazard level was determined using equivocal results, Screening A/B lists, Authoritative B Lists, measured data for a weak analog, and/or modeled data for the parent chemical or a suitable analog. Hazard classifications based on the following are generally to be considered lower confidence. If studies are truly inadequate based on expert judgment, then it may be preferable to classify the hazard endpoint as a Data Gap.

1. Studies that do not provide unequivocal results (e.g., effect is not significantly different than control when doses are below differentiating GHS criteria levels) or are assigned a low reliability (Klimisch) score (e.g., Klimisch scores of 3 or 4),[14]
2. A single non-GLP study, non-guideline study, or a non-standard hazard endpoint,
3. Multiple studies with mixed results that use comparable methods and are of similar quality, or
4. Toxicity tests evaluating a non-relevant pathway of exposure (e.g., intravenous, intraperitoneal injections).

10.2.4 GreenScreen prioritizes information as follows:

1. Valid measured data on the chemical(s) being evaluated are generally preferred over other types of information, such as hazard lists or estimated values (e.g., SAR models or suitable analogs).
2. Authoritative A lists are preferred over Authoritative B or Screening A or B lists. When lists conflict, the most conservative of the authoritative results should be used.
3. A strength of evidence approach is used when data are conflicting.

10.3 Step 5 – Assign a Data Gap (DG) to each hazard endpoint with insufficient information to assess

When assessing chemicals, it would be ideal to have access to a complete set of publicly available data covering all Hazard Endpoints in this assessment procedure. In reality, most chemicals have insufficient data to assess and classify all of the Hazard Endpoints.

10.3.1 Assign a Data Gap (DG) classification to any hazard endpoint where there is insufficient information to assess the hazard using measured data on the parent chemical, measured data on a suitable analog, or estimated data on the parent chemical or suitable analog chemical.

10.3.2 Use a "blank" if the endpoint has not been assessed or until all options for filling a Data Gap have been exhausted.

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14 H.J. Klimisch, M. A*ndreae, and U. Tillmann. 1997. A Systematic Approach for Evaluating the Quality of Experimental Toxicological and Ecotoxicological Data Regulatory Toxicology and Pharmacology* 25:1-5.

10.4 Step 6a – Document findings and conclusions

10.4.1 It is essential to provide detailed documentation of the supporting data and rationale for all hazard classifications in an assessment report. It is recommended to use the current version of the GreenScreen Assessment Template for the assessment report.

10.4.2 Reference all Information Sources.[15]

10.4.3 Indicate positive results from reviewing the Specified Lists. It is assumed that all Specified Lists are searched unless indicated otherwise in the assessment report.

10.5 Step 6b – Fill in the Hazard Summary Table

The Hazard Summary Table is part of the Assessment Template, and will be used to apply the Benchmark algorithm and assign a final Benchmark score.

10.5.1 Fill in the designated hazard classification level for each Hazard Endpoint in the respective box of the Hazard Summary Table. An example of a fully populated Hazard Summary Table is shown below in Table 4. A variation of this Hazard Summary Table may include hazard classification by route of exposure (See the GreenScreen Assessment Report Template).[16]

TABLE 4. **Example GreenScreen Hazard Summary Table**

Group I Human					Group II and II* Human									Ecotex		Fate		Physical	
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F
						SINGLE	REPEATED*	SINGLE	REPEATED*										
DG	*L*	*L*	**M**	**M**	DG	*L*	*L*	**M**	**M**	**L**	**L**	**L**	**L**	*L*	*L*	*vH*	*M*	*L*	*L*

Glossary of GreenScreen® Hazard Endpoint Abbreviations

AA Acute Aquatic Toxicity
AT Acute Mammalian Toxicity
B Bioaccumulation
C Carcinogenicity
CA Chronic Aquatic Toxicity
D Developmental Toxicity
E Endocrine Activity
F Flammability
IrE Eye Irritation
IrS Skin Irritation
M Mutagenicity and Genotoxicity
N Neurotoxicity
P Persistence
R Reproductive Toxicity
Rx Reactivity
SnS Sensitization (Skin)
SnR Respiratory Sensitization
ST Systemic/Organ Toxicity

** Repeated exposure*

10.5.2 Indicate the level of confidence using specified fonts (i.e., **BOLD** versus *ITALIC*)

10.5.3 Indicate hazard endpoint(s) with insufficient information to classify the hazard level in the Hazard Summary Table using a non-bold, non-italicized, and capitalized "DG" in the respective box.

10.5.4 The following color scheme is recommended for shading the box containing the hazard classification for each hazard endpoint:

1. vL = deep green
2. L = light green
3. M = yellow
4. H = red
5. vH = deep red
6. DG = white
7. Blank = not assessed

10.5.5 For inorganic chemicals, place an asterisk "*" after the hazard classification for Persistence in the respective box of the Hazard Summary Table and include a footnote indicating that the chemical is inorganic.

15 http://greenscreenchemicals.org/method/method-documents

16 http://greenscreenchemicals.org/method/method-documents

11. PROCEDURE FOR APPLYING GREENSCREEN BENCHMARKS™

11.1 Step 7 – Determine the preliminary Benchmark score

GreenScreen Benchmark™ Criteria apply to individual and groups of Hazard Endpoints (See Annex IV). If the chemical fails any one Benchmark criterion, then a Benchmark is established. The following steps outline the procedure for each Benchmark level, and the table provided in Annex V can be used as a worksheet, if desired. Certain modifications to the Benchmark scores are made for Data Gaps, feasible and relevant transformation products, and inorganic chemicals (Refer to Sections 10.3, 12 and 13, respectively, for guidance).

11.1.1 **Benchmark-1:** Determine if any of the following hazard endpoint groupings are true for each chemical. A Benchmark-1 is established if any statement is true, and it is not necessary to proceed to Benchmark-2. Proceed to Benchmark-2 criterion if all statements are false.

a. PBT = High P + High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
b. vPvB = very High P + very High B
c. vPT = very High P + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
d. vBT = very High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
e. High T (Group I Human)

11.1.2 **Benchmark-2:** Determine if any of the following statements are true for each chemical. A Benchmark-2 is established if any statement is true, and it is not necessary to proceed to Benchmark-3. Proceed to Benchmark-3 criterion if all statements are false.

a. Moderate P + Moderate B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
b. High P + High B
c. High P + Moderate T (Ecotoxicity or Group I, II or II* Human)
d. High B + Moderate T (Ecotoxicity or Group I, II or II* Human)
e. Moderate T (Group I Human)
f. Very High T (Ecotoxicity or Group II Human) or High T (Group II* Human)
g. High Flammability or High Reactivity

11.1.3 **Benchmark-3:** Determine if any of the following statements are true for each chemical. A Benchmark-3 is established if any statement is true, and it is not necessary to proceed to Benchmark-4. Proceed to Benchmark-4 criterion if all statements are false.

a. Moderate P or Moderate B
b. Moderate Ecotoxicity
c. Moderate T (Group II or II* Human)
d. Moderate Flammability or Moderate Reactivity

11.1.4 **Benchmark-4:** Determine if the following statement is true for each chemical. A Benchmark-4 is established if the following statement is true.

a. Low P + Low B + Low T (Ecotoxicity, Group I, II and II* Human) + Low Physical Hazards (Flammability and Reactivity) + Low (additional ecotoxicity endpoints when available). See exceptions for inorganics in Section 13.

11.2 Step 8 – Conduct a Data Gap Analysis to assign a final Benchmark score

Data requirements become more stringent with higher Benchmark scores. With solid information on a single endpoint, one can confidently assess a chemical and assign a Benchmark score of 1. Additional data are needed to assess a chemical and confidently assign it a higher Benchmark score. The number and type of Data Gaps must be considered when assigning a Benchmark score to a chemical. The following procedure defines the minimum data requirements to achieve a given Benchmark score:

11.2.1 **Benchmark-1:** Review all of the Data Gaps assigned for each chemical. The following table outlines the requirements for a Benchmark-1:

TABLE 5. **Data Gap Analysis for Benchmark-1**

Benchmark Score	Data Requirements and Permissible Data Gaps by Hazard Endpoint Category
Benchmark–1	A chemical may be assigned Benchmark-1 with data on as few as one endpoint. For example, if a chemical is definitively classified as a GHS Category 1 (High in GreenScreen) for the Group I endpoint Carcinogenicity, it would be assigned Benchmark-1. If a chemical is not classified as Benchmark-1 based on hazard then it must meet the data requirements for Benchmark-2.

11.2.2 **Benchmark-2:** Review all of the Data Gaps assigned for each chemical. To achieve Benchmark-2, a chemical must have the minimum data set as described below. If a chemical does not achieve the minimum data requirements for Benchmark-2, it will be assigned a "U" (Unspecified). The following table outlines the requirements for a Benchmark-2:

TABLE 6. **Data Gap Analysis for Benchmark-2**

Benchmark Score	Data Requirements and Permissible Data Gaps by Hazard Endpoint Category			
Benchmark–2	**Group I Human**	**Group II and II* Human**	**Ecotoxicity & Fate**	**Physical Properties**
	Data required for 3 out of 5 endpoints. Permissible Data Gaps include: 1. Endocrine Activity 2. Reproductive or Developmental Toxicity	Data required for 4 out of 7 endpoints. Permissible Data Gaps include: 1. Skin OR Respiratory Sensitization 2. Skin OR Eye Irritation 3. One other hazard endpoint (unrestricted)	Data required for 3 out of 4 endpoints. Permissible Data Gaps include: 1. Acute OR Chronic Aquatic Toxicity	Data required for all 2 endpoints.[17]

11.2.3 **Benchmark-3:** Review all of the Data Gaps assigned. To achieve Benchmark-3, a chemical must have the minimum data set as described below. If a chemical meets the hazard classification requirements of Benchmark-3 based on all available data but does not achieve the minimum data requirements for Benchmark-3, it will be assigned a downgraded Benchmark score of Benchmark-2_{DG}. If a chemical does not achieve the minimum data requirements for Benchmark-2, it will be assigned a "U" (Unspecified).

17 i. It is sufficient to classify flammability based on data in as few as one relevant sub-category (e.g., flammable liquid); and ii. it is sufficient to classify reactivity based on data in as few as one relevant sub-category (e.g., explosivity). If a chemical is not explosive, it meets the requirement for non-reactivity as long as there are no data stating otherwise.

TABLE 7. **Data Gap Analysis for Benchmark-3**

Benchmark Score	Data Requirements and Permissible Data Gaps by Hazard Endpoint Category			
Benchmark–3	**Group I Human**	**Group II and II* Human**	**Ecotoxicity & Fate**	**Physical Properties**
	Data required for 4 out of 5 endpoints (max 1 Data Gap). Permissible Data Gap is: Endocrine Activity	Data required for 5 out of 7 endpoints (max 2 Data Gaps). Permissible Data Gaps include: 1. Skin OR Respiratory Sensitization 2. One other hazard endpoint (unrestricted)	Data required for all 4 endpoints (max zero Data Gaps).	Data required for all 2 endpoints (max zero Data Gaps).[18]

11.2.4 **Benchmark-4:** Data required for all 18 endpoints. To achieve Benchmark-4, the chemical must have sufficient data to assess all Hazard Endpoints (max zero Data Gaps). Assessments based entirely on estimated values may not be sufficient to achieve Benchmark-4 based on professional judgment. If a chemical meets the hazard classification requirements of Benchmark-4 based on all available data but does not achieve the minimum data requirements for Benchmark-4, it will be assigned the next lower Benchmark score, which is Benchmark-3_{DG}. If a chemical does not achieve the minimum data requirements for Benchmark-2, it will be assigned a "U" (Unspecified).

18 i. It is sufficient to classify flammability based on data in as few as one relevant sub-category (e.g., flammable liquid); and ii. it is sufficient to classify reactivity based on data in as few as one relevant sub-category (e.g., explosivity). If a chemical is not explosive, it meets the requirement for non-reactivity as long as there are no data stating otherwise.

12. ASSESSING AND BENCHMARKING WITH ENVIRONMENTAL TRANSFORMATION PRODUCTS

Environmental transformation products shall be considered to determine the final Benchmark score of the parent chemical. Evaluation of metabolic transformation products is incorporated into the hazard assessment for the parent chemical and is outside of the scope and intention of this section.

Identifying environmental transformation products can be challenging and will require the use of professional judgment. Transformation products for most chemicals are not well studied. The goal is to identify only those environmental transformation products that are both feasible and relevant because they: 1) are known or likely to form; 2) have persistent, bioaccumulative, and/or toxic characteristics; and/or 3) could potentially result in increased risk from the use of the parent chemical across its life cycle. The functional use of the chemical in specific products should be considered.

12.1 Feasible means the transformation product is likely to occur because: 1) the structure of the parent chemical allows for certain types of transformations (e.g., hydrolysis) and 2) those transformations are likely to occur based on the functional use of the chemical across its life cycle (e.g., used in products that are discharged to water).

12.2 Relevant means the transformation product is: 1) persistent enough to be encountered after use or release of the parent chemical and 2) not a substance necessary for life or commonly formed in the ambient environment.

12.3 **Steps to Identify and Assess Feasible AND Relevant Environmental Transformation Products**

Identification of feasible and relevant environmental transformation products will require expert judgment and best available knowledge of the parent chemical's functional use, its physical/chemical properties, and review of literature and other sources for information on known transformation pathways and products, and partitioning in environmental media. The process is to first determine those that are feasible and then to narrow down the number to those that are also relevant.

12.3.1 **Step 1. Identify feasible transformation products.** Identify potential transformation products of the parent chemical based on feasible transformation pathways (e.g., biodegradation, oxidation, hydrolysis, photolysis, etc.). Resources are provided in Annex VI.

1. As a guide, consider the following questions:
    a. Does the parent chemical contain functional groups that can hydrolyze? Oxidize? Photolyze? Undergo oxidation or reduction? Are there structural alerts for these transformations? What are the kinetics? The faster the transformation, the more likely that a transformation product will form and result in exposure.
    b. Has the chemical been tested or modeled for biodegradability? Under what conditions? What test methods have been used and what media do they represent (e.g., aerobic freshwater, wastewater treatment, anaerobic biodegradation, marine environment, soil, sediment, etc.)? Is the biodegradation primary or ultimate? What are the kinetics?
    c. Based on the known functional use of the chemical in a product and the life cycle of the product, is the chemical likely to undergo the feasible transformation pathways?
2. Provide a rationale for the selection and deselection of feasible environmental transformation products.

12.3.2 **Step 2. Identify relevant transformation products.** For the feasible transformation products identified in Step 1 above, determine which are relevant. The worksheet provided in Annex VII can be used as an internal resource for this step, if desired.

1. Transformation products that are persistent, bioaccumulative, and/or toxic should be considered relevant whether predicted or found in the environment through monitoring (e.g., formation of DDD from DDT). A transformation product is not considered relevant if it is determined by expert judgment to be transient (e.g., an intermediate formed briefly and subsequently degraded, such as during aquatic biodegradation).
2. Products of ultimate biodegradation/mineralization (i.e., CO_2 and H_2O) are not considered relevant. Transformation products of chemicals that degrade rapidly and completely (i.e., ultimate biodegradation) are unlikely to form persistent biodegradation intermediates and are therefore not considered relevant. This corresponds to meeting criteria for very Low Persistence in GreenScreen (or Low Persistence with expert judgment).
3. It is helpful to keep in mind when identifying relevant transformation products that GreenScreen assessments are typically used for comparative purposes. Those transformation products that help discriminate between alternative parent chemicals may be considered relevant.
4. Provide a rationale for the selection and deselection of relevant environmental transformation products.

12.3.3 **Step 3. Screen transformation products that are BOTH feasible and relevant.** For each feasible and relevant transformation product, determine whether a GreenScreen assessment or a List Translator assessment will be performed. At a minimum, evaluate feasible and relevant transformation products using List Translator.[19] GreenScreen assessment of feasible and relevant transformation products may be necessary when a List Translator score is not definitive. Report results from screening the transformation products in the GreenScreen Assessment Template.

12.4 Impact of Transformation Products on Benchmarking

If a feasible and relevant environmental transformation product is more hazardous than the parent compound, then the score of the transformation product may be used to modify the Benchmark score of the parent compound.

12.4.1 Using results from GreenScreen assessments of feasible and relevant environmental transformation products:

1. Compare the Benchmark score of the parent chemical to the Benchmark score(s) of the feasible and relevant environmental transformation product(s). Use the lowest of the Benchmark scores from all transformation products and apply the following:
   a. If the Benchmark score of the transformation product is U, then professional judgment should be used to determine whether the parent chemical Benchmark score should be modified.
   b. Report the modified Benchmark score and the rationale for the modified Benchmark score in the hazard assessment summary section of the report. Report the modified Benchmark score with a subscript (TP) to designate that the Benchmark score was modified based on the score of the environmental transformation products (e.g., Benchmark-2_{TP}).

19 GreenScreen assessments of environmental transformation products are always preferred to assessments using the List Translator only.

12.4.2 Using results from List Translator assessments of feasible and relevant environmental transformation products:

1. If the score of the lowest scoring transformation product is LT-1, then the Benchmark score of the parent chemical is Benchmark-1_{TP}.
2. If the score of the lowest scoring transformation product is LT-P1, then more research is needed to determine whether the transformation product is LT-1 or LT-UNK.
3. If the score of the transformation product is LT-UNK, then the score of the parent chemical is not modified.

13. ASSESSING AND BENCHMARKING INORGANIC CHEMICALS

The physical properties of chemicals, particularly inorganic chemicals, are relevant to assessing their inherent hazard and toxicity. Attributes including solubility, bioavailability, and particle size are particularly relevant to benchmarking inorganic compounds. For example, water solubility can modify the hazard classification of aquatic toxicity, and particle size and shape can determine the potential for a chemical to cause respiratory irritation. The following steps should be included in the hazard evaluation for inorganic chemicals:

13.1 **Step 1.** Report the following form and physical chemical properties of the inorganic chemical (See the GreenScreen Assessment Template).[20]

a. Particle size (e.g., silica particles < 10 microns)

b. Structure (e.g., amorphous vs. crystalline)

c. Mobility (e.g., water solubility, volatility)

d. Bioavailability

13.2 **Step 2.** Identify feasible and relevant transformation products for inorganic chemicals. Consider dissociation products, moieties, and valence states in addition to those parameters normally used when identifying feasible and relevant environmental transformation products of organic chemicals.

13.3 **Step 3.** Classify hazards for the inorganic chemical and its feasible and relevant transformation product(s).

13.4 **Step 4.** Apply the Benchmarks. For inorganic chemicals, Persistence should not necessarily be considered a negative characteristic—particularly for naturally occurring minerals and metal oxides, etc.

13.4.1 Inorganic chemicals that are persistent and for which all Hazard Endpoints except Persistence are low may achieve Benchmark-4.

13.4.2 Benchmark inorganic chemicals and transformation products by considering Persistence in combination with Group I, Group II* and Chronic Aquatic Toxicity Hazard Endpoints only in the Benchmarking process. Do not consider Persistence in combination with Group II or Acute Aquatic Toxicity Hazard Endpoints in the Benchmarking process. The intent is to consider Persistence of inorganic chemicals in combination with chronic hazards only in the Benchmarking process.

20 http://greenscreenchemicals.org/method/method-documents

14. REPORTING REQUIREMENTS

GreenScreen® for Safer Chemicals is designed to use all available information to screen and compare chemicals.

14.1 Licensed GreenScreen Profilers and Authorized Greenscreen Practitioners shall be transparent in presenting assessment results, clearly communicating both data quality and data completeness.

14.2 The hazard classification summary provided for each endpoint should include a summary of the toxicity data, the rationale for the selected hazard classification and confidence level, and a discussion on selection of any suitable analogs.

14.3 The summary results of a GreenScreen assessment should include:

14.3.1 A Benchmark score assigned for each chemical based on the inherent hazards associated with the chemical and consideration of Data Gaps and transformation products as comprehensively defined in this documentation.

14.3.2 Benchmark scores that have been modified due to Data Gaps or environmental transformation products shall be presented with relevant subscripts (e.g., Benchmark-2_{DG} or Benchmark-1_{TP}).

14.3.3 Where there are Data Gaps, it is recommended to include a worst-case scenario estimate to indicate what the lowest possible Benchmark score would be if the Data Gap was filled with the highest possible hazard, unless expert judgment is deemed sufficiently strong to rule out certain hazards.

14.4 Use the reporting format shown in the example in Annex II and Annex III for reporting the Benchmark scores of chemicals in complex mixtures and polymeric materials.

15. MAKING INFORMED DECISIONS

15.1 GreenScreen is intended for use as one tool in the sustainability toolbox. It is a method for comparative chemical hazard assessment and is not intended to address impacts from energy consumption, resource extraction, etc. that are typically addressed in life cycle assessment.

15.2 GreenScreen helps to inform decision making for the design and development of products and processes, for material or product procurement, and to support and enhance environmental management systems, environmental health and safety (EHS) programs and global sustainability or environmental reporting. GreenScreen provides a clear and transparent format for presenting what is known and what is not known about the hazards associated with chemicals.

15.3 Chemicals may achieve the same Benchmark score but have very different hazard profiles. Therefore, GreenScreen Benchmark scores should be used in combination with the Hazard Summary Table and the full report that includes information on transformation products and data quality and completeness in order to avoid making regrettable substitutions when making decisions that affect consumers/users, workers, and the environment.

15.4 Data Gaps should always be considered in the context of how they relate to workers, users, end users, environmental fate, etc. For example, if there is a Data Gap for Systemic Toxicity via the inhalation exposure route for a perfume additive, an informed decision cannot be made about the safety of this chemical for workers at the factory. The Profiler or Practitioner should always document possible exposure routes for workers.

15.5 The acceptability of Data Gaps should be considered on a case-by-case basis depending on known product use or exposure scenarios. For example, while lack of data on skin irritation may be sufficient to achieve a Benchmark-3 for a chemical, it is not an acceptable Data Gap when selecting a chemical for use in a skin lotion.

16. RECORDS

16.1 Licensed GreenScreen Profilers and Authorized GreenScreen Practitioners shall keep all documents generated as a result of the implementation of this Guidance on file for the duration of the Licensing period and 5 years thereafter.

17. ANNEX I — GREENSCREEN LIST TRANSLATOR (LIST TRANSLATOR)

17.1 Introduction

GreenScreen List Translator assessment is a streamlined chemical hazard assessment based on review of GreenScreen Specified Lists only. Authoritative and screening hazard lists can be very informative as a preliminary step to quickly identify known chemicals of high concern and to prioritize chemicals for further review. GreenScreen List Translator consolidates over 40 primary authoritative and screening sources and hundreds of sub-lists that include national and international regulatory and hazard lists, influential NGO lists of chemicals of concern (screening lists), lists from authoritative scientific bodies, European Risk and Hazard Phrases and chemical hazard classifications by countries using the Globally Harmonized System of Classification and Labelling of Chemicals.

All of the Specified Lists used in GreenScreen have been compiled and subsequently mapped to hazard classifications and published in GreenScreen List Translator and in GreenScreen Hazard Criteria. Each Specified List has been reviewed and approved by GreenScreen Technical Advisory Committee (TAC). The TAC is composed of technical experts from academia, business, government, and NGOs who ensure that GreenScreen is scientifically robust and technically sound. The TAC also supports ongoing development and continual improvement of GreenScreen guidance.

17.2 List Translator Resources

While GreenScreen List Translator is included as one portion of the more comprehensive GreenScreen assessment, it can also be used as a stand-alone tool to screen for chemicals of high concern in products. In addition to this guidance, the following resources[21] are needed to complete a List Translator assessment:

1. List Translator, which includes Specified Lists
2. GreenScreen Hazard Criteria

17.3 Uses and applications of GreenScreen List Translator

Using GreenScreen List Translator is a first step toward GreenScreen assessment and an affordable way to expedite the process of assessing the hazards of chemicals found in products. While it cannot substitute for comprehensive GreenScreen assessment, there are still a variety of practical uses:

- rapid identification of “Likely Benchmark-1” or “Possible Benchmark-1” chemicals for use in an alternatives assessment process,
- earning LEED credit,[22]
- prioritizing chemicals for further review and/or phase out,
- meeting client specifications for eliminating chemicals of very high concern,
- assisting in regulatory and non-regulatory standard compliance, and
- communicating materials goals and criteria to suppliers.

21 http://greenscreenchemicals.org/method/method-documents
22 http://greenscreenchemicals.org/practice/leed

17.4 Process Overview

A List Translator assessment can be conducted manually using GreenScreen List Translator resources available on GreenScreen's website. GreenScreen List Translator maps Specified Lists to hazard classification levels and List Translator scores. The manual version of GreenScreen List Translator is not a database of scores for specific chemicals (i.e. by CASRN), however. See Section 17.10 below for automated tools that provide List Translator scores for chemicals of interest. The following table provides an overview of steps to evaluate chemicals using GreenScreen List Translator.

TABLE A-1. **Quick Steps to Conduct GreenScreen List Translator Assessments**

Step 1	Determine chemicals to assess
Step 2	Search GreenScreen Specified Lists (automated or manual search)
Step 3	Assess and classify hazards
Step 4	Determine List Translator score
Step 5	Report results: 1. Report List Translator score for each ingredient 2. Show List Translator Hazard Summary Table & lists 3. Explain resolution of any LT-P1 results

17.5 STEP 1: Determine chemicals to assess

The guidance in this Annex I applies to conducting a GreenScreen List Translator assessment for a single chemical identified by a CASRN. GreenScreen List Translator does not include assessment of environmental transformation products, such as by-products of microbial action in sediment or waste treatment, chemical transformation in surface waters, or photochemical reactions in the atmosphere. A thoughtful follow-on process will consider the ramifications of this limitation. In practice, transformation products (degradates) are often the principle cause of environmental or human toxicity. So, while a chemical might receive a List Translator score of LT-UNK, it might also be the source of a well-known, high-hazard environmental transformation product. This could lead to unfortunate circumstances, such as expensive, late-stage modifications when a toxic degradate is discovered late in the product design or specification process.

Annex VIII provides additional helpful information for identifying chemicals in mixtures and products. See also Section 7, Disclosure and Assessment Rules and Best Practice, Annex II, Assessing and Benchmarking Mixtures, and Annex III, Assessing and Benchmarking Polymeric Materials of this guidance.

17.6 STEP 2: Search GreenScreen Specified Lists

The Specified Lists resource within GreenScreen List Translator contains web links to each list. Check each list for the presence of a chemical of interest. If a chemical is found on a list, compile the name(s) of the list(s) and the related list endpoint category. The GreenScreen Hazard Criteria or List Translator spreadsheet can be used to determine which hazard endpoint(s) relate to the listing. This will be needed in later steps.

17.6.1 Individual versus Multiple Hazard Lists

Most Specified Lists affect one or more individual Hazard Endpoints. For example, several agencies have lists of carcinogens. While these carcinogens may also express other toxic properties, the source lists specifically address the individual Carcinogenicity endpoint. Chemicals with data for individual Hazard Endpoints will normally be assigned a hazard classification such as very High, High, Moderate, or Low (See Section 17.7 STEP 3: Assessing and Classifying Hazards with List Translator).

Some lists, however, address multiple Hazard Endpoints in a fashion that cannot be separated into individual GreenScreen Hazard Endpoints. This occurs most often with lists of Persistent-Bioaccumulative-Toxic (PBT) chemicals or their equivalents. When multiple hazards are not differentiated in the list, no individual hazard endpoint can be assessed. Chemicals on these lists are evaluated against separate "Multiple Endpoints" criteria. For example, presence on Canada's CEPA Toxic list translates directly to an LT-UNK. This would be considered a minimum score for the chemical, without further research.

"Multiple Endpoints" are also indicated for many GHS classifications of Reproductive Toxicity. UNEP and EU GHS classifications do not always separate reproductive or developmental effects, but rather combine them into a single Reproductive Toxicity endpoint result. In these cases, effects are translated directly to a final minimum List Translator score. In certain cases it may be possible to determine the origin of a Reproductive Toxicity listing as caused by either Reproductive or Developmental Toxicity. While this might support individual endpoint assignments, this kind of detailed analysis is normally outside the scope of a List Translator assessment.

17.6.2 Authoritative versus Screening Lists

Authoritative lists include results from hazard assessments by recognized experts, often as part of government regulatory processes. These results are considered to be of high reliability and should only be changed when new data or special circumstances clearly indicate that a new hazard classification is warranted. Intervention of a Licensed GreenScreen Profiler or CPA's Consulting Toxicologist would be required to validate such a change.

Screening Lists result in a classification with a lower level of confidence because at least one of the following is true of the list. It was:

1. developed using a less comprehensive review,
2. compiled by an organization that is not considered to be authoritative,
3. developed using predominantly or exclusively estimated data, or
4. developed to identify chemicals for further review and/or testing.

Regulatory prioritization screening lists are an example (e.g., Canada's Domestic Substances List (DSL)). In the DSL program, quantitative structure-activity relationship models were used to fill in gaps in hazard data. These types of models have inherent error bounds and cannot produce results with the same reliability as good quality experimental data. See Table A-2 below.

17.6.3 **A-Sublists and B-Sublists**

1. A-Sublists include data that give clear, focused hazard classifications. Two situations occur:
   a. One hazard endpoint with only one possible hazard classification (e.g., a US CDC occupational carcinogen can only lead to the result "High Concern" for Carcinogenicity), or
   b. A hazard classification with only one possible List Translator score (e.g., a chemical on the U.S. EPA Priority PBT list) will receive an LT-1. No other score is possible for substances on this list.
2. B-Sublists include data that cannot be captured in a single hazard classification or single hazard endpoint. For example:
   a. The G&L list identifies neurotoxic chemicals; however, no assessment of the potency of the substances or severity of the effects is offered. Presence on the G&L list is therefore classified as a range of possible hazard levels, from very High to Moderate.
   b. Current UNEP and EU GHS classification schemes combine reproductive and developmental toxicity into a single endpoint. As such, an indication of hazard cannot always be separated into either Reproductive (R) or Developmental (D) Toxicity effects. Substances on these hazard lists may not translate into the individual R and D endpoints and instead be assessed against "Multiple" criteria that combine R and D.

TABLE A-2. **Categorization of Specified Lists**

List Type	Description	Possible Combinations
Authoritative Lists	Authoritative lists are generated by recognized experts, often as part of a government regulatory process to identify chemicals and known associated hazards. These lists are considered to be of high reliability and should only be changed when new data or special circumstances clearly indicate that a new level-of-concern is warranted. Intervention of a Licensed GreenScreen Profiler or CPA's Consulting Toxicologist would be required to validate such a change.	Authoritative A* Authoritative B**
Screening Lists	Screening Lists result in a classification with a lower level of confidence because at least one of the following is true of the list. It was: a. developed using a less comprehensive review, b. compiled by an organization that is not considered to be authoritative, c. developed using predominantly or exclusively estimated data, or d. developed to identify chemicals for further review and/or testing.	Screening A* Screening B**

* A Sublists: This category in the list translates directly to one of the following: 1) a single hazard classification for a single GreenScreen Hazard Endpoint, or 2) a single Benchmark.

** B Sublists: Categories that meet one or more of the following: 1) This category in the list incorporates a single GreenScreen Hazard Endpoint and does not translate directly to a single Hazard Classification or Benchmark; AND/OR 2) This category in the list refers to more than one GreenScreen Hazard Endpoint; AND/OR 3) This category in the list specifies that the hazard is associated with a specific form of the substance or a specific exposure route.

17.6.4 Trumping Rules

The Specified Lists in GreenScreen List Translator carry inherent weighting based on the organization that publishes the list as well as the process used to develop the list. These factors are captured in the list type as explained in the list definitions in Table A-2 above. When a specific Hazard Endpoint for a given chemical is found on more than one GreenScreen Specified List, one of the lists will drive the hazard classification by taking precedence over the other list(s).

The rules for selecting which list takes precedence over the other lists are depicted in Table A-3 below. When the chemical shows up on more than one list, find the first list type in Column 1 and the second list type in Row 1. The rule found in the cell at the intersection of the two list types determines which list will control the hazard classification. Repeat this process for each hazard endpoint for which the chemical of interest appeared on more than one list.

For example, if one list is an Authoritative B list and the second is a Screening A list, then the Authoritative B list will "trump" the Screening A list and drive the hazard classification for the hazard endpoint. When a chemical shows up on more than two lists, the same procedure is used iteratively, beginning with the first two lists.

TABLE A-3. **Trumping Rules for Lists**

	Column 1	Column 2	Column 3	Column 4	Column 5
Row 1		Authoritative A	Authoritative B	Screening A	Screening B
Row 2	Authoritative A	Most Convervative	Most Conservative	Authoritative A	Authoritative A
Row 3	Authoritative B		Most Conservative	Authoritative B	Authoritative B
Row 4	Screening A			Most Conservative	Most Conservative
Row 5	Screening B				Most Conservative

17.7 STEP 3: Assess and Classify Hazards - List Translator

17.7.1 The hazard classification step in a List Translator assessment is based on hazard lists (i.e., GreenScreen Specified Lists) only. GreenScreen List Translator does not include data requirements to achieve a given List Translator score; however, GreenScreen assessments do have strict minimum data requirements for each Benchmark score.

17.7.2 GreenScreen Specified Lists and their relationship to hazard classifications are identified in GreenScreen Hazard Criteria. GreenScreen List Translator then maps the hazard lists using those hazard classifications to List Translator scores. The hazard level classifications found in the Hazard Criteria are described in the following table:

TABLE A-4. **Description of Hazard Classifications for List Translator**

Hazard Level Classification*	
vH	Very High Concern
H	High Concern
M	Moderate Concern
L	Low Concern
vL	Very Low Concern
(BLANK)	The chemical was not found on any of the authoritative or screening lists associated with GreenScreen
Range	A range may be reported for chemicals found on "B" lists. B lists sometimes include a level of uncertainty and may benefit from additional research to confirm a more specific hazard classification level

* **Bold** font indicates result was derived from an Authoritative A list; *Italics* font indicates result was derived from Authoritative B, Screening A, or Screening B lists

17.7.3 Hazard classifications should be summarized in a List Translator Hazard Summary Table (See Table A-5 below). This table includes a field for Multiple Hazard Lists (See Section 17.6.1—Individual versus Multiple Hazard Lists).

TABLE A-5. **List Translator Hazard Summary Table**

Group I Human					Group II and II* Human								Ecotex		Fate		Physical		Multiple
C	M	R	D	E	AT	ST		N		SnS*	SnR*	IrS	IrE	AA	CA	P	B	Rx	F	
						SINGLE	REPEATED*	SINGLE	REPEATED*											
			M or L	*H or M*	L	*vH*	*H*	*M*	*M or L*			*M*	**H**			*vH or H*			*H*	*Mult*

Glossary of GreenScreen® Hazard Endpoint Abbreviations

AA Acute Aquatic Toxicity
AT Acute Mammalian Toxicity
B Bioaccumulation
C Carcinogenicity
CA Chronic Aquatic Toxicity
D Developmental Toxicity
E Endocrine Activity
F Flammability
IrE Eye Irritation
IrS Skin Irritation
M Mutagenicity and Genotoxicity
N Neurotoxicity
P Persistence
R Reproductive Toxicity
Rx Reactivity
SnS Sensitization (Skin)
SnR Respiratory Sensitization
ST Systemic/Organ Toxicity

* *Repeated exposure*

17.8 STEP 4: Determine List Translator score

17.8.1 List Translator score description

Assessments based on GreenScreen List Translator only must use List Translator score nomenclature and not GreenScreen Benchmark nomenclature to communicate results. There are only 3 possible List Translator scores. To differentiate between scores generated by a List Translator assessment versus a GreenScreen assessment, List Translator scores are identified with LT (i.e., LT-1, LT-P1, LT-UNK). See Table A-6 for List Translator scoring nomenclature and how each List Translator score is related to GreenScreen Benchmark scores. Results reported as LT-P1 may be resolved by performing further research on the hazard endpoint driving the LT-P1 score to determine if the hazard classification is more appropriately LT-1 or LT-UNK (See Table A-6 for ways to resolve scores). GreenScreen List Translator cannot be used to verify that a chemical is safe or even to say that it is safer than a Benchmark-1. A chemical that receives a List Translator score of LT-UNK may be a safer chemical; however, it may also be a chemical that has not been evaluated by the organizations publishing GreenScreen Specified Lists, or it may be a chemical that has not been well tested and has minimal data available (unknown hazard). Due to the more comprehensive nature of GreenScreen assessments, Benchmark scores always trump List Translator scores.

TABLE A-6. **List Translator versus Benchmark Scores**

List Translator Score	GreenScreen Benchmark Equivalent	Derivation	Exceptions/Resolution
LT-1	Likely Benchmark-1	A LT-1 score is based on clear agreement among Authoritative lists that the substance is a Chemical of High Concern and may be considered equivalent to a GreenScreen Benchmark-1.	EXCEPTIONS: chemicals that are hazardous due to form-specific issues (e.g., silica, TiO2). RESOLUTION: The solution is to fully characterize the form (e.g., particle-size distribution, purity, etc.), and obtain a GreenScreen assessment to determine a Benchmark score.
LT-P1	Possible Benchmark-1	Frequently this means that the chemical appears on a list that does not translate directly to a single Benchmark score and Benchmark-1 is included in the range of possible Benchmark scores.	EXCEPTIONS: none RESOLUTION: It is an option to resolve LT-P1 scores to further support decision-making.[23] There are two ways to do so: 1. Evaluate only the Hazard Endpoints driving the LT-P1 score using GreenScreen guidance (e.g., P, B and T): a. If this results in a Benchmark-1 score, report the score as Benchmark-1. b. If this does not result in a Benchmark-1 score, report the score as LT-UNK. 2. Perform a GreenScreen assessment and report the final Benchmark score.
LT-UNK	Unknown Benchmark	LT-UNK ("unknown") indicates that a chemical is present on a GreenScreen Specified List but that there is insufficient information to classify the hazard as LT-1 or LT-P1. The LT-UNK score or the absence of a chemical on hazard lists does not mean it is safe. It may mean the chemical has not been reviewed by the body publishing the list or that the chemical has not yet been well tested.	A GreenScreen assessment would need to be performed to determine the Benchmark score of the chemical.

23 Resolving LT-P1 scores is required for Option 2 of the LEED v4 Optimization credit (http://www.greenscreenchemicals.org/practice/leed)

17.8.2 **Assigning a List Translator score**

Each chemical will receive a List Translator score based on the combination of the hazard level classifications reported in the List Translator Hazard Summary Table for each endpoint. An overall List Translator score is generated for each chemical based on GreenScreen List Translator scoring algorithm in Table A-7 below.

For an LT-1 score, one of the following criteria will be true based on Authoritative lists. If one of the following is true, but was based on a Screening List, the score will be LT-P1.

TABLE A-7. **List Translator Scoring Algorithm**

LT-1 Criteria	Answer (Y or N)
a. High Toxicity (Group I)	
b. High P (**< vH**) **AND** High B **AND** very High Toxicity (Ecotox or Group II) **OR** High Toxicity (Group I or II*)	
c. very High P **AND** very High B	
d. very High P **AND** very High Toxicity (Ecotox or Group II) **OR** High Toxicity (Group I or II*)	
e. very High B **AND** very High Toxicity (Ecotox or Group II) **OR** High Toxicity (Group I or II*)]	

Human Health Group I: Carcinogenicity (C), Mutagenicity & Genotoxicity (M), Reproductive Toxicity (R), Developmental Toxicity including Neurodevelopmental Toxicity (D), and Endocrine Activity (E)

Human Health Group II: Acute Toxicity (AT), Systemic Toxicity & Organ Effects (ST-single), Neurotoxicity (N-single), Skin Irritation (IrS), and Eye Irritation (IrE)

Human Health Group II*: Systemic Toxicity & Organ Effects* Repeated Exposure (ST-repeated, Neurotoxicity – Repeated Exposure (N-repeated), Skin Sensitization (SnS) and Respiratory Sensitization (SnR)

Environmental Toxicity & Fate (Ecotox): Acute Aquatic Toxicity (AA), Chronic Aquatic Toxicity (CA), Other Ecotoxicity studies when available, Persistence (P), Bioaccumulation (B)

Physical Hazards: Reactivity (Rx), and Flammability (F)

17.9 STEP 5: Report List Translator results

17.9.1 Supporting documentation for each List Translator assessment should include, at a minimum:

1. Chemical Name and CASRN (can be redacted, as applicable),
2. List Translator score,
3. List Translator Hazard Summary Table, including lists where chemical is found, and
4. Explanation of resolution of any LT-P1 results.

17.9.2 Depending on the end use of List Translator assessment, document findings using one of the following formats:

1. Health Product Declaration (HPD) Format[24]
   a. HPD Builder may be used to document a product's intentional ingredients, residuals, and hazards, as well as other information known about the product and the status of efforts for further disclosure.
2. Custom Format
   b. For Trade Secret ingredients, chemical name and CASRN may be withheld; however, report function, amount, resulting GreenScreen List Translator score, and hazards driving the score.

17.10 Automation of GreenScreen List Translator

The following software tool developed by an independent Clean Production Action Software Partner may be used to search for a chemical of interest and GreenScreen List Translator assessment results:

Chemical and Material Library (CML) in Pharos by Healthy Building Network
http://www.pharosproject.net/material

Pharos provides easy online access to chemical hazard information for over 30,000 CASRN identified substances using the hazard lists included in GreenScreen List Translator (as well as additional lists not included in List Translator). Users can look up chemicals by CASRN or substance name and find List Translator hazard classification information for human health and ecotoxicity endpoints, and the List Translator score assigned to the chemical. The Pharos Chemical and Material Library was developed by the Healthy Building Network (HBN) as part of a suite of tools to evaluate the health and environmental impact of building materials. GreenScreen Benchmark and GreenScreen List Translator scoring systems inform but are distinct from the Pharos scoring system for building products.

24 www.hpdcollaborative.org

18. ANNEX II—ASSESSING AND BENCHMARKING MIXTURES

The purpose of this guidance is to outline the process for assessing and benchmarking chemicals in mixtures. Except as otherwise described in the following sections, individual chemicals in mixtures are subject to the same general assessment and benchmarking process described in Sections 6-14 above.

18.1 Disclosure and Assessment Best Practice (Mixtures)

18.1.1 Identify each intentionally added chemical present at or above zero (0) ppm and each known impurity present at or above 100 ppm in the mixture.

18.1.2 If there are undisclosed or unknown proprietary ingredients, seek additional information. The following approaches are suggested:

1. Seek information on the identity of ingredients and/or constituents of those ingredients from the next supplier upstream.
2. Ask the next supplier upstream to conduct their own GreenScreen assessment and report results; or
3. Ask the next supplier upstream to screen the ingredients and/or constituents of those ingredients using GreenScreen List Translator and report the results; or
4. List all unknowns as “Not Reported” with concentrations in parent product.

18.1.3 Follow the procedure described in the main body of this guidance for each chemical identified.

18.2 Reporting Requirements (Mixtures)

18.2.1 Apply the general Reporting Requirements described in Section 14, in addition to the following:

1. The mixture does not receive a single Benchmark score. Report the concentration, hazard profile and Benchmark score for each individual chemical in the mixture.
2. Report product constituents at exact concentrations (include name, CASRN). If this is not feasible due to confidentiality reasons, report concentration ranges.
3. Denote a chemical as “Not Reported (NR)” in the assessment report if a chemical is unable to be assessed because a supplier will not provide formulation data.
4. Report the % of the mixture at each Benchmark score.
5. If a user chooses to develop their own scoring system such as a weighted average value, it shall be used in addition to reporting the individual Benchmark % values and identifying Benchmark-1 chemicals.

The following figure is provided as an example for reporting on mixtures:

Intentionally added chemicals or impurities ≥ 100 ppm in the parent product:

FIGURE A-1. **Example Reporting Format for Mixtures**

Chemical	CAS	% by Weight	Benchmark	BM by %
Super Safe	4365-35-6	0.3	4	0.3
Solvent	126-57-2	95.0	3	95.0
Functional Additive	303-45-2	0.00001	2	2.7
Anti-oxidant	64744-32-1	1.4	2	
Processing Aid	67-64-1	1.3	2	
Preservative	244-88-5	2.0	1	2.0

Known and Special Case Impurities < 100 ppm in the parent product:

Chemical	CAS	Concentration in final product ppm	GreenScreen List Translator Results	Reason for inclusion
Colorant	135-49-2	20	LT-P1	Possible Benchmark-1
Solvent	110-56-7	75	LT-1	Benchmark-1

19. ANNEX III—ASSESSING AND BENCHMARKING POLYMERIC MATERIALS

Report and assess constituents of polymeric materials according Table A-8 below:

TABLE A-8. **Reporting and Assessing Constituents of Polymeric Materials**

Constituent of Polymeric Material	Definition	Reporting Requirement	GreenScreen Assessment	List Translator Screening (See Annex I)
Polymer	Chains of repeating units called monomers	Report the CAS# and concentration of the major constituent(s)	Required for each polymer present at ≥ 0 ppm	N/A
Monomer	A molecule that can be bonded to other identical molecules to form a polymer	Report the CAS# and concentration of each monomer and catalyst used to produce the polymeric material	1) Required for each monomer present at ≥ 100 ppm of the final product 2) Required for each catalyst present at ≥ 100 ppm of the final product	1) Required for each monomer present at < 100 ppm of the final product 2) Required for each catalyst present at < 100 ppm of the final product
Catalysts	By definition, catalysts are not consumed in chemical reactions; however, they may be inhibited, deactivated, or destroyed by secondary processes			
Oligomer	A polymer or polymer intermediate containing relatively few structural units	Identifying transient intermediates is not required. Report % at specified MW ranges < 500 or <1000 dalton	N/A	N/A
Functional additives	Chemicals or mixtures added to impart desired physical characteristics of a polymeric material or mixture	Report CAS # and concentration of each functional additive	1) Required for each chemical intentionally added and present at ≥ 0 ppm 2) Required for each known impurity present at ≥ 100 ppm. Data from upstream suppliers may be needed to identify impurities	1) Required for each special case impurity < 100 ppm of the final product 2) If there are still unknowns, the upstream supplier may use the LT and report score
Processing aids	Chemicals used to provide a technological effect in processing but no functional effect in the product and may result in small amounts in final product (e.g., release agent)	Report the CAS# and concentration of each processing aid used to produce the polymeric material		

The following figure is provided as an example for reporting on polymeric materials.

All Constituents intentionally added or impurities in a formula:

FIGURE A-2. **Example Reporting Format for Polymeric Materials**

Chemical	CAS	% by Weight	Benchmark	BM by %
Processing Aid	146-34-2	0.3	4	0.3
Polymer	38529-31-1	95.0	3	95.0
Functional Additive	267-84-3	0.00001	2	2.7
Processing Aid	64723-88-5	1.4	2	
Processing Aid	58-34-9	1.3	2	
Monomer	502-48-8	2.0	1	2.0

Known and Special Case Impurities < 100 ppm in the formula:

Chemical	CAS	Concentration in final product ppm	GreenScreen List Translator Results	Reason for inclusion
Monomer ABC	910-23-6	20	LT-P1	Possible Benchmark-1
Catalyst XYZ	67-23-0	75	LT-1	Benchmark-1

20. ANNEX IV—BENCHMARKING CRITERIA

MARCH 2016

GreenScreen® for Safer Chemicals v1.3
GreenScreen Benchmarks™

ABBREVIATIONS

- **P** Persistence
- **B** Bioaccumulation
- **T** Human Toxicity and Ecotoxicity

GREENSCREEN BENCHMARK–4

Low P* + Low B + Low T (Ecotoxicity, Group I, II and II* Human) + Low Physical Hazards (Flammability and Reactivity) + Low (additional ecotoxicity endpoints when available)

Prefer—Safer Chemical

GREENSCREEN BENCHMARK–3

a. Moderate P or Moderate B
b. Moderate Ecotoxicity
c. Moderate T (Group II or II* Human)
d. Moderate Flammability or Moderate Reactivity

Use but Still Opportunity for Improvement

GREENSCREEN BENCHMARK–2

a. Moderate P + Moderate B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
b. High P + High B
c. High P + Moderate T (Ecotoxicity or Group I, II, or II* Human)
d. High B + Moderate T (Ecotoxicity or Group I, II, or II* Human)
e. Moderate T (Group I Human)
f. Very High T (Ecotoxicity or Group II Human) or High T (Group II* Human)
g. High Flammability or High Reactivity

Use but Search for Safer Substitutes

GREENSCREEN BENCHMARK–1

a. PBT = High P + High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
b. vPvB = very High P + very High B
c. vPT = very High P + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
d. vBT = very High B + [very High T (Ecotoxicity or Group II Human) or High T (Group I or II* Human)]
e. High T (Group I Human)

Avoid—Chemical of High Concern

GREENSCREEN BENCHMARK–U

Unspecified Due to Insufficient Data

See Guidance (GreenScreen for Safer Chemicals Hazard Assessment Guidance) at http://greenscreenchemicals.org/method/method-documents for instructions.

Group I Human includes Carcinogenicity, Mutagenicity/Genotoxicity, Reproductive Toxicity, Developmental Toxicity (incl. Developmental Neurotoxicity), and Endocrine Activity. **Group II Human** includes Acute Mammalian Toxicity, Systemic Toxicity/Organ Effects-Single Exposure, Neurotoxicity-Single Exposure, Eye Irritation and Skin Irritation. **Group II* Human** includes Systemic Toxicity/Organ Effects-Repeated Exposure, Neurotoxicity-Repeated Exposure, Respiratory Sensitization, and Skin Sensitization. Immune System Effects are included in Systemic Toxicity/Organ Effects. **Ecotoxicity** includes Acute Aquatic Toxicity and Chronic Aquatic Toxicity.

* For inorganic chemicals, Persistence alone will not be deemed problematic. See Section 13.4 in this Guidance.

21. ANNEX V—BENCHMARKING CRITERIA WORKSHEET

If a criterion statement is true for the chemical being assessed, answer Yes or No in the table below. For example, if the chemical is High P, and High B and High T (Group I Human), put a "yes" in the box for 1a.

TABLE A-9. **Benchmark Worksheet**

Benchmark	a	b	c	d	e	f	g
1							
2							
3							
4							

22. ANNEX VI—SOURCES FOR IDENTIFYING FEASIBLE AND RELEVANT TRANSFORMATION PRODUCTS

TABLE A-10. **Common Sources Used for Identifying Transformation Products**

Resource	Description
Hazardous Substances Data Bank (HSDB)	An online toxicology data file on the National Library of Medicine's (NLM) Toxicology Data Network (TOXNET®). It focuses on the toxicology of potentially hazardous chemicals. It is enhanced with information on human exposure, industrial hygiene, emergency handling procedures, environmental fate, regulatory requirements, nanomaterials, and related areas. All data are referenced and derived from a core set of books, government documents, technical reports and selected primary journal literature. HSDB is peer-reviewed by the Scientific Review Panel (SRP), a committee of experts in the major subject areas within the data bank's scope. HSDB is organized into individual chemical records, and contains over 5000 such records. The records also include a section on 'Metabolism/Metabolites.' These sources often just recap what is in the scientific literature, but you can check them first before going on to look at the literature directly.
Perform a literature search using sources such as Web of Science to search peer-reviewed journals	Success with Web of Science typically depends on known occurrence and toxicity data (i.e. if it's known to be present in the environment or has established toxicity). Well-known journals with relevant information may include (but are not limited to): 1. Environmental Science & Technology 2. Environmental Toxicology and Chemistry (ET&C) 3. Environment International 4. Chemosphere 5. Science of the Total Environment 6. Environmental Pollution 7. Journal of Environmental Monitoring
Published Risk Assessments	Those conducted by regulatory bodies such as the European Union (EU), Canadian Environmental Protection Agency (CEPA), Japan's National Institute of Technology and Evaluation (NITE) and others often contain information on transformation products.
Human and Environmental Risk Assessment (HERA)	Chemical or functional class risk assessments on ingredients of household cleaning products. http://www.heraproject.com
European Chemical Agency (ECHA) –REACH	Registered chemicals listed under European Chemical Agency (ECHA)—REACH
Textbook resources	Chemical class specific information such as degradation products of surfactants; examples of textbook resources may include (but are not limited to): Swishers Handbook of Surfactant Biodegradation or S.S. Talmage, Environmental and Human Safety of Major Surfactants (1994)
The SRC FatePointer	http://esc.syrres.com/fatepointer/search.asp
University of Minnesota Pathway Biocatalysis Biodegradation Prediction Program	While the MN DB has about 1,300 chemicals in it and addresses microbial degradation, it is less comprehensive than a literature search. (http://eawag-bbd.ethz.ch)
The Organization for Economic Co-operation and Development (OECD) QSAR Tool box	Use of models for predicting chemical biodegradation/metabolism (http://www.oecd.org/env/ehs/risk-assessment/theoecdqsartoolbox.htm)

23. ANNEX VII—IDENTIFYING FEASIBLE AND RELEVANT TRANSFORMATION PRODUCTS

The table below is provided as a worksheet that can be used to identify feasible and relevant transformation products for each parent chemical. (Note: Not all identified transformation products may end up being feasible and relevant.)

TABLE A-11. **Worksheet for Identifying Feasible and Relevant Transformation Products**

Possible TRANSFORMATION PATHWAYS	**List chemical name and CAS# of TRANSFORMATION PRODUCTS based on pathways**	**Use-Phase analysis** Describe how the chemical is typically used, released and/or managed at end of life. Describe the likely environmental transformation pathway *(e.g., the product is typically disposed of down the drain, aquatic biodegradation of the chemical is a feasible transformation pathway)*	**Identify potential hazards using GreenScreen Hazard Endpoints**
Hydrolysis			
Oxidation			
Reduction			
Substitution or elimination reactions			
Photochemical; photolysis			
Microbial biodegradation (aerobic)			
Microbial biodegradation (anaerobic)			
Other			

24. ANNEX VIII—DETERMINING CHEMICALS TO ASSESS

GreenScreen assessments and List Translator assessments require an unambiguous identification of the substances under review. Any target chemical will first need to be fully characterized with an identifying Chemical Abstracts Service Registry Number (CASRN) and chemical name. These same CASRNs are key organizing elements for all hazard information in Specified Lists.

It is important to report the disclosure threshold used for each assessment (i.e., 1000 ppm, 100 ppm, etc.). Disclosure and reporting thresholds may vary depending on the end use or application of GreenScreen List Translator results (i.e., to meet the LEED v4 Material Disclosure and Optimization credits, to support a GreenScreen assessment, or other uses).[25] The level of effort made at this ingredient identification step is typically driven by the end-use requirements for the screening process. For example, a label or certification program may have specific disclosure rules or targets and perhaps *de minimis* criteria below which ingredients are exempt from reporting.

Be aware that Safety Data Sheets (SDSs) are designed to inform workers of workplace hazards and were never intended for use as complete product ingredient inventories. OSHA only requires disclosure of hazardous ingredients to the 1% level, though carcinogens must be reported to 1000 ppm (0.1%). Reporting non-hazardous ingredients is optional for SDSs.

Complex materials comprised of many chemical substances will almost certainly require communications with suppliers or detailed literature research. For example, polymers can be mixtures of multiple polymer types. In addition, all polymers contain additives that are necessary to aid processing (e.g., mold release agents) and to add appropriate product features (e.g., anti-oxidants, flame retardants, UV stabilizers, etc.). Additives along with some residual manufacturing auxiliaries like catalysts end up in the final polymeric material.

Even chemical products whose composition is a single CASRN are often supplied at a variety of "grade" levels. Lower grade products may be less refined and contain higher levels of residuals left over from manufacturing and purification processes. The Pharos Chemical & Material Library (Pharos) provides information that may aid in identification of contaminants or residuals. For example, a chemical search in Pharos may display a "Lifecycle Hazard Quickscreen." This Quickscreen presents a list of potential manufacturing residuals (with CASRN and associated hazards) that might remain in the final product as sold. These should not be considered as authoritative, but rather as a guide for further consideration or research.

Unfortunately, the CASRN system is effective but not foolproof. On rare occasion, the same substance may have multiple CASRN or may be available in different physical forms, identified by the same CASRN. Finally, some substances are simply not listed in the CASRN system. These can be identified, but not assessed with GreenScreen List Translator only. A detailed investigation via GreenScreen assessment process may offer solutions in some cases.

25 For GreenScreen v1.3, the disclosure and assessment rules call for inventory of "every chemical intentionally added and impurities at or above 100ppm". For USGBC LEED v4 credits, the ingredient inventory threshold is 1000 ppm for the Disclosure credit and 100 ppm for the Optimization credit.

GreenScreen® for Safer Chemicals Hazard Assessment Guidance

VERSION 1.3 (1e) • JUNE 2016

The intent of guidance is to provide users with clear step-by-step instructions on how to conduct GreenScreen assessments—a comprehensive review of all available information on a chemical of interest including 1) measured data from toxicological studies in the scientific literature, 2) estimated data from suitable analogs and models, and 3) hazard lists.

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