GreenScreen® for Safer Chemicals Chemical Hazard Assessment Procedure

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1. PURPOSE

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

1.1.1 A full GreenScreen assessment includes a comprehensive review of all available information including 1) measured data from standardized tests and scientific literature, 2) estimated data from suitable analogs and models, and 3) hazard lists.

1.1.2 The hazard lists required for a full GreenScreen assessment are called GreenScreen Specified Lists and are included in the GreenScreen Hazard Criteria. They are also included in the GreenScreen List Translator (List Translator) which maps GreenScreen Specified Lists to hazard classifications. While the List Translator is not equivalent to a full GreenScreen, it can help to identify chemicals with known hazard attributes. The List Translator is available through automated software to facilitate ease of use. (See Annex I). Full procedural guidance for using the List Translator as a standalone method is currently under development.

2. SCOPE

2.1 This document includes requirements for Licensed Profilers and Certified Practitioners. It should be treated as recommended guidance for general users.

3. NORMATIVE REFERENCES

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

3.1.1 Globally Harmonized System of Classification and Labelling of Chemicals (GHS), United Nations, New York and Geneva (GHS Rev.4 (2011))[1]

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 (Version 2.0, August 2011)[2]

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

[1] http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html
[2] http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf

3.3 References that have specified dates or version numbers should be applied according to the edition specified. However, users are encouraged to review the most recent editions and any guidance documents available to gain further insight.

4. TERMS AND DEFINITIONS

Term	Definition
Acute Aquatic Toxicity	The intrinsic property of a substance to be injurious to an organism in a short-term, aquatic exposure to that substance (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Acute Mammalian Toxicity	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 (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Analog	See Suitable Analog
"Anyone"	The GreenScreen method is publically available at www.cleanproduction.org. For the purposes of the GreenScreen *Terms of Use*, "Anyone" refers to general users of the assessment method.
A Lists	A GreenScreen Specified List for which each category in the list translates directly to a single level of classification for a single GreenScreen hazard endpoint, or a single benchmark.
Assessment Report Template	A report template used to document all findings gathered during a GreenScreen assessment.
Authoritative Lists	Listing of chemicals is based on a comprehensive expert review by a recognized authoritative body.
Authoritative Secondary Sources	Peer-reviewed, "second-hand" research which integrates the scientific evidence from a number of original research studies.
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.
B Lists	GreenScreen Specified Lists that meet one or more of the following: 1) Each category in the list incorporates a single GreenScreen hazard endpoint and does not translate directly to a single level of concern or benchmark; AND/OR 2) Each category in the list refers to more than one GreenScreen hazard endpoint.
Benchmark Criteria	A set of algorithms defined in the GreenScreen method that defines the overall hazard of a chemical as Benchmark levels 1 through 4 based on individual and combinations of GreenScreen hazard endpoint classifications
Bioaccumulation	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 (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Bioconcentration	Bioconcentration refers to the net result of uptake, transformation and elimination of a substance in an organism due to waterborne exposure. (GHS Rev 4, Part 4)

BM	Benchmark
CAS #	Chemical Abstract Service Registry Number
Carcinogenicity	Capable of increasing the incidence of malignant neoplasms, reducing their latency, or increasing their severity or multiplicity (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
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
Certified Practitioner (CP)	Professional ndividuals who have undergone advanced training in the GreenScreen method and licensing by Clean Production Action to provide GS assessments for their organizations Certified Practitioners have demostrated the scientific expertise and the capacity to do high quality full GreenScreen assessments.
CHA	Chemical Hazard Assessment
Chemical of Concern (COC)	Chemicals that are frequently targets of monitoring efforts because they persist in the environment, they build up in animal tissues, and they can be toxic.
Chronic Aquatic Toxicity	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 (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Claims	A product manufacturer linking a certain GreenScreen benchmark level to a certain product
Data Gap	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
Developmental Toxicity	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 (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
DfE	Design for Environment
Draft GreenScreen Assessment	A full GreenScreen assessment that has not undergone Verification through the GreenScreen Verification Program
Endocrine Activity (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. SOURCE: 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/research/endocrine/background_disruption_en.html
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) Serious eye damage is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application (GHS Rev 4. Part 3).
Feasible Environmental Transformation Product	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 2) those transformations are likely to occur based on the functional use of the chemical across its life cycle (e.g. discharged to water)
Flammability	The ease with which a substance ignites and burns rapidly. GreenScreen criteria for flammability for solids, liquids and gases are derived from GHS (GHS Rev 4, Part 2).
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
GS	GreenScreen
Genotoxicity	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/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Hazard Summary Table	A table provided in the GreenScreen Assessment Template used to document and present the hazard classifications for all 18 hazard endpoints
Impurity	Substances inside a confined amount of liquid, gas, or solid, which differ from the chemical composition of the material or compound. Impurities are either naturally occurring or added during synthesis of a chemical or commercial product. During production, impurities may be purposely, accidentally, or incidentally added into the substance.
Intentionally added chemical	A chemical in a product that is added at any concentration to provide an intended function in a product
Licensed Profiler	A company with expertise in comparative chemical hazard assessment that is trained and licensed to provide GreenScreen assessments on a fee for service basis to any individual or organization who seeks to commission one.
List Translator	A tool that maps GreenScreen Specified Lists to hazard classifications. It is available as automated software to facilitate ease of use. The GreenScreen List Translator can also be used as a stand-alone initial screening step.
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, printing ink)
Monomer	A molecule, typically small and of low molecular weight, that can be bonded to other molecules to form a polymer (GHS)
Mutagenicity	The term mutagenic and mutagen will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms. (GHS Rev. 4, Part 3)
Neurotoxicity (N)	An adverse change in the structure or function of the central and/or peripheral nervous system following exposure to a chemical, physical, or biological agent (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
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 (from Source: 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 result in small amounts in finished product (e.g., lubricants, mold release agent)
Reactivity (Rx)	Reactivity is the tendency for a substance to undergo chemical reactions. The GreenScreen hazard endpoint Reactivity (Rx) includes criteria for multiple types of reactivity including for explosives, peroxides, strong oxidizers and more, derived from GHS (GHS Rev 4, Part 2).
Relevant Transformation Product	An environmental transformation product that is persistent enough to be encountered after use or release of the parent chemical and 2) is 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 (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Respiratory Sensitization (SnR)	Hypersensitivity of the airways following inhalation of the substance (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf)
Screening Lists	Lists are identified as Screening Lists if they were developed using a less comprehensive review; or if they have been compiled by an organization that is not considered to be authoritative; or if they are developed using exclusively estimated data; or if the chemicals are listed because they have been selected
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/Corrosion (IrS)	The production of reversible damage to the skin following the application of a test substance for up to 4 hours (from http://www.epa.gov/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf) Skin corrosion is the production of irreversible damage to the skin; namely visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to
Special Case Impurity	Chemicals of concern typically found in a chemical or material and identified based on life cycle knowledge, particularly of feedstock or upstream manufacturing processes
Specified Lists	A compilation of external Authoritative and Screening lists
Strength of Evidence	A qualitative evaluation using expert judgment of how "correct" a conclusion is based on the reliability of the data used to make the conclusion
Suitable Analog	An analog with similarities based on chemically (e.g., based on chemical structure) or biologically

	(e.g., based on metabolic breakdown, or likely mechanistic/mode of action considerations) similarities 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 analog used must be appropriate for the attribute being evaluated.
Systemic Toxicity & Organ Effects (incl. 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 included in any other endpoints previously addressed; or generalized changes of a less severe nature involving several organs
Trademark License Agreement	A legal agreement between CPA and the product manufacturer that spells out the rules of using the GreenScreen trademark and logo on products in order to make public benchmark claims
Transient Transformation Products	Not likely to give rise to the formation of persistent biodegradation intermediates
Verification	The process of verifying a GreenScreen assessment for completeness, quality and validity as defined by the GreenScreen Verification Program
Verified GS Assessment	A GreenScreen assessment that has undergone the full verification process
Weight of Evidence	The process of considering the strengths and weaknesses of various pieces of information in reaching and supporting a conclusion concerning a property of the substance[3].

[3] http://echa.europa.eu/documents/10162/13655/pg_report_weight_of_evidence_en.pdf

5. BACKGROUND

5.1 GreenScreen® for Safer Chemicals is a method for comparative Chemical Hazard Assessment (CHA) 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) Regulation, the Stockholm Convention on Persistent Organic Pollutants and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). It is freely and publicly accessible, transparent and peer reviewed.

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

6. GENERAL REQUIREMENTS

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

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

6.1.2 Results shall not be directly compared between different versions. In order to compare assessments, the older assessment should be revised to meet the criteria of the most recent version.

6.1.3 See GreenScreen Version Control Procedure for requirements for Licensed Profilers and Certified Practitioners to implement newer versions.

6.2 It is recommended that draft GreenScreen assessments be revised at a minimum of every three (3) years to ensure that the hazard profiles remain up to date.

7. PROCESS OVERVIEW

7.1 Access to the GreenScreen Resources

7.1.1 Hazard Criteria (http://www.cleanproduction.org/library/GreenScreen_v1_2-2e_CriteriaDetailed_2012_10_10w_all_Lists_vf.pdf)

7.1.2 Benchmark Criteria (http://www.cleanproduction.org/library/greenScreenv1-

2/GreenScreen_v1-2_Benchmarks_REV.pdf)

7.1.3 Assessment Report Template (includes Hazard Summary Table) (http://www.cleanproduction.org/library/greenscreen-assessment-template-2012.docx)

7.1.4 Specified Lists (i.e., The Specified Lists is a portion of the List Translator) (http://www.cleanproduction.org/library/greenscreen-translator-benchmark1-possible%20benchmark1.pdf)

7.1.5 Information Sources (http://www.cleanproduction.org/library/greenScreenv1-2/GreenScreen_1-2_InfoSources.pdf)

The following figure illustrates the GreenScreen resources to be used and the various steps performed in conducting a full GreenScreen assessment. The order of steps may vary based on individual preference.

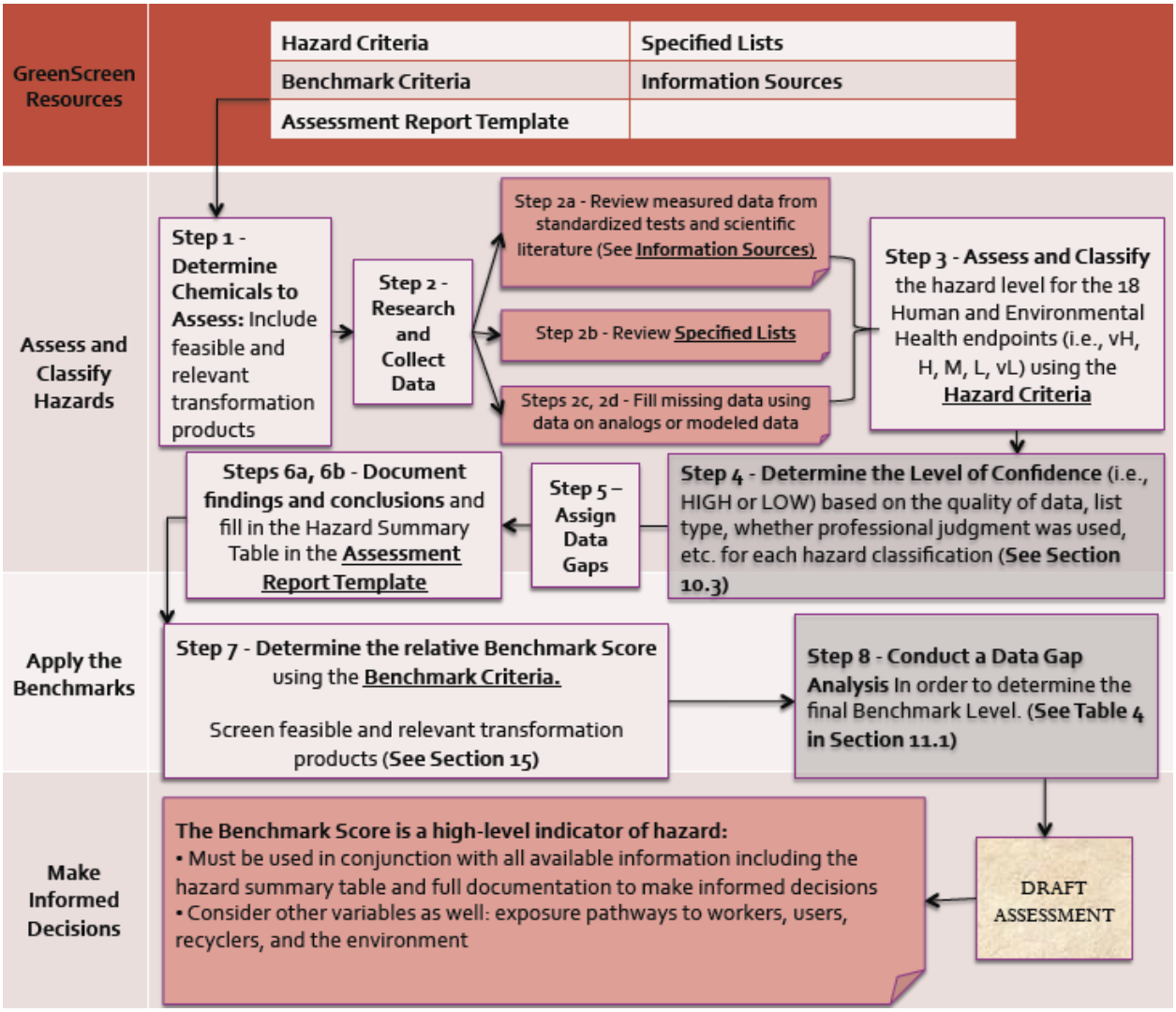

Figure 1. Performing a GreenScreen Assessment

8. DISCLOSURE AND ASSESSMENT RULES AND BEST PRACTICE

8.1 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.

8.1.1 An intentionally added chemical in a product means a chemical in a product that serves an intended function in the product component[4]. Any other chemical in the product is therefore an impurity.

8.1.2 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%).

8.1.3 Special case impurities below 100 ppm shall be screened using the List Translator[5] to determine whether they are LT-1 or LT-P1. (See Annex I).

8.2 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:

8.2.1 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 GreenScreen assessment report for every intentionally added chemical and impurity. This will allow for the equivalent comparison of alternatives.

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

8.3 The following table shows where to apply a full GreenScreen assessment versus instances where it is sufficient to screen using the List Translator only.

[4] http://www.ecy.wa.gov/pubs/wac173334.pdf

[5] 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.

Table 1. GreenScreen Disclosure and Assessment Best Practice

Type of Ingredient	Assessment Requirement
Intentionally added ingredients ≥ 0 ppm	FULL ASESSMENT
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	NO SCREENING

9. 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 Toxicity (AT)	Systemic Toxicity & Organ Effects* Repeated Exposure sub-endpoint (ST-repeat)	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) Respiratory Sensitization (SnR)	Other Ecotoxicity studies when available	
Developmental Toxicity incl. Neurodevelopmental Toxicity (D)	Skin Irritation (IrS) Eye Irritation (IrE)		Persistence (P) Bioaccumulation (B)	
Endocrine Activity (E)				

9.1 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.

9.2 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.

9.3 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.

9.3.1 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. Lacking single exposure results does not result in a data gap when repeated exposure results are present.

9.3.2 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.

9.4 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. Identify the level of hazard associated with the plausibly related adverse effect(s). Assigning the final hazard level for Endocrine Activity will use expert judgement and a weight of evidence approach[6].

9.4.1 Low Hazard

1) Low hazard classification requires data for multiple endocrine pathways (e.g., androgenicity, anti-androgenicity, thyroid effects, estrogenicity, and anti-estrogenicity)

9.4.2 Moderate Hazard

1) Endocrine Activity is classified as Moderate if there is indication of Endocrine Activity in the scientific literature.

2) All chemicals with data suggesting Endocrine Activity associated with adverse effects are initially assigned as Moderate. It is also acceptable to

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

assign a range (Moderate or High) to indicate preliminary classification.

3) For substances listed on the specified lists for Endocrine Activity, other than EU SVHC, classify them initially as Moderate. It is also acceptable to assign a range (Moderate or High) to indicate preliminary classification.

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

9.4.3 High Hazard

1) For substances listed on the EU SVHC authorization list for Endocrine Activity, classify those substances as High.

2) Where there is a High (or very High) plausibly[7] 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

[7] Plausibly related 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.

Systemic Toxicity- single dose (Thyroid)	M	M	M

9.4.4 Data Gaps

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

2) 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.

9.5 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.[8]

9.6 Physical Hazards

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

[8] 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/dfe/alternatives_assessment_criteria_for_hazard_eval.pdf

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

10.1 Step 1 – Determine Chemicals to Assess

10.1.1 Identify the parent chemical along with all feasible and relevant environmental transformation products. See Section 13.

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

10.2 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 weight of evidence approach may be used and the rationale behind the hazard level conclusion 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 (i.e., reviewing Specified Lists prior to conducting a toxicological review).

10.2.1 Step 2a – Conduct a Comprehensive Toxicological Review and Hazard Assessment

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 Material Safety Data Sheets may be used for Flammability and Reactivity when there are no other options.

10.2.2 Step 2b – Review Specified Lists

1) When conducting a GreenScreen assessment, 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) GreenScreen Specified Lists are categorized as follows:

Table 4. Types of Specified Lists

List Type	Description	Possible Combinations
Authoritative Lists	Listing is based on a comprehensive expert review by a recognized authoritative body, and result in a classification with a higher level of confidence.	**Authoritative A***
		Authoritative B**
Screening Lists	Lists are identified as Screening Lists if they were developed using a less comprehensive review; or if they have been compiled by an organization that is not considered to be authoritative; or if they are developed using exclusively estimated data; or if the chemicals are listed because they have been selected for further review and/or testing, and result in a classification with a lower level of confidence.	**Screening A***
		Screening B**

** **A Lists:** Each category in the list translates directly to one of the following: 1) a single level of concern for a single GreenScreen hazard endpoint, or 2) a single benchmark*

*** **B Lists:** Lists that meet one or more of the following: 1) Each category in the list incorporates a single GreenScreen hazard endpoint and does not translate directly to a single level of concern or benchmark; AND/OR 2) Each category in the list refers to more than one GreenScreen hazard endpoint.*

10.2.3 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 is provided below in number 3 (a-g).

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 1 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) - www.epa.gov/opptintr/sf/tools/aim.htm (accessed 4/23/13)
   b. ChemIDplus database - http://chem.sis.nlm.nih.gov/chemidplus/documentation/help/chemidfs2webAdvanced.jsp (accessed 4/23/13)
   c. REACH dossiers (Registration, Evaluation Authorisation and restriction of Chemicals) - http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances (accessed 4/23/13)
   d. High Production Volume Information System (HPVIS) - www.epa.gov/hpvis/ (accessed 4/23/13)
   e. Organisation for Economic Co-operation and Development (OECD) Guidance on the Grouping of Chemicals. Series on Testing and Assessment, Number 80.[9]
   f. Environmental Protection Agency (EPA) chemical categories (from New Chemicals program) - www.epa.gov/oppt/newchems/ (accessed 4/23/13)
   g. Other Risk assessment/risk management regulatory or government docs

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

1) At a minimum, use 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 (http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm) – Software containing physical/chemical property and environmental fate estimation programs
   b. ECOSAR (http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm) – The Ecological Structure Activity Relationships (ECOSAR) Class Program estimates the

[9] http://www.oecd.org/env/ehs/testing/seriesontestingandassessmentpublicationsbynumber.htm

acute and chronic aquatic toxicity of industrial chemicals

c. ONCOLOGIC (www.epa.gov/oppt/sf/pubs/oncologic.htm) - *A computer program that estimates the carcinogenic potential of chemicals*
d. Additional models may also be useful and are beyond the minimum scope and may require additional cost (e.g., OECD Toolbox[10])

[10] http://www.oecd.org/env/ehs/risk-assessment/theoecdqsartoolbox.htm

11. PROCEDURE FOR CLASSIFYING HAZARDS

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

11.1.1 Use the Hazard Criteria resource 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. The following figure illustrates the Hazard Criteria for Carcinogenicity:

	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	Adequate data available, and negative studies, no structural alerts, and GHS not classified.
	A Lists	EPA-C (1986)	Authoritative		Group A, B1 or B2	Group C	Group E
		EPA-C (1996, 1999, 2005)	Authoritative		Known or Likely		Not Likely
		EU CMR (1)	Authoritative		Category 1 or 2	Category 3	
		EU CMR (2)	Authoritative		Carc 1A or 1B	Carc 2	
		EU H-statements	Authoritative		H350 or H350i	H351	
		EU R-phrases	Authoritative		R45 or R49	R40	
		EU SVHC	Authoritative		Reason for inclusion: Carcinogenic		
		IARC	Authoritative		Group 1 or 2A	Group 2B	Group 4
		MAK	Authoritative		Carcinogenic Group 1 or 2	Carcinogenic Group 3, 4, or 5	
		NIOSH-C	Authoritative		Occupational Cancer		
		NTP-RoC	Authoritative		Known or Reasonably Anticipated		
		Prop 65	Authoritative		Known to the state to cause cancer		
	B Lists	EPA-C(1986)	Authoritative		Group D		
		EPA-C (1999)	Authoritative		Suggestive Evidence, but not sufficient to assess human carcinogenic potential		
		EPA-C (2005)	Authoritative		Suggestive evidence of carcinogenic potential		
		IARC	Authoritative		Group 3		

Figure 2. Hazard Criteria for Carcinogenicity

11.2 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.

11.2.1 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).

11.2.2 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.

11.2.3 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 which 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) (Klimisch et al. 1997)[11]

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.

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

4) Toxicity tests evaluating a non-relevant pathway of exposure (e.g., intravenous, intraperitoneal injections.

5) If studies are truly inadequate based on expert judgment, then it may be preferable to classify the hazard endpoint as a Data Gap.

11.2.4 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, suitable analogs).

2) Authoritative A lists are preferred over Screening A or B or Authoritative B lists. When lists conflict, the most conservative of the authoritative results should be used.

3) A weight of evidence approach is used when data are conflicting.

11.3 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.

11.3.1 Assign a Data Gap (DG) classification to any hazard endpoints 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.

11.3.2 Use a blank if the endpoint has not been assessed or until all options for filling a data gap have been exhausted.

11.4 Step 6a – Document Findings and Conclusions

11.4.1 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 GreenScreen® v1.2 Assessment Template for the assessment report.

11.4.2 Reference all information sources.

11.4.3 Results from reviewing the Specified Lists – Indicate positive results. It is

assumed that all Specified Lists are searched unless indicated otherwise in the assessment report.

11.5 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 Benchmarks and assign a final Benchmark level.

11.5.1 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 Figure 3. A variation of this Hazard Summary Table may include hazard classification by route of exposure. (See GreenScreen Assessment Report Template.)

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

Abbreviations:

C = Carcinogenicity	SnR = Respiratory sensitization	SnS = Skin sensitization
M = Mutagenicity	IrS = Skin irritation	CA = Chronic aquatic toxicity
R = Reproductive Toxicity	IrE = Eye irritation	P = Persistence
D = Developmental Toxicity	AA = Acute aquatic toxicity	B = Bioaccumulation
E = Endocrine activity	ST = Systemic toxicity	Rx = Reactivity
AT = Acute mammalian toxicity	N = Neurotoxicity	F = Flammability

Figure 3. Example Hazard Summary Table

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

11.5.3 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.

11.5.4 The following color scheme is recommended for coloring 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

11.5.5 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.

12. PROCEDURE FOR APPLYING THE BENCHMARKS

12.1 Step 7 – Determine the relative Benchmark Score

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 12.2, 13 and 14 below for guidance).

12.1.1 **Benchmark 1**: Starting with 1a and moving to 1e, 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)

12.1.2 **Benchmark 2**: Starting with 2a and moving to 2g, 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 II or II* Human)
d. High B + Moderate T (Ecotoxicity or Group II or II* Human)
e. Moderate T (Group I Human)
f. Very High T (Ecotoxicity or Group II or II* Human) or High T (Ecotoxicity or II or Group II* Human)
g. High Flammability or High Reactivity

12.1.3 **Benchmark 3**: Starting with 3a and moving to 3d, 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

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

12.2 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:

12.2.1 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.

12.2.2 **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.[12]

12.2.3 **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).

[12] i. It is sufficient to classify flammability based on data in as few as one relevant sub-category (e.g., flammable liquid);
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 0 Data Gaps).	Data required for all 2 endpoints (max 0 Data Gaps).[13]

12.2.4 **Benchmark 4**: Data required for all 18 endpoints. To achieve Benchmark 4, the chemical must have sufficient data to assess all hazard endpoints (max 0 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).

[13] i. It is sufficient to classify flammability based on data in as few as one relevant sub-category (e.g., flammable liquid);
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.

13. 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 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.

13.1 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).

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

13.3 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.

13.3.1 **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 (i.e., 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.

13.3.2 **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 not likely to form persistent biodegradation intermediates and are therefore not considered relevant. This corresponds to meeting criteria for very Low Persistence in the 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.

13.3.3 **Step 3**. Screen transformation products that are BOTH feasible and relevant. For each feasible and relevant transformation product, determine whether a full GreenScreen assessment or a List Translator screen will be performed. A full GreenScreen assessment of feasible and relevant environmental transformation products is preferred but may not be practical for DRAFT assessments:

1) For DRAFT GreenScreen assessments, evaluate feasible and relevant transformation products using the List Translator[14].

2) For VERIFIED GreenScreen assessments, full GreenScreen assessment of feasible and relevant transformation products may be required.

3) Report results from screening the transformation products in the GreenScreen assessment report.

13.4 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.

13.4.1 Using results from full 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:

2) 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.

3) 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

[14] Full GreenScreen assessments of environmental transformation products are always preferred to assessments using the List Translator only.

environmental transformation products (e.g., Benchmark 2_{TP}).

13.4.2 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-U.

3) If the score of the transformation product is LT-U, then the score of the parent chemical is not modified.

14. 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:

14.1 **Step 1**. Report the following form and physical chemical properties of the inorganic chemical (See GreenScreen® Assessment Report Template).

1) Particle size (e.g., silica particles < 10 microns)
2) Structure (e.g., amorphous vs. crystalline)
3) Mobility (e.g., water solubility, volatility)
4) Bioavailability

14.2 **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.

14.3 **Step 3**. Classify hazards for the inorganic chemical and its feasible and relevant transformation products.

14.4 **Step 4**. Apply the Benchmarking process. For inorganic chemicals, persistence should not necessarily be considered a negative characteristic – particularly for naturally occurring minerals and metal oxides, etc.

14.4.1 Inorganic chemicals that are persistent and for which all hazard endpoints except Persistence are low may achieve Benchmark 4.

14.4.2 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.

15. REPORTING REQUIREMENTS

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

15.1 Licensed Profilers and Certified Practitioners shall be transparent in presenting assessment results, clearly communicating both data quality and data completeness.

15.2 The hazard classification summary provided within 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.

15.3 The summary results of a GreenScreen assessment should include:

15.3.1 A Benchmark (BM) 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.

15.3.2 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})

15.3.3 Where there are data gaps, it is recommended to include a worst-case scenario estimate, i.e. 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.

15.4 Use the reporting format shown in the example in Annex II and Annex III for reporting the benchmark score of a complex mixtures and polymeric materials.

16. MAKING INFORMED DECISIONS

16.1 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.

16.2 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. The GreenScreen provides a clear and transparent format for presenting what is known and what is not known about the hazards associated with chemicals.

16.3 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.

16.4 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.

16.5 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.

17. RECORDS

17.1 Licensed Profilers and Certified Practitioners shall keep all documents generated as a result of the implementation of these Procedures on file for the duration of the Licensing period and 5 years thereafter.

18. ANNEX I - GREENSCREEN LIST TRANSLATOR (LIST TRANSLATOR)

18.1 Assess and Classify Hazards

The GreenScreen List Translator (List Translator) maps GreenScreen Specified Lists to hazard classifications and assists in identifying Benchmark 1 and possible Benchmark 1 chemicals. All of the GreenScreen Specified Lists and their relationship to hazard classifications are identified in the GreenScreen hazard criteria. Additional resources include:

1) **List Translator Manual Version** – A spreadsheet that maps the hazard lists (and sub-lists) to hazard classification levels and provides List Translator scores. The List Translator Manual Version does not map specific chemicals to hazard classifications.

2) **Automated Tools** –The following software tools developed by independent Clean Production Action Software Partners may be used to search for specific chemicals and their hazard classifications based on the List Translator Manual Version

   a. Chemical and Material Library in Pharos by Healthy Building Network: http://www.pharosproject.net/

   b. GreenWERCS by The Wercs: http://www.thewercs.com/products-andservices/greenwercs

18.2 Apply the Benchmarks

The List Translator may be used as a first step toward a full GreenScreen assessment, to screen Transformation Products and Special Case Impurities, and as a stand-alone method to provide a preliminary assessment of a chemical. Results from a full GreenScreen assessment are more credible than results from List Translator only. When In doubt, apply the full GreenScreen method.

1) The hazard classification results for a List Translator screen support generation of GreenScreen Benchmark scores using the full GreenScreen method.

2) **Assessments based on List Translator only MUST use List Translator score nomenclature and not GreenScreen Benchmark nomenclature to communicate results.** Results are reported as LT-1, LT-P1 and LT-U. See Table A-1 for LT scoring nomenclature and GreenScreen Benchmark equivalencies.

3) Results reported at 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 LT-1 or LT-U.

18.3 The following table shows the List Translator scores and how they relate to GreenScreen Benchmarks:

Table A-1. List Translator Scoring Equivalencies

LT Score*	GreenScreen® Benchmark Equivalency	Derivation
LT-1	Benchmark 1	A LT-1 List Translator score reflects the presence of a chemical on Authoritative A list(s) for hazard classification(s) that are expected to result in a Benchmark 1 score using the full GreenScreen method.
LT-P1	Possible Benchmark 1	A LT-P1 List Translator score reflects the presence of a chemical on hazard lists that are Screening A, Screening B or Authoritative B for hazard endpoints that MAY result in a Benchmark 1 score. Further assessment using the full GreenScreen method is needed to determine if the chemical is a GreenScreen Benchmark 1 or not.
LT-U	Unspecified Benchmark	A LT-U List Translator score indicates that there is insufficient information to generate a GreenScreen Benchmark score. That can be a good sign. Typically, only hazardous chemicals are found on hazard lists. However, lack of presence on hazard lists can also mean that the chemical has not been well tested. A LT-U score is NOT the same as Benchmark U. A full GreenScreen assessment will need to be performed to determine if a chemical is a Benchmark 2, 3 or 4 or U.
** While authoritative lists are likely to generate definitive Benchmark scores, results from a full GreenScreen assessment **always** take precedence over results from the List Translator*		

19. ANNEX II – ASSESSING AND BENCHMARKING MIXTURES

The purpose of this guidance is to outline the process for assessing and benchmarking products that contains multiple chemicals, such as mixtures. Except as otherwise described in the following sections, individual chemicals in mixtures are subject to the same general assessment and benchmarking process described above in Sections 9-14.

19.1 Disclosure and Assessment Best Practice (Mixtures)

19.1.1 Identify each intentionally added chemical present at or above 0 ppm and each known impurity present at or above 100 ppm in the mixture.

19.1.2 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 GS assessment and report results; or

3) Ask the next supplier upstream to screen the ingredients and/or constituents of those ingredients using the GreenScreen List Translator and report the results; or

4) List all unknowns as "Not Reported" with concentrations in parent product.

19.1.3 Follow the procedure described in Sections 9-14 for each chemical identified.

19.2 Reporting Requirements (Mixtures)

19.2.1 Apply the general Reporting Requirements described in Section 15, 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, CAS number). 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.

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

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

Chemical	CAS	% by Weight	Benchmark	BM by %
Super Safe	64742-81-2	0.3	4	0.3
Solvent	125-45-5	95.0	3	95.0
Functional Additive	301-82-1	0.00001	2	2.7
Anti-oxidant	64742-89-8	1.4	2	
Processing Aid	67-64-1	1.3	2	
Preservative	502-12-4	2.0	1	2.0

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

Chemical	CAS	Concentration in final product ppm	GS LT Results	Reason for inclusion
BBT	XX-XX-X	20	LT-P1	Possible Benchmark 1
Preservative	XX-XX-X	75	LT-1	Benchmark 1

Figure A-1. Example Reporting Format for Mixtures

20. ANNEX III – ASSESSING AND BENCHMARKING POLYMERIC MATERIALS

Report and assess constituents of polymeric materials according **Table A-2** below:

Constituent of Polymeric Material	Definition	Reporting Requirement	Full GreenScreen Assessment	List Translator (LT) Screening (See Annex I)
Polymer	Chains of repeating units called monomers	Report the CAS# and concentration of the major constituent(s)	Required for each polymers 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 monomers and catalyst used to produce the polymeric material	1) Required for each monomers 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		

All Constituents intentionally added or impurities in a formula:

Chemical	CAS	% by Weight	Benchmark	BM by %
Processing Aid	64742-81-2	0.3	4	0.3
Polymer	125-45-5	95.0	3	95.0
Functional Additive	301-82-1	0.00001	2	2.7
Processing Aid	64742-89-8	1.4	2	
Processing Aid	67-64-1	1.3	2	
Monomer	502-12-4	2.0	1	2.0

Known and Special Case Impurities < 100 in the formula:

Chemical	CAS	Concentration in final product ppm	GS LT Results	Reason for inclusion
Monomer ABC	XX-XX-X	20	LT-P1	Possible Benchmark 1
Catalyst XYZ	XX-XX-X	75	LT-1	Benchmark 1

Figure A-2. Example Reporting Format for Polymeric Materials

21. ANNEX IV –BENCHMARKING CRITERIA

OCTOBER 2011 (v2)

GreenScreen™ for Safer Chemicals v 1.2 Benchmarks

Start at Benchmark 1 (red) and progress to Benchmark 4 (green)

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

This chemical passes all of the criteria.

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

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

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 4.

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

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 3.

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

If this chemical and its breakdown products pass all of these criteria, then move on to Benchmark 2.

BENCHMARK U
- Unspecified Due to Insufficient Data

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.

Note: The level of hazard indicated is the lowest hazard level at which a chemical would fail that criterion. However, if the chemical has a higher hazard level than what is listed (e.g. chemical is very High and the criterion is High), it would also fail that criterion.

* For inorganic chemicals with Low B, Low T (Ecotoxicity, Group I, II and II* Human) and Low Physical Hazards (Flammability and Reactivity), persistence alone will not be deemed problematic. Inorganic chemicals that are only persistent may achieve Benchmark 4.

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22. ANNEX V –BENCHMARKING CRITERIA WORKSHEET

Put a "no" in the box when the chemical passes a sub-criterion and a "yes" when it fails (i.e., meets) a sub-criterion. 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-3. Benchmark Worksheet

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

23. ANNEX VI – SOURCES FOR IDENTIFYING FEASIBLE AND RELEVANT TRANSFORMATION PRODUCTS

Table A-4. 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 there 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): i. Environmental Science & Technology ii. Environmental Toxicology and Chemistry (ET&C) iii. Environment International iv. Chemosphere v. Science of the Total Environment vi. Environmental Pollution vii. Journal of Environmental Monitoring
Published Risk Assessments	Those conducted by regulatory bodies such as the European Union (EU), Canadian Environmental Protection Agency (CEPA), Japans 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) –	Registered chemicals listed under European Chemical Agency (ECHA) –

REACH	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://umbbd.msi.umn.edu/predict/)
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)

24. ANNEX VII – WORKSHEET: 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-5. 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			