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## EXPOSURE ASSESSMENT METHODOLOGY REVISION HISTORY

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1 DOCUMENT OVERVIEW

1.1 PURPOSE AND CONTENT

The Cradle to Cradle Certified exposure assessment method is briefly described in the Cradle to Cradle Certified Material Health Assessment Methodology document. The purpose of this document is to clarify and further define how to complete an exposure assessment.

An exposure assessment is completed after hazard ratings have been assigned to individual endpoints. Once an exposure assessment is complete, risk flags, abc-x single chemical risk ratings, and ABC-X material assessment ratings may be assigned. The process for assigning hazard ratings, risk flags, abc-x single chemical risk ratings, and ABC-X material assessments are further described in the Cradle to Cradle Certified Material Health Assessment Methodology.

1.2 SUPPORTING DOCUMENTS

The following documents are to be used in conjunction with this document:

- Cradle to Cradle Certified™ Product Standard
- Cradle to Cradle Certified™ Material Health Assessment Methodology
- Any additional Cradle to Cradle Certified standard documents and methodology documents posted on the C2CPII website.

2 EXPOSURE ASSESSMENT OVERVIEW

2.1 A QUALITATIVE, NOT QUANTITATIVE APPROACH

Exposure to a chemical substance in conjunction with its inherent hazard properties will determine its effect on target organisms or target organs/tissues. In the Cradle to Cradle Certified Material Health Assessment and Exposure Assessment Methodologies, the likelihood of detrimental effects, or risk, is considered to be a function of intrinsic hazard and exposure. The Cradle to Cradle methodology differs from traditional exposure and risk assessment in that no attempt is made to quantify the amount of exposure that occurs.

2.2 SUMMARY OF METHODOLOGY

The exposure assessment for an individual chemical begins when the chemical has been associated with a particular material and product, and the chemical hazard profile has been completed. At this point, each hazard endpoint will have been assigned a GREEN, YELLOW, RED or GREY hazard rating. An exposure assessment is then completed separately for individual hazard endpoints.
An exposure assessment is primarily undertaken when RED or GREY hazard ratings for one or more endpoints have been assigned. Exposure assessment is optional in the case of a YELLOW or GREEN hazard rating. Therefore, for the remainder of these instructions it is assumed that only RED and GREY hazard ratings are under consideration.

If exposure is unlikely to occur, one or more RED or GREY hazard ratings can be assigned YELLOW risk flags. In order to assign a YELLOW risk flag to an endpoint with a RED or GREY hazard rating, it must be determined that relevant exposure is unlikely in all use cycle stages\(^1\), beginning with the final manufacturing stage. If there is uncertainty regarding whether or not exposure will occur, a precautionary approach is applied and exposure is assumed to occur.

Step 1 of the method addresses cases where exposure assessments are not required, either due to certain exceptions to the rules or because data gaps do not affect the single chemical risk rating. Step 2 explains how to incorporate exposure considerations when required. If, after Step 1 is complete, only YELLOW and GREEN hazard ratings remain for the chemical under consideration, then a single chemical risk rating of ‘c’ may be assigned and the exposure assessment is complete (i.e. it is not necessary to conduct Step 2).

It usually will not be necessary to go through every step of the exposure assessment process for each RED or GREY endpoint, depending on the specific chemical’s hazard profile, the material it is in, and product context. This is because a single RED risk flag leads to an x single chemical risk rating, thus obviating the need for further assessment. If a definitive abc-x rating can be derived for a substance following any subset of the rules below for any number of endpoints, the remainder of the rules and/or endpoints need not be evaluated. In addition, the Cradle to Cradle Mixture Rules should be consulted as they may influence whether or not an exposure assessment is required.

2.3 SPECIAL CONSIDERATIONS: TOXICITY TESTING OF MIXTURES

In some cases, toxicity testing may have been performed on an entire homogeneous material or formulation. If such testing makes it possible to assign a GREEN or YELLOW hazard rating to one or more endpoints for a homogeneous material, this may be used in place of toxicity data and associated hazard ratings for individual chemicals within the material or formulation. In this case an exposure assessment would not be required for the relevant endpoints of the individual chemicals. Instead, if relevant RED hazard ratings are identified for the homogeneous material, an exposure assessment should be undertaken for the homogeneous material. Tests that are sometimes available for homogeneous materials or formulations are those relevant to the Sensitization of Skin and Airways, aquatic toxicity (Fish Toxicity, Daphnia Toxicity and Algae Toxicity), and acute toxicity (Oral Toxicity) endpoints.

\(^1\) All use cycle stages = final manufacturing, installation, use, and end of use (e.g., recycling, incineration, backyard burning and/or landfill). Commonly known as life-cycle stages.
2.4 MAINTAINING CONSISTENCY

For the purposes of Cradle to Cradle certification and the Cradle to Cradle Material Health Certificate Program, exposure assessments are conducted by Cradle to Cradle Products Innovation Institute (C2CPII) accredited material health assessment bodies, who have expertise in the areas of chemistry and toxicology. Assessors are required to follow the methodology described in this document when carrying out an exposure assessment to ensure consistency among Material Health assessments.

This methodology aligns with current Cradle to Cradle Certified exposure assessment practices and covers common chemicals, materials, and product types. However, new and/or uncommon chemicals and materials, or unique exposure scenarios, may occasionally need to be assessed. In addition, the availability of new information, data, and/or techniques may result in the need for altered methods. Therefore, assessors must use their expert knowledge and critical thinking when completing each exposure assessment to ensure that a precautionary approach is always taken. In the case that an assessor finds that the method below would result in a less than precautionary outcome, or believes that these rules do not result in the correct assessment rating, that assessor is required to notify C2CPII so that the best approach can be determined and consistency can be maintained. Assessors may use alternative exposure assessment methods only upon discussion with and pre-approval from C2CPII.

3 EXPOSURE ASSESSMENT METHODOLOGY

3.1 STEP 1: IDENTIFY ENDPOINTS AND SPECIFIC ROUTES OF EXPOSURE WITHIN ENDPOINTS THAT DO NOT REQUIRE AN EXPOSURE ASSESSMENT

The Outcome of Step 1:
- If Step 1A requires that a RED risk flag and x single chemical risk rating be assigned to any endpoint, the homogeneous material will be X assessed.
- If Step 1A does not require that a RED risk flag be assigned to any endpoint, and any GREY hazard ratings are due to data gaps that do not affect the single chemical risk rating as described in Steps 1A and 2A, then the single chemical risk rating will be ‘c’ and the homogeneous material will be C assessed.
- For all other endpoints that are still assigned either RED or GREY hazard ratings after Step 1 is complete, follow the methodology outlined in Step 2.
3.1.1 Step 1A: Exclude endpoints for which there are exceptions to the rules

1. Chemicals of regulatory concern,\(^2\) are always assigned risk flags equal to their hazard ratings. Therefore, an exposure assessment is not necessary in these cases. The relevant regulatory conditions including thresholds apply. An exposure assessment may be completed when these substances are used in non-regulated applications or below the relevant threshold.\(^3\)

2. Substances with a RED hazard rating for Persistence and Bioaccumulation as well as a RED hazard rating for toxicity of any type (i.e. any endpoint) will always be assessed. This is because persistence and bioaccumulation enhance the exposure potential. For such substances, it is assumed that exposure will eventually occur. (However, see the special conditions for metals listed in point #5 below which take precedence.)

3. The exposure assessment does not need to be completed for the following endpoints when they have been assigned GREY hazard ratings: Carcinogenicity, Endocrine Disruption, Neurotoxicity and Terrestrial Toxicity. This is because a GREY hazard rating for these endpoints does not affect the single chemical risk rating.

4. There are several additional cases for certain material types where GREY hazard ratings do not affect the single chemical risk rating. These materials are covered by specific guidelines. Currently they include pigments, which are assessed according to the Colorants Assessment Methodology, and certain biological and geological materials, as outlined in the Biological Materials Assessment Methodology and the Geological Materials Assessment Methodology. Please see the most recent versions of those documents for further information.

5. If a RED hazard rating has been assigned to the Climatic Relevance, Organohalogen, or Toxic Metals endpoints, the chemical will be assessed, unless one of the exceptions for Toxic Metals listed below applies, given the material/product context. In these cases, all endpoints with RED or GREY hazard ratings related to the metal in question may be assigned a YELLOW risk flag and the material may be C assessed (assuming no other RED or GREY risk flags are present for other chemicals in the material) as

\(^2\) Per Standard version 3.1, a chemical of regulatory concern is defined as any chemical currently restricted under REACH Annex XVII (see the conditions listed by REACH; e.g. at the time of writing this document, all category 1 & 2 CMRs were of “regulatory concern” when used in "mixtures intended for supply to the general public" i.e. formulated consumer products) on the REACH candidate list for Substances of Very High Concern (SVHC), or on the POPs list of the Stockholm Convention. This set of lists is subject to change. The most current version of the lists or regulations is to be used at the time of the Material Health assessment is being conducted.

\(^3\) Rationale: This approach is taken for several reasons: Prior to inclusion in the regulatory lists indicated, some consideration of exposure and risk has already occurred. In addition, this approach will ensure that chemicals or materials that cannot be sold into the EU will not be Cradle to Cradle C or B-assessed or allowed in Gold certified products. The approach also ensures that manufacturers participating in the program are made aware of the chemicals of regulatory concern within their products and are encouraged to work on phasing these chemicals out.

\(^4\) Note: Organohalogenes and the toxic metals lead, cadmium, mercury and hexavalent chromium are subject to review at any level. However, a material will always be X assessed only if these substances are present ≥100 ppm. Lower thresholds apply for these Toxic Metals in biological nutrients (2ppm Cd, 90ppm Pb, 100 ppm Cr+6, 1ppm Hg).
long as the answers to the final manufacturing stage questions in Step 2, when relevant to handling of the material in question, are YES.

Cases for which a RED hazard rating for Toxic Metals may not lead to an X assessment:

a. The toxic metal is used in a colorant and it is in a stable crystalline form exhibiting low toxicity (e.g. spinel and rutile forms). See the Colorants Assessment Methodology for further information.

b. The toxic metal is fused within glass. The metal is not present at ≥ 100 ppm in the crystalline form (i.e. it is not in the form of a salt, for example a metal oxide or metal sulfate) but is present only in the ionic form and is bound within the silicate glass structure. Leaching tests are required to demonstrate non-detectable migration unless studies clearly support lack of migration and subsequent exposure concerns for the product type under consideration (e.g. testing would be required for leaded glass in food contact).

c. The toxic metal is lead contaminating a metal alloy (e.g. A380) due to use of recycled content. In this case the thresholds for lead are aligned with the RoHS thresholds when answers to Step 3 use stage questions 3a and 3b (Oral) are YES. The RoHS threshold for lead in aluminum is 0.4% at time of publication. This threshold may be lowered to 0.1% in the future. The RoHS threshold for lead in steel is 0.35%. This threshold will be applied to all metal alloys other than aluminum. Therefore, at the time of publication, if the conditions within point c are met, lead may be present in aluminum at ≤ 0.4% and in other metals at ≤ 0.35% and the metal may be C assessed.\(^5\) If lead is intentionally added to improve machinability of aluminum, steel, or brass, the 0.01% (100 ppm) threshold applies and the metal must be X assessed (but also see point e below). Note that standard composition information for some metal alloys does not always list percentage lead content even though lead may be present. If lead is not listed, the assessor is expected to communicate with suppliers and/or obtain information from the relevant metal industry group or producer regarding typical lead content for the alloy under consideration to ensure that full material disclosure has been obtained prior to assigning a C assessment.

d. The toxic metal is nickel within a steel alloy and it does not come into contact with human skin as a part of the product’s intended use. If it is intended to come into prolonged or repeated contact with human skin during the product’s use, it is given a RED risk flag for Sensitization of Skin and Airways and the Toxic Metals endpoints and the steel will be X assessed, unless the nickel release rate is shown to be below 0.5 µg/cm\(^2\)/week or below 0.2 µg/cm\(^2\)/week for parts of products inserted into pierced ears and other pierced parts of the human body, or in direct

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\(^5\) Notes: Currently, the prior RoHS exemption for lead in aluminum has expired but will most likely be extended. The allowance is 0.4% but could eventually be lowered to 0.1%. RoHS Exemption FAQ (accessed May 17, 2017) per The Aluminum Association. Lead in aluminum threshold for children’s products in the US is 300 ppm (100 ppm for other materials used in children’s products). See: Petition Requesting Exception from the Lead Content Limits, 2011 AND Technological Feasibility of 100 ppm for Lead Content, 2011, AND Final Decision. EU Directive relevant to children’s products/toys that may be mouthed sets limit at 0.05% lead by weight: Commission Regulation (EU) 2015/628.
contact with skin as determined via leaching tests on the material in accordance with the standards adopted by the European Committee for Standardization.\textsuperscript{6}

e. Note that theoretically there is also the potential for materials containing toxic metals to be assessed in the case that a recycling system under the control of the manufacturer is fully functioning, taking back 80% or more of products sold, and exposure is unlikely in the other use cycle stages based on the assessment process below. However, a situation such as this has not yet been identified.

3.1.2 Step 1B: Exclude endpoints and specific routes of exposure within endpoints based on physico-chemical properties

1. Data gaps are to be ignored for any route-specific endpoint, or individual routes of exposure within endpoints, that are deemed scientifically unjustified (i.e. exposure is unlikely or of low concern) based on the physico-chemical properties listed below.\textsuperscript{7} However, if there are data indicating a hazard through a given route of exposure, it must be considered and the exposure assessment conducted, even if that route of exposure could be excluded based on these properties.

The following is a list of default situations by exposure route in which data gaps are to be ignored because exposure is unlikely or of low concern. Consider the temperature thresholds below in the context of the temperatures expected to occur during all use cycle stages including likely unintended use, cutting of materials during installation, etc. to ensure unlikely exposure. If extreme conditions are expected to occur, it may be necessary to alter these default assumptions (for example some home ovens can reach 500°F/260°C).

a. Oral exposure is of low concern when consumption or absorption are unlikely.
   i. Consumption is unlikely when the chemical is highly volatile (defined as boiling point less than 0°C).\textsuperscript{8}
   ii. Absorption is unlikely when molecular weight is greater than 1000 g/mol\textsuperscript{9} and the molecule is known not to undergo hydrolysis or cleave under acidic conditions (e.g. starch has a molecular weight much greater than 1000 but is absorbed once ingested).
   iii. Absorption is unlikely when the substance meets at least three of the following conditions\textsuperscript{10}:

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\textsuperscript{6} As of the time of writing the applicable test methods are EN 1811, and if nickel-containing alloy is coated additionally EN 12472. EN 16128 is to be used for glasses. Any future applicable test methods that may be released by the European Committee for Standardization for nickel leaching tests are also to be used.

\textsuperscript{7} Note: This point is tied both to whether or not toxicity data need to be collected for specific endpoints, as well as to whether or not certain routes of exposure need to be considered when completing Step 2. For example, \textit{Mutagenicity} and \textit{Endocrine Disruption} tests typically do not provide information regarding route of exposure. For this reason, it will be useful to determine if some routes are of low concern prior to completing Step 2. On the other hand, if inhalation exposure is deemed of low concern due to the boiling point, data would not be required for the \textit{Inhalation Toxicity} endpoint when completing the chemical profile (i.e. a GREY hazard rating would not affect the overall abc-x rating).


\textsuperscript{9} \textit{Hazardous Substances in Plastic Materials}, Danish Technological Institute, 2013.
1. Molecular weight is greater than 500 g/mol
2. The octanol-water partition coefficient (log Kow) is greater than 5
3. The substance has more than 5 hydrogen bond donors (defined as the total number of nitrogen-hydrogen and oxygen-hydrogen bonds)
4. The substance has more than 10 hydrogen bond acceptors (defined as all nitrogen and oxygen atoms)

b. Dermal exposure (i.e. dermal absorption) is of low concern when:
   i. Molecular weight is greater than 1000 g/mol\textsuperscript{11,12,13} OR;
   ii. Molecular weight is greater than 500 g/mol AND the log Kow is greater than 4.\textsuperscript{14}

c. Inhalation exposure to volatiles is of low concern when:
   i. Boiling point is greater than 240°C,\textsuperscript{15} OR;
   ii. Vapor pressure is less than 10^{-6} mm Hg AND boiling point is greater than 400°C.\textsuperscript{16}

d. Inhalation exposure to particulates and aerosols is of low concern when the aerodynamic diameter is greater than 100 µm.\textsuperscript{17}

e. Aquatic toxicity is of low concern when solubility is less than 0.001 mg/l.\textsuperscript{18} The combined aquatic risk flag and associated instructions further define situations in which exposure to the aquatic environment is of low concern. At higher solubilities, a comparison between the solubility level and toxic concentrations can be made, as explained in the Aquatic Toxicity section of the Material Health Assessment Methodology (see paragraph on \textit{Poorly Soluble Substances}).

\textsuperscript{10} Note: This is Lipinski’s rule of 5. There are many references available on this topic.
\textsuperscript{12} “Generally the smaller the molecule the more easily it may be absorbed. Molecular weights below 500 are favorable for absorption; molecular weights above 1000 do not favor absorption.” Source: Guidance for Human Health Risk Assessment (Biocides), ECHA, 2013.
\textsuperscript{13} This reference states that “...a rule of thumb on dermal absorption used in the EPA/OEPR New Chemical Program assumes 10% dermal absorption (multiply exposure value by 0.1) for chemicals with MW > 500 AND log Kow <-1 or >4 and assume 100% dermal absorption for all other chemicals.” Interpretive Assistance Document for Assessment of Discrete Organic Chemicals, Sustainable Futures Summary Assessment, US EPA, June 2013 (accessed May 17, 2017)
\textsuperscript{14} per conversations with the American Chemistry Council (ACC) referencing EPA Sustainable Futures, OECD, and ECHA. Also, based on unpublished work by the ACC that compared these properties between two groups of substances (one group of high concern and another group of low concern).
\textsuperscript{16} per the American Chemistry Council (ACC) referencing EPA Sustainable Futures (2013) and the U.S. EPA higher limit for the definition of semi-volatile
\textsuperscript{17} Threshold Limit Values for Chemical Substances and Physical Agents, ACGIH, 1993.
\textsuperscript{18} Flame Retardants in Printed Circuit Boards, US EPA, August 2015 and references therein.
3.2  STEP 2: DETERMINE IF PROCESSES AND PRODUCT ARE DESIGNED TO PREVENT EXPOSURE

How to apply Step 2:
- If considering a RED or GREY hazard for an environmental health (EH) endpoint, then the questions below marked for EH are to be asked. If considering a RED or GREY hazard for a human health (HH) endpoint, then the questions marked for both HH and EH are to be asked.
- Only those routes of exposure that are possibly relevant to the endpoint in question (as determined in Step 1) need to be considered. In the case that some endpoints and routes of exposure within endpoints were not excluded (i.e. determined to be unlikely/low concern) within Step 1, then the following must be assumed to be possibly relevant when beginning Step 2: Oral exposure, dermal exposure, exposure via inhalation, and exposure to the environment (i.e. release to air/water/soil). These routes of exposure are possibly relevant to all endpoints except where the endpoint, by definition, applies only to certain exposure routes (e.g. for Oral Toxicity the oral and environmental exposure routes are to be considered possibly relevant when beginning Step 2).
- Note that in some cases where the assessment process below would result in a RED risk flag, it would be possible for the assessor and applicant to follow up by having specific tests completed to show that the chemical of concern is removed, degraded, or not migrating, leaching, or washing out, etc. above thresholds of concern (e.g. if it is shown that a textile produced using a sensitizing dye is not in itself sensitizing). However, specific testing methods and thresholds that would be required and acceptable for Cradle to Cradle Certified have not yet been developed. Appropriate tests would need to be approved by C2CPII at which point they would be added to this document. This note has been inserted within the methodology as a holding place and to indicate that this approach will be further developed in the future.

The outcome of Step 2:
- In the case of a RED risk flag resulting from a RED risk in one or more use cycle stages, the single chemical risk rating will be ‘x’ and the homogeneous material will be X assessed. In the case of a GREY risk flag, the single chemical risk rating will depend on whether or not there are any RED risk flags for other endpoints. If not, the rating will be GREY.
- In the case that exposure is unlikely in all use cycle stages, a YELLOW risk flag may be assigned to the endpoint in question. When all endpoints for the chemical in question receive YELLOW or GREEN risk flags, the single chemical risk rating will be ‘c’ or ‘b’, respectively.

3.2.1 Final Manufacture
The final manufacturing stage includes the processes defined by the Cradle to Cradle Methodology for Applying the Final Manufacturing Stage Requirements. A site visit is required at the final manufacturing stage facility or facilities to verify answers to the questions below.

19 Refer to the Cradle to Cradle Colorants (Textile Dyestuffs and Pigments) Assessment Methodology.
Answers to all relevant questions must be **YES** in order to assign a YELLOW risk flag for this stage (unless considering an endpoint that may be GREY without affecting the single chemical risk rating as mentioned in Step 1). If the answers are **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for installation and maintenance, use and end-of-use).

### a. HH: Are effective administrative or engineering controls\(^{20}\) in place and/or is sufficient personal protective equipment (PPE) in use?
Assessor to consider EU & US OSHA requirements for the relevant industry, OSHA compliance, and Safety Data Sheet (SDS) indications when determining what, where, and how PPE should be used. If the manufacturer is located in a country with well-developed and enforced worker health and safety regulations\(^{21}\) and the manufacturer has not had any OSHA violations or similar (depending on region) in the last two years relevant to chemical toxicity, then it may be assumed, at the assessor’s discretion and upon consideration during the site visit, that sufficient PPE is in use. If insufficient controls or PPE are used, assign a risk flag equal to the hazard rating (i.e. if the hazard rating is RED or GREY, the risk flag will also be RED or GREY).

### b. HH & EH: Are sufficient controls in place to keep the chemical out of environmental media (air/water/soil)?
Assessor to consider Best Available Techniques (BATs)\(^{22}\) for the industry in question and adherence to these techniques in determining if sufficient controls are in place. However, release to the environment and subsequent human and environmental exposure (e.g. via ground or surface water) is deemed likely in cases where the effluent used in product manufacture leaves the facility (i.e. process water is not kept flowing in a closed loop) unless one or more of the following is true:

i. Testing using appropriate analytical methods and detection levels for the contaminant in question has shown that the chemical with the RED or GREY hazard rating is not present in effluent\(^{23}\);

ii. Water only comes into contact with the product at a point when the chemical with a RED or GREY hazard rating is unavailable for release (i.e. it is reacted into the material matrix as described below in use stage question 3a);

iii. The chemical's hazard rating for **Persistence** is GREEN or, in the case of the aquatic toxicity endpoints (fish, daphnia, algae), the combined aquatic toxicity flag is YELLOW (i.e. Persistence and Bioaccumulation are both GREEN when the aquatic toxicity hazard rating and risk rating are RED or GREY).

### 3.2.2 Installation and Maintenance
This stage is not applicable if there is no installation or maintenance stage aside from operations typically completed by the end user.

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\(^{20}\) **Definition of administrative and engineering controls** per the Center for Disease Control.

\(^{21}\) Countries currently assumed to have well-developed and enforced worker health and safety regulations are countries within the EU, Switzerland, United Kingdom, United States, Canada and Japan. Note: This list may be extended in the future.

\(^{22}\) Link to **Best Available Techniques** documents (EU).

\(^{23}\) Note: Appropriate analytical methods and detection limits have not been defined yet for Cradle to Cradle Certified.
Answers to all relevant questions must be **YES** in order to assign a YELLOW risk flag for this stage (unless considering an endpoint that may be GREY without affecting the single chemical risk rating as mentioned in Step 1). If the answer is **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for use and end-of-use).

**a. HH: Is sufficient personal protective equipment (PPE) in use?** Assessor to consider SDS indications and the manufacturer’s installation and maintenance instructions to determine if PPE is necessary. If PPE is necessary to avoid exposure during installation and maintenance, sufficient use of PPE may only be assumed if a product is installed and maintained by professional installers/contractors trained by the manufacturer or entity contracted by the manufacturer on use of appropriate PPE. Otherwise, the answer to this question is NO.

**b. HH & EH: Are sufficient controls in place to keep the chemical out of environmental media (air/water/soil)?** Controls are necessary in order to avoid release to the environment when chemicals are known to be released to air, water, or soil in solution or in aerosol or particulate form (with particles of less than 1 millimeter in size, i.e. in the micrometer range or less). If use of controls is necessary to avoid release to the environment during installation or maintenance, sufficient use of controls may only be assumed if a product is installed and maintained by professional installers/contractors trained by the manufacturer or entity contracted by the manufacturer on use of appropriate controls. Otherwise, the answer to this question is NO. Note that all wet applied and sprayed on products must be assumed to come into contact with the environment during installation.

### 3.2.3 Use

The use stage is not applicable to the assessment of process chemicals that are not present in the final product.

The use stage includes likely unintended use and installation, maintenance, and disassembly for recycling if completed by the product user.

The answer must be **YES** to one of the following (a-c) in order to assign a YELLOW risk flag for this stage. If the answers are all **NO** or unsure, assign a RED or GREY risk flag as appropriate. If a RED or GREY risk flag is assigned for this stage, the exposure assessment is complete (i.e. there is no need to continue to the questions for end-of-use).

**a. HH & EH: Is the chemical reacted into the material in both new and old/worn/damaged product such that exposure is not likely to occur?** The answer to this question will be **YES**, when the chemical is:

i. Bound to or encapsulated by the material matrix (e.g. titanium dioxide and carbon black as polymer fillers/pigments, other inorganic pigments within polymers, polymer crosslinkers, and colorants fused within a glass matrix). This includes the molecules of the matrix itself, as in the case of solid plastics and other substances with molecules of diameter greater than 950 µm.24

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ii. A polymer additive with molecular weight greater than 1000 g/mol. For example, flame retardants and plasticizers with molecular weights greater than 1000 may be considered bound by the polymer. Substances with low molecular weights including residual monomers, some oligomers (e.g. styrene trimers and dimers), some additive flame retardants, residual solvents, and substances that are known to degrade to substances with molecular weights less than 1000 once incorporated into a polymer cannot be assumed to remain within the polymer matrix.

Certain conditions may affect whether or not a substance remains bound within a material. When exposure to such conditions will occur regularly during use, the effect on the integrity of the material as the product ages must be considered. Conditions to consider in the context of the questions above include, but are not limited to, exposure to extreme temperatures, acidic to basic pH, ultraviolet (UV) light, solvents (including environmental solutions such as rain water, sweat, etc.), irradiation (microwave, x-ray, and others), air pollution, and mechanical forces/abrasion. These conditions may cause corrosion, break chemical bonds, and result in the release of chemicals or particles that were previously bound within the material. If the material will regularly be exposed to one or more of these conditions, it must be assumed that the chemical with a RED or GREY hazard rating will be released from the material and made available for exposure to occur, unless it can be determined, based on published research, that this will not be the case. “Regularly” is defined as a standard part of the product’s intended or likely unintended use. For example, outdoor use products will regularly be exposed to UV. Watches and jewelry will regularly be exposed to human sweat. Tires, brake pads, and shoe soles are regularly exposed to friction and subsequently abrade.

b. Is the product installed or used in such a way that plausible exposure for all relevant exposure routes is ruled out? The answers must be YES to all questions below pertaining to all relevant exposure route(s) in order to assign a YELLOW risk flag for the use stage based on question b.

i. **HH - Oral: Will the product or part of product be unavailable for oral contact to occur during use?** For example, it is installed out of reach (by an installation professional using PPE if necessary per use stage question #2) such as within a wall or it is within an assembly that cannot be disassembled using common household tools, OR all of the following conditions are met:
   1. The product will not be marketed to/for children (mouthing is assumed to occur in the case of children's products).
   2. The product is not meant to be used on/applied to/in contact with the skin during use. (i.e. oral exposure is assumed to occur for the following and similar product types: cosmetics, washing soap, toothbrush, facial tissue, bedding, clothing, etc.).
   3. The product will not be used to prepare, hold, or serve food or come into contact with food by some other means (i.e. oral exposure is assumed to occur for the following and similar product types: kitchen counter, table top, desk top, dish detergent, etc.).
   4. The product is not a liquid for use in or around the home (the assumption is that children or others may accidently drink such liquids).
   5. The product is not intended to be hand-held or used as an arts and craft supply (some users will commonly chew on hand-held devices such as pens or paint brushes, even if they are not intended to be used in such a way).
ii. **HH - Dermal:** Will the product or part of product be unavailable for dermal contact to occur during use? For example, it is installed out of reach (by an installation professional using PPE if necessary per use stage question #2) such as on a ceiling, or within a wall, is within an assembly that is not typically accessed by the user, or is enclosed by another material (e.g. foam within a polymer layer on an arm rest). If NO or unsure, and if chemical has a RED or GREY hazard rating for *Sensitization of Skin and Airways*, go to the next question below.

1. **HH - Dermal (sensitization of skin):** Will the product or part of product be used or installed such that repeated (i.e. once a month or more frequent) dermal contact is unlikely to occur?

iii. **HH - Inhalation/release of volatiles:** Will volatile chemicals be unavailable for contact to occur during use? The product is used exclusively outdoors. Definition of volatile for the purpose of this question: Boiling point is less than 240°C (the opposite of the threshold indicated in Step 1, point #5). Consider in the context of use stage temperatures.

OR, Has the product passed the Cradle to Cradle Certified VOC testing requirement?

iv. **HH & EH - Can contact of the product or part of product with the environment (air/water/soil) be excluded during use? OR, If environmental contact is expected, does the chemical degrade into a substance of low toxicity?** Environmental exposure during use and subsequent human exposure (e.g. via ground and surface water contamination) in the case of HH endpoints must be assumed for the following product types without GREEN hazard ratings for *Persistence*:

- Any liquid product (soaps, paints that will be applied by the final user/consumer, etc.),
- Personal care products,
- Textiles and clothing that may be washed in water,
- Products that will be used outdoors or are otherwise exposed to water and/or other environmental elements (e.g. tools, outdoor furniture, exterior building components),
- Products known to wear, abrade, and/or release particulates during regular use (e.g. brake pads, tires, shoe soles),
- Products commonly found in roadside litter (e.g. single use packaging including carry out bags)
- All volatiles.

For products types that are not listed, the default answer to this question is YES; lack of environmental exposure during use is assumed.

c. **HH & EH:** Is the product manufactured with a functional barrier that encloses the material containing the chemical, preventing migration/release of and contact with the chemical? In order to answer YES to this question, testing must have been performed under the range of use conditions identified (including old/damage/worn conditions and exposure to conditions listed in 3a if relevant) to ensure that this is the case. Examples: Foil or wax layers in food contact packaging or a sealed assembly that restricts release of dry graphite lubricant particles. Note: Test methods acceptable to Cradle to Cradle Certified are still to be determined and approved by C2CPII.
3.2.4 End-of-use

The answer must be YES to all of the questions below for all end-of-use scenarios accounting for 80% of products sold in order to assign a YELLOW risk flag for this stage. In cases of products that are just reaching the market, and will take several years until end of life is reached, a realistic forecast of % distribution would be admissible based on company take-back plans, waste management practices in the regions where the product is sold and recycled, and return rates for similar products. If unsure about the percentages of product or material that will be processed via the common end-of-use scenarios listed below, all end-of-use scenarios are to be considered (although compost only needs to be considered for Biological Nutrients). If any answers are NO or unsure, assign a RED or GREY risk flag as appropriate (also see exceptions for Toxic Metals listed in Step 1).

a. Landfill - HH & EH: Will the chemical remain in the material matrix and therefore remain in the landfill OR degrade into substance of low toxicity if released from landfill? Alternatively, is the dermal route of exposure the only route of concern?

   i. If the dermal route of exposure is the only route of concern, the default answer to this question is YES (i.e. skin contact and dermal exposure are not considered relevant to the landfill scenario).

   ii. If the hazard rating is GREY for Sensitization of Skin and Airways and/or for Skin, Eye, and Respiratory Corrosion/Irritation this will not affect the risk rating for the landfill scenario.

   iii. For chemicals within polymers or glass that were determined to be bound within the material matrix per use stage question 3a, the default answer to this question is YES. However, it may not be assumed that products with stable barriers maintain their integrity within a landfill (as in 3c).

   iv. All other chemicals and endpoints:

      1. When the hazard rating for Persistence is YELLOW or GREEN, the default answer to this question is YES.

      2. In all other cases, it is assumed that release to the environment (air/water/soil) occurs and subsequent human exposure may occur (e.g. via ground and surface water contamination resulting from landfill leaching).

b. Recycling - HH & EH: Is release of and exposure to the chemical unlikely during recycling?

   i. When recycling is done by the manufacturer or other known manufacturers: Ask the same questions that were posed for the final manufacturing stage in the recycling context.

   ii. When a well-developed recycling industry for the material in question exists that is outside the manufacturer’s control: Consider scientific studies and other publicly available information to determine if the chemical is of HH or EH concern during recycling. This may be done for the commonly recycled metals (aluminum, steel, copper), glass, and paper. If there is no information available regarding exposure to or fate of the chemical during recycling processes, or the evidence is insufficient to indicate low risk, a RED or GREY hazard rating will result in a RED or GREY risk flag. It cannot be assumed that sufficient PPE or controls on release to the environment

will be used by all recyclers if these would be necessary to prevent exposure due to the global nature of the scrap trading and recycling industry.\textsuperscript{26}

iii. When a recycling infrastructure is not well-developed and is also outside the manufacturer’s control (assumed for materials that are not listed above in point ii): It must be assumed that the material will be landfilled and/or incinerated. See the questions for those end of use scenarios in this case.

c. Compost - HH & EH (Biological Nutrients only): Does the chemical degrade or react into a substance of low toxicity in typical home or industrial (as relevant) composting conditions? Combined aquatic toxicity risk flags of RED or GREY are not altered (e.g. if the combined aquatic toxicity risk flag is RED, the single chemical risk rating will be RED for the composting scenario). For all other endpoints, when the chemical’s hazard rating for Persistence is GREEN, the default answer to this question is YES. In all other cases, it is assumed that release to the environment (air/water/soil) occurs and subsequent human exposure may occur (e.g. via ground and surface water contamination).

d. Incineration and backyard burning - HH & EH: Is the chemical free of organohalogens and toxic metals? This end-of-use scenario only concerns the Toxic Metals and Organohalogens endpoints (and no others). For these chemical classes, the hazard rating is equal to the risk rating due to the likely release of highly toxic substances during combustion. Therefore, a material containing an organohalogen or toxic metal that may end up being incinerated or burned will always be X assessed with several exceptions for the toxic metals as described in Step 1. Furthermore, this scenario must be considered likely for the toxic metals and organohalogens in all cases other than for the exceptions described in Step 1. In the case of the Step 1 exceptions the answer may be NO to this question and a YELLOW risk flag may be assigned to the Toxic Metals endpoint. Otherwise, if the answer to this question is NO, a RED risk flag must be assigned.

\textsuperscript{26} Locating and Estimating Air Emissions from Sources of Lead and Lead Compounds, US EPA, 1998. “Each processing step in the secondary aluminum industry is a potential source of lead emissions, which are generally emitted as PM. Lead emissions will be a small fraction of total particulate emissions and will vary with the lead content of the scrap.” AND Inhalation Exposure in Secondary Aluminium Smelting, Elsevier Science Ltd on behalf of British Occupational Hygiene Society, 2001 Heavy Metals in Waste, EU Commission, 2002. “Cadmium, lead and mercury may be present as contaminant in iron and steel scrap, making secondary steel production an important source of release of these metals to air. Chromium and to some extent lead is also used as alloy in steel. The heavy metals may as well be present in aluminium scrap, but compared to steel scrap the total turnover with aluminium scrap is small.”
4 DEFAULTS FOR COMMON CHEMICALS

This section provides examples of common chemicals used in consumer products, their context, and their typical assessment ratings:

1. The following substances are carcinogenic via inhalation. When incorporated into a polymer, exposure to these chemicals is assumed to be unlikely to occur in all use cycle stages. The polymer containing these substances may be C assessed.
   a. Titanium dioxide, CAS 13463-67-7
   b. Carbon black, CAS 1333-86-4 (Note: If there is potential exposure to PAHs, for example when carbon black containing PAHs is used in toys, this must be considered as part of the assessment as well per the Cradle to Cradle Certified Product Standard Version 3.1).
   c. Silica dust, crystalline, in the form of quartz or cristobalite, CAS 14808-60-7 (However, when the polymer itself is the subject of certification, and hence exposure may occur during the final manufacturing stage, exposure to these materials needs to be considered.)

2. Antimony trioxide: Antimony trioxide is typically present above 100 ppm in PET when used as the catalyst and is carcinogenic via all routes of exposure (oral, dermal, inhalation). PET-containing antimony trioxide will always be X assessed. Exposure is deemed likely during end-of-use when the polymer is burned or recycled (in particular if recycled for textile applications where antimony leaches from polymers during the dyeing and washing processes).

3. Aluminum alloy with intentionally added lead above 100 ppm (e.g. to improve machinability): Lead (CAS 7439-92-1) is a toxic metal with RED hazard ratings for Carcinogenicity, Endocrine Disruption, Reproductive Toxicity, Mutagenicity, Neurotoxicity, and combined aquatic toxicity (PBT). Aluminum is highly recycled. Release of lead to the environment during secondary aluminum processing does occur and is of concern (both particulates and volatilized lead are released per the US EPA and others). For this reason, lead that is intentionally added at 100 ppm or above will receive a RED risk flag for the Toxic Metals endpoint and the aluminum will be X assessed. Exception: See below.

4. Aluminum alloy containing recycled content: Some aluminum alloys (e.g. die cast aluminum A380) contain between 500 and 3,500 ppm lead. An exception to the 100 ppm threshold has been instituted in the case of aluminum and other metals containing recycled content. The reason for the exception is that it is not currently feasible in many cases to reduce the lead concentration below 100 ppm when recycled content is used. This is due to the lead content of the recycled material. The threshold in this case aligns with RoHS (0.4% at time of publication; likely to be lowered to 0.1% or 1000 ppm in the future for aluminum). The higher threshold may only be applied in the case that:
   a. Sufficient PPE and controls on environmental release are used during the manufacturing stage.

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27 Aluminum Alloys for die casting according to the Japanese Standards (accessed on March 15, 2017).
b. The material/product meets the requirements listed in use stage question 3a and 3b (i.e. it will not regularly be exposed to conditions resulting in release of the lead AND it is not a product marketed to children, used to cook food, etc.).

If the material meets the requirements above, it may be C-assessed when lead is present at 100-4000 ppm.

5. Steel alloy containing nickel. Nickel (CAS 7440-02-0) is a toxic metal with RED hazard ratings for Carcinogenicity (with some conflicting data), Oral, Dermal, and Inhalation Toxicity, Sensitization of Skin and Airways and combined aquatic toxicity. Nickel is bound within the steel alloy such that exposure via any route, as well as release to the environment during the use stage, is unlikely. It is assumed that sufficient PPE is in use during manufacturing. In addition, steel is highly recycled and nickel is unlikely to be released to the environment in concentrations of concern in the end-of-use stage. The steel alloy may in this case receive a C assessment. However, if the steel alloy will be in dermal contact as part of its intended use, sensitization may occur. Exposure to human sweat may result in release of nickel ions and subsequent dermal absorption. Therefore, for products that will be in contact with human skin (and presumably sweat) during their intended use, nickel will receive a RED risk flag for Sensitization of Skin and Airways and Toxic Metals and the alloy will be X assessed (and may be further restricted under v4 as per the current Restricted Substances List (RSL) draft). See Step 1 for additional information.