



CHEMFORWARD GUIDANCE: CRADLE TO CRADLE CERTIFIED CHEMICAL RATINGS v 1.2



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C2CC Chemical Ratings

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### Resources

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<u>C2CC Exposure Assessment Methodology</u> <u>C2CC Material Health Assessment Methodology</u>

C2CC v3 banned list PDF download C2CC v4 draft RSL PDF download



### Introduction

The Cradle to Cradle Certified (C2CC) Material Health Methodology was developed to assign ratings to individual chemicals and homogeneous materials that are subject to further review as part of the C2CC certification process. C2CC Chemical Ratings are hazard-based ratings and do not represent the full C2CC Material Health Methodology. C2CC Chemical Ratings do not not consider product use and associated exposure as is done in the full C2CC Material Health Methodology.

This is the first time that C2CC Chemical Ratings have been used as a stand-alone hazard scoring method. While it is possible to tease out the C2CC Chemical Rating method from the full C2CC Material Health Methodology, Chem*FORWARD* has prepared this concise, step-by-step document with associated flow charts to illustrate exactly how C2CC Chemical Ratings are assigned.

These individual C2CC Chemical Ratings are useful in informing chemical suppliers and product manufacturers about the hazard profiles of the chemicals used in products. Chem*FORWARD* is committed to creating a database of chemical hazard assessments of safer alternative chemicals. We believe that C2CC Chemical Ratings for safer alternative chemicals will expedite green formulation, safe and circular product design, and meaningful product certification, including C2CC product certification.

# Step 1. Assign hazards to each endpoint

### C2CC reference: Material Health, Section 3

For the purposes of the C2CC Chemical Rating, it can be helpful to divide endpoints into three classes, as each class is treated slightly differently. For endpoints in the third class (subdivided by exposure route), the highest hazard from any route is assigned as the overall hazard, ordered red>yellow>green>grey. In other words, any hazard level, including green, will take precedence over a GREY (data gap). If carcinogenicity has green oral, yellow dermal, and grey inhalation, the overall endpoint hazard would be yellow.

- 1. Endpoints that are not explicitly evaluated through exposure routes
  - a. Mutagenicity
  - b. Endocrine Disruption
  - c. Persistence & Biodegradation
  - d. Bioaccumulation
  - e. Climatic Relevance
  - f. Terrestrial Toxicity
  - g. Other (Human Health & Physical Properties)



- h. Organohalogens
- i. Toxic Metals
- j. Other (Environmental Health)
- 2. Endpoints that are defined by a single exposure route/species
  - a. Oral Toxicity
  - b. Dermal Toxicity
  - c. Inhalation Toxicity
  - d. Algae Toxicity
  - e. Daphnia Toxicity
  - f. Fish Toxicity
- 3. Endpoints subdivided by exposure route
  - a. Carcinogenicity
    - O, D, I
  - b. Reproductive & Developmental Toxicity
    - O, D, I
  - c. Neurotoxicity
    - O, D, I
  - d. Corrosion/Irritation
    - D, I
  - e. Sensitization of Skin and Airways

■ D, I

These classes will be referenced again below as part of calculating risk flags.

# Step 2. Assign C2CC Chemical Ratings that don't depend on exposure / risk flags

C2CC reference: Exposure Assessment, Section 3.1.1 (Step 1A: 1, 2, and 5) Check substances against the following criteria in the order listed, stopping if one of the criteria is met.

### 1. Substances on the banned list receive a 'banned' C2CC Chemical Rating.

If a substance is on the <u>v3 Cradle to Cradle Certified™ Banned List of Chemicals</u> it gets a special 'banned' C2CC Chemical Rating that overrides any other C2CC Chemical Rating.

### 2. Toxic metals receive an x\*-CMR C2CC Chemical Rating.

If a substance has a RED hazard rating for the toxic metal endpoint, assign an x\*-CMR C2CC Chemical Rating to the chemical. The \* should link to a footnote or mouseover text that identified the substance as a toxic metal and links to the conditions under which its use may be



deemed acceptable (see Exposure Assessment Methodology Step 1A: 5. a-f). Note: the  $x^*$ -CMR C2CC Chemical Rating takes precedence over the x-PBT C2CC Chemical Rating.

# 3. Chemicals of "regulatory concern" that haven't already received a 'banned' C2CC Chemical Rating receive an x or x-CMR C2CC Chemical Rating.

Per Standard version 3.1, a chemical of regulatory concern is defined as any chemical

- currently restricted under <u>REACH Annex XVII</u> (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 <u>REACH Authorization list for Substances of Very High Concern</u> (SVHC)
- on the <u>POPs list of the Stockholm Convention</u>

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. Free online databases such as <u>Pharos</u> can make it easier to check if a chemical is on one of these lists. To use Pharos, visit the profile of the chemical under review and check the hazard and RSL sections for any of the following list names:

- EU REACH Annex XVII CMRs
- EU REACH Annex XVII non-CMRs
- EU SVHC Authorisation List
- UNEP Stockholm Conv Persistent Organic Pollutants

### 4. PBTs receive an x-PBT C2CC Chemical Rating.

Assign an x-PBT C2CC Chemical Rating to any substance with a RED hazard rating for both the Persistence and Bioaccumulation endpoints and at least one RED hazard rating in any other hazard endpoint.

# 5. Organohalogens and climatically relevant substances receive an x C2CC Chemical Rating.

If a substance has a RED hazard rating for the organohalogen or climate endpoint, assign an x C2CC Chemical Rating to the chemical.

# Step 3. Perform limited exposure assessment to assign risk flags

C2CC reference: Exposure Assessment, Section 3.1.2

[Divergence from C2CC documentation for use in ChemForward: First, perform a check that the CF data requirements are met. Assign a GREY risk flag where any of the following are true:

• Data are missing for 3 or more of the 4 chronic human health endpoints (C, M and R/D and E); in C2CC, M and R/D are prioritized for data



- Data are missing for 3 or more of the 6 other human health endpoints (Oral Toxicity, Dermal Toxicity, Inhalation Toxicity, Neurotoxicity, Skin, Eye, and Respiratory Corrosion/Irritation, and Sensitization of Skin and Airways)
- Data are missing for persistence, bioaccumulation, and aquatic toxicity endpoints]

Endpoints with RED, YELLOW, or GREEN hazard levels get risk flags equal to their hazard level. This applies to all endpoints except

- The five that go into the combined aquatic toxicity risk flag (fish, daphnia, algae, persistence, and bioaccumulation). Instructions for these follow in Step 4 below.
- The endpoints Other (Human Health) and Other (Environmental Health). These endpoints aren't included in the C2CC score at present, so they are given EXEMPT risk flags.

In the ChemForward use of the C2CC methodology, exposure assessments only determine how data gaps are treated. Absent a product-specific context, red or yellow hazard ratings cannot be mitigated with a lower risk flag.

[Slight change in terminology from C2CC documentation: where it says 'ignore this endpoint', ChemForward gives that endpoint an EXEMPT risk flag. Conditions which warrant an EXEMPT risk flag are defined below and can include endpoints with limited data availability or physical parameters that indicate low concern.]

Exemption 1 GREY hazards in certain endpoints receive EXEMPT risk flags C2CC Reference Exposure Assessment, Section 3.1.1.3 (Step 1A)

For GREY hazard ratings in the Carcinogenicity, Endocrine Disruption, Neurotoxicity and Terrestrial Toxicity endpoints, assign an EXEMPT risk flag.

#### Exemption 2

# GREY hazards in certain endpoints may receive EXEMPT risk flags based on physical parameters.

#### C2CC reference: Exposure Assessment

GREY hazard ratings are assigned an EXEMPT risk flag in the route/species-specific endpoints and sub-endpoints (listed above in Step 2, classes 2 and 3) if the conditions in step 1B of the Exposure Assessment Methodology (copied here) indicate low concern:



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

- a. 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).
  - Absorption is unlikely when molecular weight is greater than 1000 g/mol 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:
    - 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 OR;
  - ii. Molecular weight is greater than 500 g/mol AND the log Kow is greater than 4.
- c. c. Inhalation exposure to volatiles is of low concern when:
  - i. Boiling point is greater than 240°C, OR;
  - ii. Vapor pressure is less than 10-6 mm Hg AND boiling point is greater than 400°C.
- Inhalation exposure to particulates and aerosols is of low concern when the
  aerodynamic diameter is greater than 100 µm.
- e. Aquatic toxicity is of low concern [and endpoints receive YELLOW risk flags] when solubility is less than 0.001 mg/l. 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 Poorly Soluble Substances).

For Carcinogenicity and Neurotoxicity, Exemption 1 takes precedence, i.e. a GREY hazard score for Cancer or Neurotoxicity receives an EXEMPT risk flag regardless of the physical parameters.



## Step 4. Derive combined aquatic toxicity risk flag

#### C2CC reference: Material Health Section 4.5

Derive combined aquatic toxicity risk flag based on either the three aquatic toxicity hazard ratings OR the YELLOW risk flag if one was assigned via step 3 above AND the Persistence and Bioaccumulation hazard ratings.

# Step 5. Assign C2CC Chemical Rating to chemical based on risk flags

C2CC reference: Material Health Section 5

Only assign a C2CC Chemical Rating via the following rules if the substance hasn't been assigned a C2CC Chemical Rating in step 2 above.

Note, users familiar with C2CC will notice a slight departure here from their scoring methodology. The ChemForward scores x/c, grey/c, and c/b can't be narrowed to the C2CC single letter scores of x, c, grey, or b due to a lack of product/use specific information. A full C2CC assessment would continue on to analyze the substance in the product use context, allowing the assignment of a single letter score.

- 1. If any of the risk flags are RED, assign an 'x/c' C2CC Chemical Rating.
- 2. Otherwise, if any of the risk flags are GREY, assign an 'grey/c' C2CC Chemical Rating.
- 3. Otherwise, if any of the hazard ratings or risk flags are YELLOW, assign a 'c/b' C2CC Chemical Rating.
- 4. Otherwise, if cancer has an EXEMPT risk flag, assign a 'b' C2CC Chemical Rating.
- 5. Otherwise, assign an 'a' C2CC Chemical Rating (all non-cancer risk flags are GREEN or EXEMPT).

# Step 6. Append CMR(1) or CMR(2) designation if applicable

If the C2CC Chemical Rating for the chemical is x/c AND there is a RED hazard rating for at least one of the three CMR endpoints (Carcinogenicity, Mutagenicity, and Reproductive/Developmental Toxicity), append the CMR designation to the C2CC Chemical Rating. If the RED hazard rating is associated with GHS Category 1 classification, append CMR(1). If the RED hazard rating is associated with GHS Category 2 classification, first check hazard rating for Endocrine disruption (see Step 7) and if hazard rating for Endocrine disruption is NOT RED, append CMR(2).



# Step 7. Append CRE or E designation if applicable

If the C2CC Chemical Rating for the chemical is c/b AND there is YELLOW hazard rating for Carcinogenicity, Reproductive/Developmental Toxicity, or Endocrine Disruption, append c/b-CRE. If the C2CC Chemical Rating for the chemical is x/c or x/c-CMR(2) AND there is RED hazard rating for Endocrine Disruption, append x/c-E.

# C2CC Chemical Ratings

The possible C2CC Chemical Ratings that can result from ChemForward's simplified C2CC chemical rating logic are:

C2CC Chemical Rating	Color	Short Definition	Rules Summary
Banned	purple	banned in all applications	Chemical is on the C2CC banned list.
x-CMR	red	problematic in all applications	Chemical has a RED hazard based on regulatory concerns for Cancer, Mutagenicity, or Reproductive toxicity.
x*-CMR	red	problematic in all applications	Chemical is a toxic metal, all of which have a RED hazard for Cancer, Mutagenicity, or Reproductive toxicity.
x-PBT	red	problematic in all applications	Chemical has a RED hazard for Persistence, Bioaccumulation, and another endpoint
x	red	problematic in all applications	Chemical is on a regulatory concern list, is climatically active, and/or is an organohalogen.
grey	grey	does not meet CF data requirements	Data are missing for 3 or more of the 4 chronic human health endpoints (esp M and R/D) or Data are missing for 3 or more of the 6 other human health endpoints or



# C2CC Chemical Ratings Guidance Updated 19 October 2020

			Data are missing for persistence, bioaccumulation, and aquatic toxicity endpoints
x/c-CMR (Append further to indicate whether the CMR is based on GHS Category 1 or 2. Label as x/c-CMR(1) when the CM or R is Category 1 and x/c-CMR(2) when the CM or R is Category 2.	red/ yellow	may be acceptable or problematic depending on application	Chemical has one or more RED risk flags before considering application. Applications where exposure is possible would result in a 'x' score. Applications with low exposure and risk would result in a 'c' score.
x/c-E	red/ yellow	may be acceptable or problematic depending on application	Chemical has one or more RED risk flags before considering application. Applications where exposure is possible would result in a 'x' score. Applications with low exposure and risk would result in a 'c' score].
x/c	red/ yellow	may be acceptable or problematic depending on application	Chemical has one or more RED risk flags before considering application. Applications where exposure is possible would result in a 'x' score. Applications with low exposure and risk would result in a 'c' score].
grey <b>/c</b>	grey/ yellow	insufficient information available	Chemical has one or more GREY risk flags before considering application. Applications where exposure is possible would result in a 'grey' score. Applications with low exposure and risk would result in a 'c' score.



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c/b-CRE	yellow/ green	acceptable in all applications	Chemical has one or more YELLOW risk flags before considering application. Applications where exposure is possible would result in a 'c' score. Applications with low exposure and risk would result in a 'b' score.
c/b	yellow/ green	acceptable in all applications	Chemical has one or more YELLOW risk flags before considering application. Applications where exposure is possible would result in a 'c' score. Applications with low exposure and risk would result in a 'b' score.
b	green	preferred in all applications	Chemical has no YELLOW hazards but lacks long-term cancer studies.
а	green	preferred in all applications	Chemical has no YELLOW or RED hazards or Cancer data gaps.



# Appendix 1. C2CC Chemical Rating calculation flowchart





# Appendix 2. Limited Exposure Assessment Flowchart

