



## **Colorants (Textile Dyestuffs and Pigments) Assessment Methodology**

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## REVISION HISTORY

REVISION DATE	SECTION	TYPE OF CHANGE	AUTHORIZED BY
June 2015	Initial Release		S. Klosterhaus
February 2016	1.1 & 3.2	Clarified purpose and preconditions for use of the assessment methodology contained in this document	S. Klosterhaus
February 2016	3.3.1	Added explanation of the exposure scenarios that were considered in the development of the assessment criteria	S. Klosterhaus
February 2016	3.5.5 & 3.5.6	Clarified situations in which irritation or sensitization testing for the dyed textile is not required despite a dyestuff product being sensitizing or irritating	S. Klosterhaus
February 2016	3.5.8	Clarified the trumping rules for various types of mutagenicity data that may be evaluated for the purpose of determining criteria compliance (the REACH approach is to be followed)	S. Klosterhaus
February 2016	3.5.11	Added explanation regarding permissible approaches in cases where neither experimental BCF data are available nor QSAR works	S. Klosterhaus
February 2016	3.5.14	Added explanation regarding what should be done when a dyestuff product is known to be toxic in endpoints not covered by this criteria set	S. Klosterhaus
April 2017	4.3.1	<p>Clarified that the molecular structure criteria for pigments only apply to pigments present at 100 ppm or above in a homogenous material of the finished product</p> <p>Added hematite and inorganic pigments of similar stability to the types of crystal structures for which an exception to the toxic elements rule for pigments applies</p> <p>Specified how data from dissolution tests may be used to evaluate pigment stability</p>	S. Klosterhaus
April 2017	4.3.3	<p>Clarified how potential contamination of commercially available pigments must be considered.</p> <p>Clarified how inhalation risk is to be considered for products in which pigments in an inhalable form are used as part of the final manufacturing stage</p>	S. Klosterhaus

September 2018	4.3.1	Clarified that a product containing a homogeneous material with $\geq 100$ ppm of a pigment containing carcinogenic aromatic amines is limited to the Bronze level of certification.	S. Klosterhaus
June 2019	2 and 3.5.12	Clarified exposure assumptions to be used in the assessment of dyestuff auxiliaries under this methodology	S. Klosterhaus

# 1 OVERVIEW

## 1.1 PURPOSE AND CONTENT

This document outlines a customized methodology for the material health assessment of colorants, specifically textile dyestuffs and pigments, as part of the Material Health requirements in the Cradle to Cradle Certified® Product Standard (the 'Standard'). This methodology differs from the general Material Health Assessment Methodology (the [Methodology](#)) for use with other substance types, but is aligned with the current practices used in product assessments for textile dyestuffs and pigments. Information in this document supersedes any conflicting information that may be present in the original Standard document, but only for the specific substance and material classes discussed and only if the preconditions for application of this guidance document have been fulfilled.

## 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® Product Standard User Guidance
- Cradle to Cradle Certified® Material Health Assessment Methodology
- Any applicable supporting documents and guidance posted on the C2CPII website

Visit the Cradle to Cradle Products Innovation Institute website to download the Standard documents and obtain the most current information regarding the product Standard ([http://www.c2ccertified.org/product\\_certification/c2ccertified\\_product\\_standard](http://www.c2ccertified.org/product_certification/c2ccertified_product_standard)).

## 2 INTRODUCTION

Because toxicity data are limited, most colorants would receive a single chemical risk rating of GREY due to missing toxicological information using the general assessment [Methodology outlined in the Standard](#). This would prevent products with colorant-containing materials as a primary component (25% by weight or more) from reaching the Bronze level of certification or higher, thereby preventing them from maintaining certification after the two-year, Basic-level provisional certification period has run its course. To allow for the inclusion of products containing textile dyestuffs and pigments in the certification program, customized assessment approaches were developed that take into consideration the specific aspects of potential exposure that distinguish these substance classes from others, as well as the amount and quality of toxicity data that is typically available. Because of the fundamental differences in their physicochemical properties and applications, two separate approaches were developed for these colorant classes, one for textile dyestuffs and one for pigments.

For dyestuffs, a modified methodology that yields a final ABC-X material assessment rating for the commercial dyestuff product was developed. This methodology applies to the assessment of textile dyestuff products applying for certification as such, or textiles that have been dyed with the dyestuff product. For the most part, this methodology was developed with the specific exposure scenarios that apply to textile dyestuffs already taken into account, therefore allowing the final assessment rating to be derived in one step. This is in contrast to the general assessment [Methodology](#), in which hazard criteria are applied initially to derive hazard ratings for each chemical substance and exposure considerations follow in a secondary step. An exception to this is the assessment of the auxiliaries in the dyestuff product, for which the general assessment [Methodology](#) for deriving the single chemical risk ratings (abc-x) must still be used, albeit using the dyestuff product-specific exposure assumptions described in Section 3.3.1. While the assessment criteria in this customized methodology are primarily hazard-based, their selection was informed by exposure considerations that have narrowed the endpoints to only those hazards that are directly relevant in the dyestuff manufacture, use, and end-of-use context. Because this assessment approach only considers exposure scenarios related to the use of dyestuff products on textiles, it does not apply to dyestuff products used for other applications (e.g., paper, foodstuff, or hair coloring). The general assessment [Methodology](#) must be used to assess dyestuff products in non-textile applications.

For pigments, a modified methodology that yields abc-x single chemical risk ratings for pigments as pure chemical substances was developed. This methodology consists of a set of customized screening criteria that are applied prior to following the general [Methodology](#). If a pigment has passed all of the customized screening criteria, GREY hazard endpoint ratings are then ignored when deriving a pigment's single chemical risk rating. The rating obtained for each pigment is then rolled into the final ABC-X assessment rating for any material containing the pigment.

# 3 ASSESSMENT OF TEXTILE DYE STUFFS

## 3.1 DEFINITION AND PROPERTIES

Dyestuffs are colored compounds that are soluble or dispersible in a liquid (usually water) and have the ability to permanently adhere to a material by covalent, electrostatic, or van der Waals bonds or just by migration and distribution into the material itself.

The term “dyestuff” is used to describe two different types of substances:

1. **Dyestuff molecule:** The dyestuff molecule is the pure, active chemical compound itself. It is a colored compound that sticks to the fiber after being applied in the dye bath. It is a pure chemical substance with a certain color index (C.I.) number and a unique CAS number (e.g., *Acid Blue 1*, Color Index # 42045 with CAS # 116-95-0). In contrast to the CAS number, the C.I. designation is not a molecular identifier; thus, knowing the C.I. number alone is not sufficient. The CAS number is a prerequisite for the toxicity assessment.
2. **Dyestuff product:** The dyestuff product is the commercial mixture containing the dyestuff molecule and the dyestuff formulation auxiliaries. Common dyestuff formulation auxiliaries include salts, solvents, de-dusting agents, preservatives, chelators, dispersants, and surfactants. A dyestuff product has a brand name and extension (e.g., *Drimaren® Yellow CL-S gr* produced by the dyestuff supplier *Archroma*). The commercial mixture, including both the dyestuff molecule and the dyestuff auxiliaries, will be referred to as the dyestuff product in this document.

Textile dyestuffs are typically classified according to the dyeing mechanism and the substrate. The most important classes with respect to textiles are the following:

- Reactive dyes for dyeing cellulose fibers (e.g., cotton)
- Vat dyes for dyeing cellulose fibers (e.g., cotton)
- Disperse dyes for dyeing polyester fibers (e.g., PET or PLA)
- Acidic (*or* anionic) dyes for dyeing polyamide fibers (e.g., silk, wool, or nylon)
- Basic (*or* cationic) dyes for dyeing polyacrylonitrile (PAN) and certain types of polyamide fibers
- Direct (*or* substantive) dyes for various substrates
- Sulfur dyes for dyeing cellulose fibers (e.g., cotton)

Dyestuffs can also be classified with respect to the chemical group responsible for the color (i.e., the chromophoric group). Some examples under this classification are the following:

- Azo dyes
- Anthraquinone dyes
- Triarylmethane dyes
- Acridine dyes
- Nitro dyes



More detailed information on dyestuffs, classification systems, and the mechanism of dyeing can be found in standard technical literature, e.g. ULLMANN'S Encyclopedia of Industrial Chemistry [1] and Industrial Dyes [2].

## 3.2 PRECONDITIONS FOR THE USE OF THIS METHODOLOGY FOR DYESTUFF PRODUCTS

In developing the assessment criteria contained herein, certain assumptions were made regarding the exposure of workers to dyestuff products during the textile dyeing process (see the following section). Specifically, the dyeing process in the dyehouse is assumed to be performed by trained personnel using protective equipment that prevents significant oral, dermal, or inhalation exposure to the dyestuff product. Consequently, these criteria may only be applied for the assessment of dyed textiles or products containing dyed textiles when lack of significant exposure to dyehouse workers is guaranteed. Furthermore, the ratings and achievement levels of dyestuff products assessed with this methodology will be based on an assumed lack of exposure during product application and only be valid in such contexts. If a textile manufacturer is not able to provide such a guarantee, or if plausible routes of exposure of workers to the dyestuff product are observed during the site visit in the context of a textile product being assessed for certification, the assessment criteria contained in this methodology document may not be used and the general Methodology must instead be employed to assess the dyestuff product. Even dyestuff products certified at the Gold level in Material Health cannot be assumed to be safe under conditions in which direct exposure of workers to the raw (i.e. non-textile bound) dyestuff product exists.

## 3.3 ASSESSMENT CRITERIA DEVELOPMENT

The methodology described in this section was developed for use in deriving A, B, C, X, or GREY assessment ratings for commercial textile dyestuff products. The methodology considers dyestuff-specific toxicity data and typical exposure scenarios during the life cycle of a textile dyestuff product, from the final textile manufacturing phase and textile use through to textile end-of-use.

### 3.3.1 Exposure Scenarios

The following exposure scenarios during textile dyestuff application, use, and end-of-use phases have been considered:

1. Dyehouse (final manufacturing step):

The dyeing process in the dyehouse is assumed to be performed by trained and protected

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1 Wiley: ULLMANN'S Encyclopedia of Industrial Chemistry. John Wiley and Sons, Inc. NY 2014

2 Hunger K, (ed.): Industrial Dyes – Chemistry, Properties, Applications. WILEY-VCH Verlag GmbH&Co. KGaA, Weinheim 2003

personnel, resulting in limited exposure of workers to the dyestuff product. Since some of the dyestuff molecule and most of the dyestuff auxiliaries reach the wastewater, a high level of environmental exposure to the dyestuff product is assumed.

2. Textile use:

During use of the textile, oral and inhalation uptake of the dyestuff is assumed to be rather limited, as the dyestuff molecule adheres to the fiber. However, dermal exposure to the fiber-bound dyestuff molecule takes place and dermal uptake with sweat as a carrier may occur.

3. End-of-use scenario 1 (intended / biological nutrient):

In the case of composting biodegradable textiles (e.g. a dyed cotton shirt), the dyestuff molecule is assumed to be slowly released and degraded. The dyestuff molecule must neither prevent biodegradation of the fiber nor form very toxic or persistent metabolites itself.

4. End-of-use scenario 2 (intended / technical nutrient):

In the case of recycling of the dyed textile, the dyestuff molecule is assumed to be either regained (and reused) or combusted.

5. End-of-use scenario 3 (highly likely unintended / incineration):

In the case of incinerating the textile after use, the dyestuff molecule is assumed to be completely destroyed.

### 3.3.2 Assessment Criteria

The assessment criteria described in this methodology differ from those in the general [Methodology](#), as they are customized to apply to the limited amount and type of information typically available for dyestuff products. Toxicity data for dyestuffs are typically limited to the information that can be obtained from the dyestuff product material safety data sheet (MSDS) and from direct information from the dyestuff manufacturer.

The following hazard endpoints and other topics were selected for inclusion in the assessment of textile dyestuff products based on the specific exposure conditions that apply to dyestuff products, the specific hazards that are most frequently associated with dyestuff molecules, and the toxicity data that are typically available for these products:

- Toxic metal content (dyestuff molecule only)
- Organohalogen content (dyestuff molecule and formulation auxiliaries)
- Cleavable carcinogenic amines (azo dyestuffs only)
- Acute oral toxicity (dyestuff product)
- Irritant effect on skin/eyes (dyestuff molecule after application)
- Sensitization (dyestuff molecule after application)
- Aquatic toxicity (dyestuff product)
- Mutagenicity (dyestuff product)
- Carcinogenicity (dyestuff molecule)
- Degradation products (dyestuff product)
- Bioaccumulation potential (dyestuff molecule only)
- Dyestuff formulation auxiliaries
- Impurities of dyestuff product

## 3.4 ASSESSMENT METHODOLOGY

### 3.4.1 Data Collection

The following information is needed in order to conduct the assessment of a dyestuff product:

1. Dyestuff product MSDS
2. Structure of dyestuff molecule
3. List of dyestuff formulation auxiliaries and their CAS numbers from the dyestuff product manufacturer
4. Standard hazard data resources as specified in the general [Methodology](#) (for formulation auxiliaries only)
5. In case of incomplete MSDS data, a statement from the dyestuff manufacturer with toxicity data for endpoints not addressed in the MSDS

### 3.4.2 Assessment Rules

Using the assessment criteria in Table 1, an A, B, C, X, or GREY rating is assigned to the dyestuff product using the following rules:

The overall dyestuff product ABC-X rating is determined by the best (i.e., leftmost) rating column in which all criteria are fulfilled.

If any of the criteria are not fulfilled because the toxicological properties are worse than the condition in the rightmost column (i.e., column C), the rating for the dyestuff product is X.

Otherwise, if any of the criteria in the rightmost column (i.e., column C) are not fulfilled due to lack of data, the rating for the dyestuff product is GREY. The only assessment criteria that can be fulfilled without data or signed statements are carcinogenicity and degradation products (topics 9 and 10).

A more detailed description of each assessment endpoint and topic is provided in Section 3.5.

Note: When assessing a dyestuff product applied to a textile, the final assessment rating for the dyed textile is equal to the lower rating between the base textile material and the dyestuff product in the order X, GREY, C, B, A.

### 3.4.3 Material Assessment Ratings

**A-rated dyestuff products** are ideal from a Cradle to Cradle® perspective: They are fully defined, contain neither metals nor organohalogen compounds, are neither toxic nor ecotoxic, and cannot cleave off carcinogenic aromatic amines. All of their biodegradation products are known and do not pose a risk to human health or the environment.

**B-rated dyestuff products** largely support Cradle to Cradle® objectives: They are fully defined. However, they may contain moderately problematic (c-assessed) formulation auxiliaries and the dyestuff molecules' biodegradation products are not known.

**C-rated dyestuff products** have moderately problematic properties in terms of quality from a Cradle to Cradle® perspective: They are fully defined. The dyestuffs may contain copper when used in technical cycles or very low amounts of organohalogen compounds, and may have moderate toxicity to humans or aquatic organisms. Their non-mutagenicity is indicated based on negative Ames test only and data on the biodegradation of the dyestuff molecules or the formulation auxiliaries are not available.

**Table 1: Assessment Criteria for Textile Dyestuffs.**

	<b>Endpoint/Topic</b>	<b>A</b>	<b>B</b>	<b>C</b>
1	Toxic metal content	Dyestuff molecule is free of toxic metals.	Dyestuff molecule is free of toxic metals.	Dyestuff molecule is free of toxic metals. For fibers going into the technical metabolism, copper complex dyestuffs are acceptable.
2	Organohalogen content	Dyestuff molecule(s) is(are) free of non-hydrolysable carbon-halogen bonds.	Dyestuff molecule(s) is(are) free of non-hydrolysable carbon-halogen bonds.	Content of non-hydrolysable organohalogen compounds is below 0.1% in the dyestuff product.
3	Cleavable carcinogenic aromatic amines	Dyestuff molecule cannot cleave off any aromatic amine listed either under last update of 2002/61/EC or under MAK III 3B or other carcinogenic aromatic amines (either reductively or hydrolytically).	Dyestuff molecule cannot cleave off any aromatic amine listed either under last update of 2002/61/EC or under MAK III 3B or other carcinogenic aromatic amines (either reductively or hydrolytically).	Dyestuff molecule cannot cleave off any aromatic amine listed under last update of 2002/61/EC under reductive conditions.
4	Acute oral toxicity	LD50 (oral, mammal) of dyestuff product > 2,000 mg/kg.	LD50 (oral, mammal) of dyestuff product > 2,000 mg/kg.	LD50 (oral, mammal) of dyestuff product > 300 mg/kg.
5	Irritation potential	Dyestuff product is <u>not</u> labelled with H314, H315, H318 or H319.	Dyestuff product is <u>not</u> labelled with H314, H315, H318 or H319.	Dyestuff product is <u>not</u> labelled with H314 or H318 (exception: dyestuff products that are irritating before application only, see Section 3.5.5).
6	Sensitization potential	Dyestuff product is non-sensitizing as shown by test (such as Mouse Local Lymph Node Assay).	Dyestuff product is non-sensitizing as shown by test <u>or</u> no reported cases of sensitization*	Dyestuff product is non-sensitizing as shown by test <u>or</u> no reported cases of sensitization* (exception: dyestuff products that are sensitizing before application only, see Section 3.5.6).

	<b>Endpoint/Topic</b>	<b>A</b>	<b>B</b>	<b>C</b>
7	Acute aquatic toxicity	LC50 fish (96 h) of dyestuff product > 100 mg/l and LC50 daphnia (48 h) of dyestuff product > 100 mg/l **	LC50 fish (96 h) of dyestuff product > 100 mg/l and LC50 daphnia (48 h) of dyestuff product > 100 mg/l **	LC50 fish (96 h) of dyestuff product > 10 mg/l or LC50 daphnia (48 h) of dyestuff product > 10 mg/l ** (at least one value available; MSDS values must be > 10 mg/l)
8	Mutagenicity	Dyestuff product or dyestuff molecule have been tested and are not mutagenic.	Dyestuff product or dyestuff molecule have been tested and are not mutagenic.	Dyestuff product is not suspected of being mutagenic based on a negative Ames test only.
9	Carcinogenicity	Dyestuff molecule is neither a known nor a suspected carcinogen.	Dyestuff molecule is neither a known nor a suspected carcinogen.	Dyestuff molecule is neither a known nor a suspected carcinogen.
10	Degradation Products	Information on degradation pathway exists for all formulation components (including the dyestuff molecule) and has been reviewed; no risks have been identified.	Information on degradation pathway exists at least for the dyestuff auxiliaries and has been reviewed; no severe risks have been identified	No information available.
11	Bioaccumulation potential	BCF of dyestuff molecule < 100 <u>or</u> solubility in water > 1 g/L (25°C)	BCF of dyestuff molecule < 100 <u>or</u> solubility in water > 1 g/L (25°C)	100 < BCF of dyestuff molecule < 500
12	Dyestuff formulation auxiliaries	All formulation auxiliaries are declared and assessed according as a or b.	All formulation auxiliaries are declared and assessed according as a, b or c.	All formulation auxiliaries are declared and assessed according as a, b or c.
13	Impurities	Dyestuff product meets ETAD standard for impurities.	Dyestuff product meets ETAD standard for impurities.	Dyestuff product meets ETAD standard for impurities.

\* Sensitization: “No reported cases of sensitization” means that the dyestuff supplier has provided a signed statement that there have been no reported cases of sensitization.

\*\* Acute aquatic toxicity: If the solubility of the dyestuff is lower than the LC50/EC50 value, the endpoint is not applicable.

## 3.5 ENDPOINT AND TOPIC DESCRIPTIONS

### 3.5.1 Toxic Metals

This endpoint applies to the dyestuff molecule only.

Certain dyestuff molecules, commonly referred to as metal complex dyes, contain metal atoms as a central part of their chromophore. As of the time of this writing, only four different types of

metal atoms are typically used in metal complex dyes: nickel, cobalt, chromium, and copper. During combustion, nickel, cobalt, and sometimes chromium complex dyes form carcinogenic compounds. Therefore, all dyestuff products containing these metal complex dyes receive an X assessment rating.

Copper compounds formed by combustion are less problematic. Copper complex dyes are therefore acceptable for use when used on textiles intended to enter a technical cycle after use. However, many copper compounds are ecotoxic. Copper complex dyes are therefore not acceptable for textiles intended to enter a biological cycle (e.g., through composting) after use.

If other metal atoms are used in a metal complex dye, the metal must be assessed following the general [Methodology](#). Toxicity data for simple inorganic or the pure forms of the metal may be used, as chemical transformation is likely once the metal complex dye is released into the environment (during the dyeing process or likely unintended end-of-use scenarios of the dyed textile).

Data Source: Comprehensive data about the metal content in a specific dyestuff product can be obtained from the structure of the dyestuff molecule and from its product MSDS. A typical entry in the MSDS would be in Section 12 (Ecological information): “The product does not contain heavy metals in concentrations of concern for waste water.”

### 3.5.2 Organohalogenes

This endpoint applies to the dyestuff molecule only. However, in the MSDS organohalogen content is sometimes specified as a percent of the dyestuff product overall.

Dyestuff molecules often contain stable halogen-carbon bonds for coloristic reasons. Several common dyestuff products will therefore be X-assessed for the purposes of Cradle to Cradle certification.

On the other hand, many reactive dyes contain halogens in the anchor group. This halogen-carbon bond is usually hydrolyzed during formation of the bond between dyestuff molecule and textile fiber, forming harmless halides (i.e., fluoride, chloride, bromide). If the organohalogen group in a dyestuff molecule is cleavable (hydrolyzable), the dyestuff product is acceptable with respect to this endpoint.

Sometimes small amounts of additional organohalogen dyestuff molecules used for the final adjustment of shade are added to the dyestuff product. With typically 1% of the dyestuff molecule on the fiber, amounts of 0.1% halogen in the dyestuff product lead to approximately 10 ppm halogen on the fiber, which is deemed acceptable (i.e., C-rated dyestuff product).

Data Source: Comprehensive data regarding the halogen content in a specific dyestuff product can be obtained from the structure of the dyestuff molecule and from its product MSDS. A typical entry in the MSDS would be in Section 12 (Ecological information): “Product does not add to the AOX-value of the sewage.”

### 3.5.3 Cleavable carcinogenic aromatic amines

This endpoint applies to the dyestuff molecule only.

Azo dyestuffs are characterized by their specific chromophore, the azo group: -N=N-. This dyestuff class is important because it encompasses more dyestuffs than all of the other dyestuff classes combined.

Azo dyestuffs may cleave off aromatic amines by reductive cleavage of the azo group. A number of such amines are known to be carcinogenic. Because reductive cleavage may occur within the human gut and under other conditions, it is important to evaluate the potential of an azo dye to cleave off carcinogenic amines when assessing its safety for humans and the environment. The use of azo dyestuffs that may cleave off certain carcinogenic aromatic amines has been forbidden in the European Union<sup>3</sup>; however, such dyestuffs may still be in use outside of the European Union. While category C just considers the specific aromatic amines referenced on the European legislation [3], categories A and B moreover consider any known or suspected carcinogenic aromatic amines that may be cleaved off under reductive or hydrolytic conditions.

Data Source: The structure of the dyestuff molecule provides sufficient information about cleavable aromatic amines.

### 3.5.4 Acute oral toxicity

This endpoint applies to the dyestuff product.

Acute oral toxicity is the standard indicator for toxicity. It has been determined for nearly every substance.

Data Source: Acute oral toxicity data for a specific dyestuff product can be obtained from the dyestuff product MSDS. A typical entry in the MSDS would be in Section 11 (Toxicological information): "Acute oral toxicity: LD50 > 2,000 mg/kg (rat)."

### 3.5.5 Irritation potential

This endpoint applies to the dyestuff molecule only. However, in the MSDS the irritation potential is usually specified for the whole dyestuff product.

Irritation potential is an important parameter for the dyed textile due to intensive skin contact between textile and consumer. Therefore, irritating dyestuffs should not be used. However, if the dyestuff manufacturer can prove by testing that the dyed textile is not irritating, the dyestuff product may be used. Testing is not necessary if the irritation potential of the dyestuff product before application originates from one of the following:

- *dyestuff formulation auxiliaries that are known not to stay on the fiber after dyeing and rinsing, or*
- *reactive dyestuffs that form a chemical bond with the textile fiber during the dyeing process, after which the original dyestuff as such is no longer present [4]*

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3 Point 43 of Annex I of Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC) (OJ L 262, 27.9.1976, p. 201) lastly amended on 21.11.2008. Available in consolidated form at: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0769:20081211:EN:PDF>.

4 Hunger K, (ed.): Industrial Dyes – Chemistry, Properties, Applications. WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim (p. 627) 2003

Data Source: Irritation potential for a specific dyestuff product can be obtained from the dyestuff product MSDS. A typical entry in the MSDS would be in Section 11 (Toxicological information): “Irritant effect on skin: non-irritant (rabbit).” If the MSDS indicates irritation potential for the dyestuff product but the dyestuff manufacturer has conducted testing indicating the dyed textile is not irritating, the manufacturer may submit a report on the tests performed by a textile laboratory on textiles dyed with the product to the assessor. If the report indicates that the dyed textile is not irritating, the dyestuff product may qualify for a C assessment rating. In the case of reactive dyes, any irritation is assumed to be caused by the unreacted dyestuff molecule only and the dyestuff product can qualify for a ‘C’ rating based on this endpoint without any additional data being required.

### 3.5.6 Sensitization potential

This endpoint applies to the dyestuff molecule only. However, in the MSDS the sensitization potential is usually specified for the whole dyestuff product.

Similar to irritation potential, sensitization potential is an important parameter for the dyed textile due to intensive skin contact between the textile and the consumer. Therefore, sensitizing dyestuffs should not be used. However, if the dyestuff manufacturer can demonstrate via testing that the dyed textile is not sensitizing, the dyestuff product may be used. Testing is not necessary if the sensitization potential of the dyestuff product before application originates from one of the following:

- *dyestuff formulation auxiliaries that are known not to stay on the fiber after dyeing and rinsing, or*
- *reactive dyestuffs that form a chemical bond with the textile fiber during the dyeing process, after which the original dyestuff as such is no longer present [5]*

Data Source: Sensitization potential for a specific dyestuff product can be obtained from the dyestuff product MSDS. A typical entry in the MSDS would be in Section 11 (Toxicological information): “Sensitization: Non-sensitizing (mouse); Method: Mouse Local Lymph Node Assay (LLNA).” If the MSDS indicates sensitization potential for the dyestuff product but the dyestuff manufacturer has conducted testing indicating the dyed textile is not sensitizing, the manufacturer may submit a report on the tests performed by a textile laboratory on textiles dyed with the product to the assessor. If the report indicates that the dyed textile is not sensitizing, the dyestuff product may qualify for a C assessment rating. In the case of reactive dyes, any sensitization is assumed to be caused by the unreacted dyestuff molecule only and the dyestuff product can qualify for a ‘C’ rating based on this endpoint without any additional data being required.

### 3.5.7 Acute aquatic toxicity

This endpoint applies to the dyestuff product.

During typical dyeing processes, a significant portion of the dyestuff molecule, as well as most of the dyestuff auxiliaries, reach the wastewater. Thus, there is a large potential for exposure to the dyestuff product in aquatic environments. As such, aquatic toxicity is an important parameter to consider in the assessment of a dyestuff product. If both acute fish and acute daphnia toxicity

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5 Hunger K, (ed.): Industrial Dyes – Chemistry, Properties, Applications. WILEY-VCH Verlag GmbH&Co. KGaA, Weinheim (p. 627) 2003



data are available, both need to be considered, with the overall assessment rating driven by the target species with the lowest LC50 value (i.e., highest toxicity). If data for only one target species is available, this is deemed sufficient for the assessment of a textile dyestuff product and the available data point will determine categorization for this endpoint. Chronic toxicity data is typically not available and does not need to be considered. Algae toxicity data are not appropriate, as light absorption by the dye solution always leads to reduced algae growth (the measured endpoint), thus obscuring possible toxicity impacts.

Data Source: Acute aquatic toxicity for a specific dyestuff product can be obtained from the dyestuff product MSDS\_or from the dyestuff manufacturer. A typical entry in the MSDS would be in Section 12 (Ecotoxicological information): “Fish toxicity: LC50 > 100 mg/l (96 h, guppy (Lebistes reticulatus)).”

### 3.5.8 Mutagenicity

This endpoint applies to both the dyestuff molecule and the dyestuff product.

Mutagenicity is an important indicator for carcinogenicity. It is an essential endpoint, as many dyestuff molecules are derivatives of carcinogenic compounds, especially aromatic amines. Dyestuff products without mutagenicity data are GREY-assessed.

At a minimum, a negative Ames test (OECD 471) is required. This would be sufficient for a C rating. For a dyestuff product to receive an A or B rating, data on additional mutagenicity/genotoxicity tests are required. Any of the tests listed in Section 7.1.3 of the general [Methodology](#) are acceptable for this purpose.

In contrast to non-dyestuff substances that are assessed following the general [Methodology](#), dyestuffs are assessed following the REACH approach. This means that a positive Ames test can be superseded by a negative *in vitro* mammalian chromosomal aberration test plus a negative *in vitro* mammalian gene mutation test. A positive *in vitro* mammalian cell test can be superseded by a negative *in vivo* mammalian cell test. For details of the REACH approach, see “Proposed Integrated Decision-tree Testing Strategies for Mutagenicity and Carcinogenicity in Relation to the EU REACH Legislation” [6] and “Integrated testing strategy for mutagenicity under REACH” [7].

Data Source: Mutagenicity data for a specific dyestuff product can be obtained from the dyestuff product MSDS\_or from the dyestuff manufacturer. A typical entry in the MSDS would be in Section 11 (Toxicological information): “Mutagenicity: No mutagenic response in the Ames-Test.”

### 3.5.9 Carcinogenicity

This endpoint applies to the dyestuff molecule only. However, if addressed in the MSDS, the carcinogenicity of the complete dyestuff product is typically specified.

Carcinogenicity data are typically not available for dyestuff molecules due to the high costs of the required animal tests. Should data be available, they need to be considered for the rating of the dyestuff product. Rating of carcinogenicity is performed according to the hazard endpoint

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6 R.Combes, C.Grindon, M.Cronin, D.Roberts and J.Garrod : Proposed Integrated Decision-tree Testing Strategies for Mutagenicity and Carcinogenicity in Relation to the EU REACH Legislation. Altern Lab Anim 35 ,267-287, 2007  
7 [http://www.prc.cnrs-gif.fr/reach/diagrams\\_en/testing\\_strategy\\_muta\\_en.pdf](http://www.prc.cnrs-gif.fr/reach/diagrams_en/testing_strategy_muta_en.pdf)

criteria specified for carcinogenicity in the general [Methodology](#), i.e. if the dyestuff molecule meets the “red” criteria for the carcinogenicity endpoint, the dyestuff product will be rated X.

Data Source: While carcinogenicity data is rarely available for dyestuff products, it may appear on the dyestuff product MSDS or be provided by the dyestuff manufacturer. No additional sources need to be checked for the dyestuff molecule with regards to this endpoint.

### 3.5.10 Degradation products

This topic applies to the dyestuff molecule and the dyestuff auxiliary molecules.

Knowledge about the degradation products of the dyestuff molecule is important for the assessment of the environmental risk posed by the dyestuff in the textile’s end-of-use phase, especially in case of release to soil. Unfortunately, these data on degradation products exist only for a small number of dyestuff molecules. Thus, this information is only required to obtain an A rating for the dyestuff product.

To obtain an A rating, all known degradation products of the dyestuff molecule and auxiliaries must have been assessed following the general [Methodology](#) and must have received an a or b single chemical risk rating.

To obtain a B rating, information on the degradation products of all dyestuff auxiliaries must have been obtained and they must have been assessed following the general [Methodology](#). None of these degradation products may have received a single chemical risk rating of x.

As a substitute for knowledge of degradation products, the assumption is made that a dyestuff molecule that contains neither organohalogens nor toxic metal atoms will likely degrade into non-toxic and non-persistent molecules (metal and organohalogen content are already covered by the first and second endpoints, see above). Thus, a C rating for a dyestuff product can be obtained even if no additional information on degradation products is available.

Data Source: The identities of degradation products of dyestuff molecules and auxiliaries are to be obtained from peer-reviewed scientific papers on the topic such as [8] and [9].

### 3.5.11 Bioaccumulation potential

This endpoint applies to the dyestuff molecule only.

In contrast to their persistence, most textile dyestuffs are readily water-soluble and therefore not suspected of being bioaccumulative. However, certain dyestuffs (e.g., disperse and vat dyes) are not water-soluble. Their bioaccumulation potential needs to be known, especially if they are used for coloration of biodegradable fibers. If dyestuff solubility in water is higher than 1 g/L (25°C), the BCF value is assumed to be far below 100 and no specific BCF data is needed.

Data Source: Data on bioaccumulation potential can be found in the product MSDS or can be requested from the dyestuff supplier. Alternatively, bioaccumulation potential can be calculated

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8 I K Konstantinou and T A Albanis. TiO<sub>2</sub>-assisted photocatalytic degradation of azo dyes in aqueous solution: kinetic and mechanistic investigations. Applied Catalysis B: Environmental 49 (2004) 1-14 Elsevier  
9 X Zhao, I R Hardin and H-M Hwang. Biodegradation of a model azo disperse dye by the white rot fungus *Pleurotus ostreatus*. International Biodeterioration & Biodegradation 57 (2006) 1-6 Elsevier

by standard QSAR methods for substances with  $\log K_{ow} < 6$  (see Standard Section 7.1.15). However, experimental data always supersede QSAR data. In cases in which neither experimental BCF data are available nor QSAR works, additional dyestuff molecule properties (i.e. molecular weight, molecule size, and solubility in octanol) may be considered. In particular, a dyestuff molecule with molecular weight higher than 500 atomic mass units and solubility in octanol lower than 10 mg/l can be assumed not to be bioaccumulative [10]. A typical entry in the MSDS would be in Section 9 (Physical and chemical properties): “Solubility in water: 40 g/l (25 °C)” – meaning good water solubility and consequently no bioaccumulation potential.

### 3.5.12 Formulation auxiliaries

This topic applies to the formulation auxiliaries in the dyestuff product.

As the majority of formulation auxiliaries will reach the wastewater during the textile dyeing process, knowledge of their fate and impact on the environment (particularly the aquatic environment), is crucial. Therefore, the dyestuff manufacturer needs to reveal all auxiliaries present in the dyestuff product at concentrations of 100 ppm or above. Without such disclosure by the dyestuff manufacturer, the assessment of dyestuff products is not possible, leading to a GREY rating for the dyestuff product. It is not necessary to reveal the exact percentages of each auxiliary in the dyestuff product, as long as all auxiliaries present at 100 ppm or above have been provided. If this is guaranteed by the dyestuff product manufacturer, it is sufficient to report approximate concentration ranges for each substance in the dyestuff product (i.e., <0.1%, 0.1 – 1.0%, 1.0 – 10%, and >10%). In cases in which multiple dyestuff products from the same manufacturer are being assessed, the manufacturer may submit one list containing all auxiliaries for a group of dyestuff products.

Auxiliaries are assessed following the general [Methodology](#) (albeit using the dyestuff product-specific exposure assumptions described in Section 3.3.1). For a dyestuff product to obtain an A rating, all auxiliaries must have received a single chemical risk rating of either a or b. For a dyestuff product to obtain a B or C rating, all auxiliaries must have received a single chemical risk rating of either a, b, or c.

Data Source: Formulation information must be obtained from the dyestuff supplier. Toxicity data can be obtained from the standard scientific data resources.

### 3.5.13 Impurities

This topic applies to the dyestuff product.

Dyestuff products may contain impurities due to impurities in reactants or raw materials, residues of solvents, reactants or reaction by-products, metal traces from the use of metal catalysts in synthesis, or from corrosion of manufacturing equipment. The concentrations of these impurities are a measure of product quality. The members of the dyestuff suppliers' association ETAD (“The Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers”) guarantee that their products do not exceed certain, well-defined impurity thresholds.

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10 R.Anliker, P.Moser, D.Poppinger: Bioaccumulation of dyestuffs and organic pigments in fish. Relationships to hydrophobicity and steric factors. Chemosphere, Vol.17, No.8, pp 1631-1644, 1988

Data Source: A dyestuff supplier must follow the ETAD limits to receive an A, B, or C rating for the dyestuff product. Dyestuff products from manufacturers that are ETAD members are preferred. If the manufacturer is not an ETAD member, they must sign and submit a written declaration guaranteeing that none of the impurities specified in ETAD guidelines are present in the product above their allowable concentration limit. Limit values are published in *ETAD recommendation for threshold limits on impurities in dyes, 2014* (<http://www.etad.com/lang-en/publications.html>).

### **3.5.14 Further Information**

Should the MSDS or other data from the dyestuff manufacturer indicate high chronic toxicity, reproductive toxicity, or endocrine disruption potential of the product, this information needs to be considered and reflected in the final rating (i.e. the substances with this toxicity potential need to be evaluated separately following the general Methodology instead of the simplified Methodology contained herein).

# 4 ASSESSMENT OF PIGMENTS

## 4.1 DEFINITION AND PROPERTIES

Pigments are colored, insoluble chemical compounds with the ability to give color to another material. The fundamental difference between dyestuffs and pigments is that pigments are not intended to be soluble in order to adhere to a material. Pigments have to be dispersed in the material to imbue it with color. Alternatively, they can be dispersed within a binder matrix, which is then applied to the surface of a material. In contrast to dyestuffs, pigments keep their original shape (as small crystals) over the complete life cycle, a consideration that must be taken into account during the material health assessment process.

Pigments are typically classified according to their chemical make-up and can be divided into two groups:

1. Inorganic pigments: Inorganic pigments, often metal oxides or metal sulfides, usually show high light fastness and temperature stability, but often limited brilliance. Important inorganic pigments are titanium dioxide, iron oxide, zinc oxide, zinc sulfide, barium sulfate, chromium(III) oxide, cobalt blue, lead oxide, cinnabar and cadmium yellow.
2. Organic pigments: Similar to dyestuff molecules, organic pigments can be classified according to their chemical structure. Classes of organic pigments include:
  - Azo pigments
  - Disazo pigments
  - Polycyclic pigments
  - Anthraquinone pigment
  - Dioxazine pigments
  - Triarylcarbonium pigments
  - Quinophthalone pigments

Similar to azo dyestuff products, the azo pigments are the commercially most important group of organic pigments.

Pigments are often marked with a specific number, the color index (C.I.) number. In contrast to dyestuffs, there is a distinct correlation between pigment name, CAS number, C.I. name, and C.I. number (e.g., titanium dioxide, TiO<sub>2</sub>, CAS # 13463-67-7, Pigment White 6, C.I. 77891).

Pigments are applied as pure pigments or as pigment formulations (i.e., pigment masterbatches). Masterbatches are used to avoid dust formation in the factory (for occupational safety) and to simplify pigment dispersion in the matrix.

More detailed information on pigments, their use, and their classification systems can be found in standard technical literature, e.g. ULLMANN'S Encyclopedia of Industrial Chemistry [11] and Industrial Organic Pigments [12].

In contrast to dyestuff products, pigments are used in a wide range of applications, which include paints, inks, coatings, fiber bulk colorations, plastics, rubber, paper, cosmetics, and ceramics. The below assessment methodology is applicable to any application of pigments as long as the conditions described under 'Limitations' in Section 4.3.3 are fulfilled.

## 4.2 ASSESSMENT METHODOLOGY DEVELOPMENT

Several toxicity studies have been performed on pigments for select hazard endpoints including acute toxicity, mutagenicity, and irritation potential<sup>13</sup>. The results showed that very few pigments are hazardous. The main reason for this is that most pigments are poorly water soluble and predominantly chemically inert, and as a consequence are not bioavailable. In many applications (e.g., coatings, paints, colored plastics) pigments are embedded in a matrix and therefore exposure is limited. For this reason, there has been little attention devoted to the toxicological characterization of pigments and the availability of toxicity data for pigments is relatively poor. If pigments were to be assessed following the general [Methodology](#), most pigments would receive a GREY rating due to a lack of toxicity data.

The general Standard [Methodology](#) was therefore modified to allow for the assessment of pigments when little toxicity information is available. This modified approach is based on the specific physicochemical properties of pigments and assumes that an ideal pigment is chemically stable (i.e., inert) and insoluble in any solvent. Due to its stability and insolubility, it is assumed that such a pigment does not change its macroscopic crystalline shape during use and the solid pigment crystals are too large to pass through biological membranes. As a consequence, an ideal pigment would not be bioavailable, would pass through the body unchanged in the event of ingestion, and as such would not be toxic via ingestion. These considerations apply to both organic and inorganic pigments.

Although these considerations are valid for ideal pigments only, it can simplify the toxicity assessment of pigments actually in use. For these, only deviations from this non-toxic ideal are considered with respect to assessing their toxicological impact. As a result, the primary questions that drive the assessment are:

- Can the pigment be dissolved, without changing its chemical structure, under any realistic and probable circumstances during its life cycle?, and
- Is the pigment chemically unstable and may it form, release, or cleave-off any toxic substance under any realistic and probable circumstances during its life cycle?

In addition, all probable chemical impacts on the pigment during its life cycle need to be considered:

- Elevated temperature (e.g., during extrusion of colored plastics)
- Acidic conditions (e.g., after ingestion of pigmented materials)

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11 Wiley: ULLMANN'S Encyclopedia of Industrial Chemistry. John Wiley and Sons, Inc. NY 2014

12 Herbst W, Hunger K: Industrial Organic Pigments – Production, Properties, Applications. WILEY-VCH Verlag GmbH & Co. KGaA Weinheim 2004

13 Herbst W, Hunger K: Industrial Organic Pigments – Production, Properties, Applications. WILEY-VCH Verlag GmbH & Co. KGaA Weinheim 2004

- Alkaline conditions (e.g., during reductive bleaching in paper recycling)
- Reductive conditions (e.g., during reductive bleaching in paper recycling)
- Oxidative conditions (e.g., during combustion of pigmented products)

The last of these probable life-cycle conditions, oxidation, deserves special considerations. Organic pigments completely degrade during combustion and the main oxidation products are usually carbon dioxide, water, and nitrogen. However, if a pigment contains other elements as well, further combustion products are formed. In particular, if a pigment contains halogens, small amounts of volatile organohalogen compounds will be formed during combustion. These combustion products are likely to be persistent, bioaccumulative, and toxic. For these reasons, halogen-containing pigments should be excluded from use.

## 4.3 ASSESSMENT METHODOLOGY

### 4.3.1 Molecular Structure Screening

The first step when assessing pigments is to establish whether they are chemically stable (i.e., like an 'ideal' pigment) or whether they have the potential to form hazardous reaction products. Based on the common chemistries of pigments that are in use, the vast majority of pigments with the potential to form hazardous reaction products can be captured by screening against the following three endpoints, which are based on the molecular structure of the pigment:

- organohalogens
- toxic elements
- reductively cleavable aromatic amines

While pigments are generally subject to review at any concentration, these three screening endpoints are applied only for pigments used at a concentration of 100 ppm or greater in a homogenous material of the finished product:

1. *Organohalogens* – A pigment containing a covalent fluoro-carbon, chloro-carbon, bromo-carbon or iodo-carbon bond will have a single chemical risk rating of 'x'.
2. *Toxic Elements* – A pigment containing lead, cadmium, mercury, vanadium, chromium(VI), cobalt, nickel, arsenic, antimony or selenium will have a single chemical risk rating of 'x'.

An exception to this rule is made for inert complex inorganic color pigments with a rutile, spinel, inverse spinel, or hematite structure [14]. These pigments show high chemical, light, and temperature stability and several contain toxic elements (e.g. antimony, cobalt, nickel). However, on a molecular level these potentially hazardous atoms are fixed firmly in a crystal lattice structure and cannot be released under normal use conditions, in alkaline or acidic media, or even during waste incineration [15,16]. Consequently, these pigments in their pure form do not pose any risk to human health or the environment, leading to a single chemical risk rating of c.

14 Buxbaum G (ed.): Industrial Inorganic Pigments. WILEY-VCH Verlag GmbH Weinheim; New York; Singapore 1998

15 Ullmann's Encyclopedia of Industrial Chemistry, "Pigments, Inorganic", Vol. A20; VCH, 1992.

16 Bomhard, E. et al. Subchronic oral toxicity and analytical studies on Nickel Rutile Yellow and Chrome Rutile Yellow with rats. Toxicol. Lett. 1982, **14**,189–194.

Inorganic pigments with differing crystal structures that are of similar stability as the above-mentioned ones may receive a single chemical risk rating of c as well. However, in these cases proof of their stability in all possible exposure scenarios connected with the considered application – during and after use – has to be provided. This can take place either by scientific literature or by dissolution tests.

A dissolution test under standardized, worst-case conditions, intended to emulate leaching via gastric fluid upon accidental pigment ingestion (GST, pH 1.5), may show whether a pigment is stable or not. For many pigments such tests have been performed. The results can be found in major toxicological databases, e.g. in the ECHA chemical database [17].

If the values are not documented by ECHA and no other data are available about the solubility under worst-case conditions, a new dissolution test has to be performed. No internationally agreed OECD guideline exists for testing with artificial gastric fluid; however, within the REACH framework, bioavailability under such conditions was determined on the basis of OECD 29 [18]. Therefore, a test according to the conditions described in OECD 29 is required, with the following modifications: the test media selected must include artificial gastric fluid (GST, pH 1.5) and test temperature must be  $37 \pm 2^\circ\text{C}$ .

The amount of toxic metals that can be dissolved under such conditions reveals whether the toxic metal is bioaccessible or not. All pigments for which less than 1 mg of metals are dissolved for every g pigment (pigment to solvent loading ratio is 100 mg/L) tested for 24h or more at pH1.5 can be assumed to be practically insoluble and therefore non-toxic. This threshold value was derived based on conservative estimates regarding the approximate trace amounts of toxic metals that may safely be released from pigments under worst-case exposure conditions, without causing any negative impacts on human and environmental safety. Therefore, pigments which release less than 1 mg/g of toxic metal under such worst-case exposure conditions can practically be considered as insoluble and non-toxic for the purpose of this assessment.

The metal dissolution ratio is calculated as a ratio as follows: mass of metal dissolved at pH1.5 after 24 hours (= analyzed value) divided by total mass of used pigment (= initial weight).

If the ratio is smaller than 1 mg of dissolved toxic metal per g of pigment, the pigment receives a 'c' rating.

If the ratio is higher than 1 mg of dissolved toxic metal per g of pigment, the pigment receives an 'x' rating.

It should be stressed that this approach is based on solubility of the pigment and does not consider the specific toxicity of the pigment.

3. *Reductively Cleavable Aromatic Amines* – An azo pigment containing one or more carcinogenic aromatic amines as defined in European regulation 76/769/EEC (Annex / Point 43) [19] will have a single chemical risk rating of 'x'. This means that a product

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17 <https://www.echa.europa.eu/information-on-chemicals/registered-substances> (accessed on March 16, 2017)

18 [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2001\)9&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2001)9&doclanguage=en) (accessed on March 16, 2017)

19 Point 43 of Annex I of Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (76/769/EEC) (OJ L 262, 27.9.1976, p. 201) lastly amended on 21.11.2008. Available in consolidated form at: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1976L0769:20081211:EN:PDF>



containing a homogeneous material with  $\geq 100$  ppm of such a pigment cannot achieve a certification level higher than Bronze.

### 4.3.2 Full Assessment

A pigment that has not received an x-assessment as a result of a functional group of concern in its molecular structure and does not belong to the complex inorganic pigment group (i.e., a pigment that has passed the screening described in Section 4.3.1) must then be assessed following the general Standard [Methodology](#). However, as a result of the considerations described in Section 4.2, any endpoint data gaps remaining in the pigment's hazard profile after the assessor has exhausted all available resources (i.e., GREY ratings) may be ignored when deriving the pigment's single chemical risk rating. The single chemical risk rating assigned to the pigment is then rolled into the final assessment rating for the homogenous material in which it is present, as described in the Cradle to Cradle Certified Material Health Assessment Methodology.

### 4.3.3 Limitations

This modified approach for assessing pigments has the following limitations:

1. It is only valid for pure pigments, meaning pure chemical substances with a single CAS number. Contamination of commercially available pigments with synthesis by-products is not considered in the approach and must be verified separately by the assessor. For example, inorganic pigments may contain toxic metal impurities depending on the origin and quality of raw materials and the production processes used for their manufacture. Such contaminants, if present at a concentration that makes them subject to review in a product, require a case-by-case review based on additional information from the specific pigment manufacturer. In such cases, contaminants are to be assessed separately following the general Standard [Methodology](#).
2. It is not valid for pigments in the form of nano-particles, as nano-sized pigment particles could pass biological membranes in some cases and their toxicological effect could be fundamentally different. Specific assessment rules for nano-particles may be developed at a future time, but for the time being they are to be assessed following the general Standard [Methodology](#), not the modified approach described in this document. The availability of toxicity information for nano-particles is relatively poor at present, even when compared to other pigment types. Thus, nano-sized pigments are very likely to obtain a single chemical risk rating of GREY.
3. It does not cover exposure by inhalation. In cases where dust loads are high, even dust from generally low-hazard substances may lead to toxic effects. For products in which pigments in an inhalable form are used as part of the final manufacturing stage, inhalation hazard and exposure needs to be assessed separately from the rules included in the methodology above. Any relevant inhalation exposure to inhalable pigments based on insufficient protection or unsafe operating procedures at the facility will result in a single chemical risk rating of 'x' for the pigment in that product, unless the pigment has received a YELLOW or GREEN hazard for Inhalation Toxicity and any other hazard endpoint for which inhalation exposure may be relevant (i.e. GREY ratings may not be ignored in this case).