Eurocolour
pigments, dyes and fillers

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Guidance document for the Registration of Complex Inorganic Coloured Pigments

1. Introduction

Complex Inorganic Colored Pigments (CICPs) are chemical substances manufactured by means of an industrial process, which involves a chemical reaction. In this process, a mixture of raw materials (typically consisting of metal oxides and salts) undergoes a calcination reaction at high temperatures forming a specific crystalline matrix.

For the identification of CICPs, color and crystal structure have been widely used as main parameters by industry. The Color Pigment Manufacturers Association (CPMA) maintains a list of inorganic pigments grouped into 14 crystalline structures with different contributing elements and colors. Colour Index International is a reference database listing thousands of dyes and pigments either organic or inorganic describing a commercial product by usage, its hue and a serial number.

The purpose of this document is to guide potential registrants of CICPs in determining the substance identity of these complex substances for the Registration under the REACH Regulation. The criteria used to define the boundaries of what is considered the same substance under REACH affects the number of substances that will be registered jointly and defines the corresponding obligations to generate relevant Annex VII-XI data.

2. REACH Substance Identification

The REACH Regulation distinguishes between two types of well-defined substances and substances of unknown or variable composition for the purpose of Substance Identification.

- Mono-constituent substances in which one constituent is present at a concentration of at least 80% (w/w)
- Multi-constituent substances consisting of several main constituents present at concentrations generally above or equal to 10% and below 80% (w/w)
- Substances of unknown or variable composition, complex reaction products, or biological materials (UVCBs)

In the past, CICPs have been considered as mono-constituent substances using the CPMA nomenclature, including CAS and EINECS numbers, for the joint REACH Registrations. This approach encountered certain issues with Substance Identification under REACH, mainly due to the variability of the compositions within the same CICP.

The CPMA entries allow for so-called color modifiers, which may be incorporated into a CICP without any restrictions as long as the crystal structure is unchanged. In addition, a mineralizer may be used to control pigment formation by facilitating crystal growth.

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Consequently, CICPs with significantly different compositions had been registered jointly with the same name and Substance Identity. For this reason, Registrations using the CPMA nomenclature came under scrutiny due to the lack of transparency and problems with substance identification.

One option might be to consider CICPs as UVCBs, which allows for variations in composition. Subsequently following the Guidance for identification and naming of substances under REACH and CLP, UVCBs should be identified as a combination of composition, source (raw materials) and manufacturing process.
These parameters are however not relevant for CICPs, because a single CICP can be manufactured using a variety of raw materials or different industrial conditions. In addition, the concept of impurities, which does not apply to UVCBs, is relevant for CICPs.

So neither the identification as mono-constituent substances nor as UVCBs will allow for the necessary derogations from the strict principles for naming substances under REACH and CLP. A minimal variation in composition, impurity concentration, type of raw material or processing conditions would trigger a separate REACH Registration, which would result in a burden especially to small and medium-sized enterprises producing CICPs. The aim of the present guidelines is to overcome these challenges and set specific rules for substance identification of CICPs under the principles of REACH Regulation.

3. Naming and Substance Identification of CICP under REACH

X-ray fluorescence (XRF), and Inductively Coupled Plasma (ICP) for metals are widely used for the chemical analysis of CICP. The chemical composition is of prime importance for Substance Identification under REACH. In addition to composition, the crystalline structure is a very relevant parameter, which is investigated by X-ray Diffraction (XRD). Scientific studies of the crystalline structure use this technique extensively.

For naming and Substance Identification under REACH, a CICP therefore will be identified by its crystal structure and composition, considering all main contributing elements.

The so-called 80%-10% rule (see section 3.1) is the basis for the nomenclature of CICPs under REACH. More specifically, the basic rules to name CICPs under REACH and CLP are the following:

- Main contributing elements always present in the name
- Name of element (e.g. aluminium, chromium) instead of metal speciation (aluminate, chromite)
- Crystalline structure included at the end of the name (e.g. spinel, rutile)
- Colour not mentioned in the name

3.1. **Main contributing elements present in concentration above 10 %**

All contributing elements above a concentration of 10% (expressed as oxides) are considered as main elements and will contribute to the name. The sum of all main elements (expressed as oxides) must add to more than 80% of the substance.

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The following examples of the so-called 80%-10% rule illustrate the naming principle:

- A spinel with more than 80% (w/w) cobalt and chromium oxides combined, and less than 10% (w/w) aluminium oxide is named “Cobalt Chromium Spinel”.
- A spinel with cobalt and chromium oxides, containing also aluminium oxide in a concentration above 10% (w/w), and more than 80% (w/w) all combined, is named “Cobalt Chromium Aluminium Spinel”

There are cases where some flexibility to the 10% rule is needed, for example where a contributing element always represents 8-12% of a given pigment. In this case, all the compositions of the same CICPs should be registered jointly (see section 3.3).

3.2. **Main contributing elements present in concentration below 10 %**

Certain elements may be present in concentrations below 10% while being color-determining, therefore necessary for the identification of a given substance. In these cases, naming and SID need to include such contributing elements for the sake of transparency.

So for example, praseodymium oxides or vanadium oxides are always present in quantities less than 10% in certain zircon pigments. Yet they are main elements, important to define the yellow or blue color of the substances. If 80-10 % rule were to be strictly followed, these pigments would be included in the same Registration dossier and considered as the same substance (zirconium silicon zircon). Additional examples are nickel, chromium and antimony oxide in rutile pigments, chromium oxide in sphene pigments, or vanadium oxide in pigments with baddeleyite structure.

These contributing elements in the following list of CICPs are considered main contributing elements, though in all cases they appear below 10%, and contribute to the name. in the following list, all concentrations are expressed as oxides, with the exception of sulfur and selenium appearing in the first and second entries:

- Silicon zirconium cadmium selenium sulphur-encapsulated zircon (EC# 310-077-5) — 0.5%≤ CdO ≤6%, 0.5% S+Se ≤5%
- Cadmium sulphur zirconium silicon zircon (EC# 277-135-9) — 0.5%≤ CdO ≤5%, 0.5%≤S ≤3%
- Zirconium praseodymium silicon zircon (EC# 269-075-7) — 0.5%≤ Pr_4O_{11}≤7%
- Zirconium vanadium silicon zircon (EC# 269-057-9) — 0.5%≤ V2O5 ≤5%
- Antimony nickel titanium rutile (EC# 232-353-3) — 0.5%≤ NiO ≤6%
- Chrome antinomy titanium rutile (EC# 269-052-1) — 0.5%≤ Cr2O3 ≤9%
- Chrome tin cassiterite (EC# 269-104-3) — 0.3≤ Cr2O3 ≤1.5 %
- Chrome tin calcium silicon sphene (269-073-6) — 0.5≤ Cr2O3 ≤3%
- Manganese aluminium corundum (EC#269-061-0) — 0.5%≤ MnO ≤10%
- Vanadium zirconium baddeleyite (269-063-1) — 0.5%≤ V2O5 ≤4%

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3.3. **Flexible use of the 80% - 10% rule**

In certain cases, the strict application of the 80%-10% rule would lead to a situation where additional Registration dossiers would be required because of contributing elements present in concentrations close to 10%. The table below illustrates two examples of this situation and the reported percentages of these “borderline elements”.
In the first example, with flexible use of the 80 %- 10 % rule two new dossiers are required, while a strict application of the rule would trigger four new dossiers.
In the second example, with flexible use of the rule two new dossiers are required, but with strict application of the 80%-10% rules three new Registrations dossiers will be needed.

In these and few other cases, the limit could be up to 12% to avoid an excessive burden to industry and excessive multiplication of Registration dossiers with minimal changes in compositions. It would prevent a potential situation where a registrant whose composition contains 9% of a given element needs to prepare a different Registration dossier than another registrant whose composition contains 11% of the same element.

Current name	**CAS**	**EC#**	**C.I.**	**New dossiers (flexibility in 10% rule)**	**Reported % of borderline oxides**
Zinc iron chromite brown spinel	68186-88-9	269-050-0	C.I 77503	Zinc iron chromium spinel	NiO ≤ 11% SiO_2 ≤ 12%
				Zinc iron chromium aluminium spinel	
Cobalt chromite blue green spinel	68187-11-1	269-072-0	C.I. 77343	Cobalt chromium aluminium spinel	MgO ≤ 11%
				Cobalt chromium aluminium zinc spinel	

In other cases where a main contributing element is present either in less or more than 10% (depending on the specific composition) these compositions should be included in the same Registration dossier. The main elements are always present in the name of the substance, be it below or above 10%. This would be the case in the following examples:

- Chrome tungsten titanium rutile (EC# 269-054-2) 8%≤ Cr2O3 ≤15%
- Manganese antimony titanium rutile (EC# 270-185-2) 8%≤ MnO ≤15%
- Tin antimony cassiterite (EC# 269-105-9) 2%≤ Sb2O3 ≤12%

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4. Use of boundary composition

As outlined above, CICPs are composed of main and minor contributing elements.

The Lead Registrant dossier has to report the boundary composition on behalf of all members of the joint submission. For a CICP, the boundary composition is defined by the crystal structure and

- the main contributing elements, expressed as the list of the respective oxides in a certain range covering all the compositions of all registrants in the joint submission
- the minor contributing elements with a range of 0 to < 10 % (so-called color modifiers).

It is the responsibility of the individual registrants to maintain the composition for their respective legal entities in their individual REACH dossier, listing minor contributing elements which may not be included in the boundary composition as well as impurities. As a consequence, the individual registrants need to assess whether their individual compositions are adequately covered by the joint chemical safety assessment. If the hazard profile of the dossier is not affected the lead registrant will update the boundary compositions upon request of the individual registrant.

If minor elements are triggering a different hazard profile, the company will have the possibility to opt-out for the relevant part of the joint dossier and conduct its own specific chemical safety assessment.

EUROCOLOUR is the umbrella organization for manufacturers of pigments, dyes and fillers in Europe.

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