

## **Eurocolour's statement on the proposal for a harmonized classification of Pigment Red 53:1**

*Based on the CLH dossier submitted by Germany's Federal Institute for Occupational Safety and Health (BAuA), Pigment Red 53:1 (CAS 5160-02-1) has been proposed to be classified as a carcinogen, category 2. However, several expert groups concluded Pigment Red 53:1 to not act as a carcinogen and the presented arguments do not show the opposite.*

*Without a sufficient justification of the classification and no evidence for a potential danger for worker, user, or consumer, a classification as proposed is not appropriate and would only undermine the science-based classification system and thus weaken the hazard communication. On this basis, Eurocolour does not support any classification.*

Eurocolour would like to use this opportunity to provide input as a harmonized classification is from our point of view neither necessary nor justified. Initial concerns on the safety of bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate] (CAS 5160-02-1) – more commonly known as C.I. Pigment Red 53:1 – expressed by Germany's Federal Institute for Occupational Safety and Health (BAuA) during the substance evaluation have already been addressed in the REACH dossier.

Pigment Red 53:1 (CAS 5160-02-1) was tested for its carcinogenic potential in several studies. Several expert groups concluded that Pigment Red 53:1 does not act as a primary carcinogen or a genotoxic carcinogen. According to the CLP Regulation (EC 1272/2008) sufficient evidence for carcinogenicity is evident if "a causal relationship has been established between the agent and an increased incidence of malignant neoplasms or of an appropriate combination of benign and malignant neoplasms in (a) two or more species of animals or (b) two or more independent studies in one species carried out at different times or in different laboratories or under different protocols." Such evidence is not given for Pigment Red 53:1. A detailed overview of relevant studies and the respective results are given in the input provided by the manufacturers.

The material is handled safely by worker and professionals. Personal precautions, protective equipment as well as protective clothing are established to minimize the risk of exposure in manufacturing and processing processes by inhalation or dermal contact, and by accidental oral exposure.

Additionally, the pure substance is not handled by the general population. In consumer articles the material is included at very low concentrations, embedded in a matrix, e.g. a polymer matrix or binders matrix. Uptake of the substance at dose level relevant for adverse toxic effects is not expected.

Without a sufficient justification of the classification and no evidence for a potential danger for worker, user, or consumer, a classification as proposed is not appropriate and would only undermine the science-based classification system and thus weaken the hazard communication. On this basis, Eurocolour does not support any classification.

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About Eurocolour:

*Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.*