



Translation for information purposes
Original: German

Fact Sheet and Current Situation: Classification of Azo Pigments in Water Hazard Classes

5th version (status: 9th February 2021)

Classification of key pigments as non-hazardous to water

With the publication of the MAK and BAT values list 2020 on 1st July 2020¹ the three key pigments Pigment Yellow 12, Pigment Yellow 13 and Pigment Yellow 83 of the azo pigment group were newly added and classified in the MAK carcinogenicity category IV².

The classification of the mentioned pigments in the MAK carcinogenicity category IV was based on solubility studies (biodissolution) in which it was confirmed that the three pigments are not soluble. At the request of the VdMi, a re-evaluation of the substances was also carried out at the Federal Environment Agency (UBA) in accordance with Section 7 (1) AwSV (Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen / The ordinance on plants for the handling of water-polluting substances).

The three pigments are now classified as non-hazardous to water (nicht wassergefährdend / NWG) according to the decision of the Federal Environment Agency (UBA) (notification of 13th October 2020, identification no. 10561, 10562, 10563) in accordance with AwSV. Publication in the Federal Gazette (Bundesanzeiger) followed by means of announcements on 2nd and 3rd February 2021³. The classification can also be found in the Rigoletto database <https://webrigoletto.uba.de/rigoletto/> under the identification numbers 10561, 10562 and 10563.

This clarifies that for these three key pigments of the group of azo pigments, Pigment Yellow 12, Pigment Yellow 13 and Pigment Yellow 83, the suspicion of carcinogenic potential has been ruled out as unfounded.

Entry for other azo pigments

In the AwSV as well as in the publication in the Rigoletto database of the Federal Environment Agency (UBA), identification no. 9001, the group entry “azo dyes/azo compounds that potentially undergo reductive cleavage of azo groups to release amines classified as carcinogens” continues

¹ [mbwl_2020_eng.pdf \(publisso.de\)](#)

² Substances with carcinogenic properties are classified in categories IV and V, the effectiveness of which can be assessed on the basis of the available information. For this purpose, exposure at the workplace is defined (MAK or BAT value) in which no or very small contribution to the risk of cancer for humans is to be expected. Category IV includes substances with a non-genotoxic mechanism of action in the foreground.

³ <https://www.bundesanzeiger.de/pub/publication/JaqFb9CqcslitNS6aQ7/content/JaqFb9CqcslitNS6aQ7/BAAnz%20AT%2002.02.2021%20B9.pdf>

<https://www.bundesanzeiger.de/pub/publication/rno2WfwMyqokAAOHufU/content/rno2WfwMyqokAAOHufU/BAAnz%20AT%2003.02.2021%20B13.pdf>

<https://www.bundesanzeiger.de/pub/publication/usfIPey5dfuXP3K4RJI/content/usfIPey5dfuXP3K4RJI/BAAnz%20AT%2003.02.2021%20B12.pdf>

to exist as highly hazardous to water (WGK 3). In addition to azo dyes, other azo pigments than the above three key pigments are also recorded in the entry.

The manufacturers of these azo pigments take the view that, unlike dyes, the azo pigments referred to there, are not covered by this group entry. This can be scientifically justified by the very different properties of dyes and pigments. However, it is currently common practice that the substances have to be evaluated individually by the Federal Environment Agency (UBA). The VdMi has contacted the Federal Environment Agency with the request to change the group entry due to the comparable properties of the pigments concerned.

Some key arguments are listed below:

Solubility / Bioavailability

Unlike dyes, it is an outstanding characteristic of pigments that they are insoluble in the respective application medium (like coatings, printing inks or plastics).

For example, the group entry explicitly names pigments manufactured on the basis of 3,3'-dichlorobenzidine. In contrast to dyes, which are based on unsubstituted benzidine, these pigments are ca. 10,000 times less soluble in water. Given their extremely low solubility in water (and also in n-octanol) and because of further physical-chemical properties, the impacted azo pigments can be deemed not bioavailable.

- LogPow <2,2
- No hydrolysis in aqueous solution
- No release of 3,3'-dichlorobenzidine after oral intake

Reductive cleavage of the azo group

The possibility of a reductive cleavage of azo dyes, with a release of the respective aromatic amine on which they are based, was already examined in the 1990s within a revised version of the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung). When using the method named in the Consumer Goods Ordinance, a reductive cleavage on the azo bond can be proven for dyes based on unsubstituted benzidine. Not least due to this behaviour, benzidine dyes were classified as carcinogenic in category 1A in the 90s of the last century.

By contrast, no such reductive cleavage is observed in the same conditions for pigments based on 3,3'-dichlorobenzidine because of their extremely low solubility.

Toxicological behavior of the impacted azo pigments

Based on the toxicological data submitted within REACH registrations, these points can be summed up for the impacted azo pigments based on 3,3'-dichlorobenzidine:

- No detection of 3,3'-dichlorobenzidine in toxicologically relevant quantities in toxicokinetic studies
- No toxic effect in studies on acute toxicity, irritant/corrosive effect, skin sensitising effect and toxicity after repeated dose
- Not carcinogenic
- Not mutagenic
- Not toxic to reproduction

The available toxicological assessments substantiate that the impacted pigments should not be classified as hazardous substances under the EU hazardous substances legislation.

Independent evaluations

Furthermore, evaluations by independent bodies (e.g. Advisory Committee on Existing Chemicals of Environmental Relevance/BUA, 1989) and the Canadian environmental agency (Environment Canada, 2014) conclude that the examined pigments based on 3,3'-dichlorobenzidine are not released in the environment in quantities that would constitute a danger for the environment or human health.

Based on the given data, the impacted azo pigments are to be classified as “not water-polluting” (“nicht wassergefährdend/NWG”) regarding the water hazard class.

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The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e.g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e.g. silica), carbon black, ceramic and glass colours, food colorants, artists' and school paints, masterbatches and products for applied photocatalysis.