ETAD

Ecological and Toxicological Association of
Dyes and Organic Pigment Manufacturers

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To Whom it may concern
European Trades Union Confederation
European Trades Union Institute

Trade Union Priority List for REACH Authorisation

The aim of ETAD (The Ecological and Toxicological Association of Dyes and Pigments Manufacturer's) http://www.etad.com/index.php is to minimize possible negative effects on health and the environment arising from manufacture and use of synthetic organic colorants and to ensure information on the best practicable protection is provided to the purchasers of these products.

The Association has supported REACH since its inception and worked with the member companies to ensure a cost effective implementation. We would support also the replacement of substances shown scientifically to be of high concern; indeed in our code of ethics we write "The manufacture and sale of certain dyes identified as hazardous by regulation or classification by expert bodies is incompatible with ETAD membership. These dyes are referred to in Annexes A and B. (Attached) Member companies shall comply with the Code of Ethics and shall make every effort to ensure that their subsidiaries do so."

We have reviewed the substances in the Trade Union Priority List for REACH Authorisation and have concerns about the inclusion of two substances and would respectfully request that they are removed from the list.

The two substances of concern are

CAS: 3520-72-7

4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one] commonly referred to according it's Colour Index Generic name as C.I. Pigment Orange 13

and

CAS : 5468-75-7

2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide] commonly referred to according to its Colour Index Generic name as C.I. Pigment Yellow 14

The reason for inclusion in both cases is that they are classified as possible Carcinogens IARC 2A.

The data source used to document the Trade Union list was the RISCTOX database (http://www.istas.net/risctox/) which they write contains information on more than 100,000 chemicals. We have also been into this data base to look at the information present on these two substances.

Pigment Orange 13 (CAS: 3520-72-7)
http://www.istas.net/risctox/dn_risctox_ficha_sustancia.asp?id_sustancia=959138

Pigment Yellow 14 (CAS: 5468-75-7)
http://www.istas.net/risctox/dn_risctox_ficha_sustancia.asp?id_sustancia=959139

In both cases we see that they are assigned to Group 2A based on supplement 7 from 1987. Viz:

Grupo: 2A Volumen: (SUPL. 7; 1987) Notas: (NB: TODA LA EVALUACIÓN AUMENTADA DE 2B A 1 CON LA AYUDA DE LA EVIDENCIA DE OTROS DATOS RELEVANTES DE LA EVALUACIÓN DE CARCENOGENEICIDAD Y SUS MECANISMOS)

We have reviewed the IARC data base and can find no information or publication referring to these pigments. On the IARC website it is mentioned that the Suppl. 7 is superseded by Vol. 99. The Vol 99 has not been published yet.

Supplement 7 (http://monographs.iarc.fr/ENG/Monographs/suppl7/suppl7.pdf) from 1987 contains a section about BENZIDINE-BASED DYES (Group 2A):

" A. Evidence for carcinogenicity to humans (inadequate for benzidine-based dyes)

The epidemiological data were inadequate to evaluate the carcinogenicity of three benzidine-based dyes, Direct Black 38, Direct Blue 6 and Direct Brown 95, to humans. However, a study of silk dyers and painters who had had multiple exposure to benzidine-based and other dyes indicated that those exposures were strongly associated with the occurrence of bladder cancer [ref: 1].

B. Evidence for carcinogenicity to animals (sufficient for technical-grade Direct Black 38, technical-grade Direct Blue 6 and technical-grade Direct Brown 95)

Direct Black 38 was tested for carcinogenicity in mice by administration in drinking-water, producing liver and mammary tumours. Commercial Direct Black 38 produced hepatocellular carcinomas within 13 weeks after administration in the diet to rats and small numbers of carcinomas in the urinary bladder, liver and colon after administration to rats in drinking-water [ref: 1].
In a single study, commercial Direct Blue 6 produced hepatocellular carcinomas in rats within 13 weeks after its oral administration.
Commercial Direct Brown 95 produced neoplastic nodules in the livers of 4/8 female rats and a hepatocellular carcinoma in one, after its oral administration in a single study terminated after 13 weeks. The finding of preneoplastic lesions after such a short exposure prior indicates a carcinogenic effect similar to that of Direct Black 38 and Direct Blue 6 [ref: 1].

Overall evaluation
Benzidine-based dyes are *probably carcinogenic to humans (Group 2A)*.

Three benzidene-based dyes are mentioned viz: Direct Black 38, Direct Blue 6 and Direct Brown 95.

However the two substances at issue here are pigments and are based on 3,3'-Dichlorobenzidene.

Pigments and dyestuffs are quite different classes, while according to DIN they are both classified as colorants, dyestuffs are essentially soluble in the application media while pigments are insoluble and exist as a final divided crystalline particle. This is a critical difference which explains the lack of bioavailability of pigments vis-a-vis dyestuffs. Indeed the marketing and use directive (DIRECTIVE 2002/61/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 July 2002 amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (azocolourants) in the Annex specifically restricts its application to azo dyes."

As mentioned in the preamble ETAD believes that any possible negative effects on health and the environment should be minimized if necessary by restricting the manufacture and marketing of certain substances. However we also believe that all such decisions should be based on sound science.

As both these substances are not on the IARC list and additionally we do not see any sound scientific reasons for their inclusion in the Trades Union priority listing we would respectfully request that they be removed.

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Annex A

Azo dyes or preparations of azo dyes used in consumer applications, which contain, or release by reductive cleavage of azo bonds, more than 0.1 % of any of the following amines

CAS-No.	Name	EU (Annex I)	MAK III
60-09-3	4-Aminoazobenzene	Cat. 2	--
90-04-0	o-Anisidine	Cat. 2	Cat. 2
91-59-8	2-Naphthylamine	Cat. 1	Cat. 1
91-94-1	3,3’-Dichlorobenzidine	Cat. 2	Cat. 2
92-67-1	4-Aminobiphenyl	Cat. 1	Cat. 1
92-87-5	Benzidine	Cat. 1	Cat. 1
95-53-4	o-Toluidine	Cat. 2	Cat. 2
95-69-2	4-Chlor-o-toluidine	--	Cat. 1
95-80-7	4-Methyl-1,3-phenylenediamine	Cat. 2	Cat. 2
97-56-3	o-Aminoazotoluene	Cat. 2	Cat. 2
99-55-8	5-Nitro-o-toluidine	--	Cat. 2
101-14-4	4,4’-Methylene-bis-(2-chloraniline)	Cat. 2	Cat. 2
101-77-9	4,4’-Methylenedianiline	Cat. 2	Cat. 2
101-80-4	4,4’-Oxydianiline	--	Cat. 2
106-47-8	4-Chloroaniline	Cat. 2	Cat. 2
119-90-4	3,3’-Dimethoxybenzidine	Cat. 2	Cat. 2
119-93-7	3,3’-Dimethylbenzidine	Cat. 2	Cat. 2
120-71-8	p-Cresidine	--	Cat. 2
137-17-7	2,4,5-Trimethylaniline	--	Cat. 2
139-65-1	4,4’-Thiodianiline	--	Cat. 2
615-05-4	4-Methoxy-m-phenylenediamine	--	Cat. 2
838-88-0	4,4'-Methylenedi-o-toluidine	Cat. 2	Cat. 2

Annex B

Individual Dyestuffs

CAS-No.	C.I. No.	C.I. Name	EU (Annex I)	MAK III	IARC
569-61-9	42500	Basic Red 9	Cat. 2	--	Group 2b
3761-53-3	16150	Acid Red 26	--	--	Group 2b
60-11-7	11020	Solvent Yellow 2	--	--	Group 2b
6358-53-8	12156	Solvent Red 80	--	--	Group 2b

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