

Annex XV SVHC dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name(s): Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] - 5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)

EC Number(s): 217-710-3

CAS Number(s): 1937-37-7

Submitted by: The Netherlands

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EC Number(s): 217-710-3

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The substance is proposed to be identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen category 1B.

Summary of how the substance meets the criteria set out in Article 57 (a) of REACH (Carcinogen 1B)

Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38) is listed by Index number 611-025-00-7 in Regulation (EC) No 1272/2008¹ and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as carcinogen, Carc. 1B (H350: “May cause cancer”).

Therefore, this classification of C.I. Direct Black 38 in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57(a) of REACH.

Registration dossiers submitted for the substance:

The substance is not registered within REACH.

¹ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

PART I

JUSTIFICATION

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

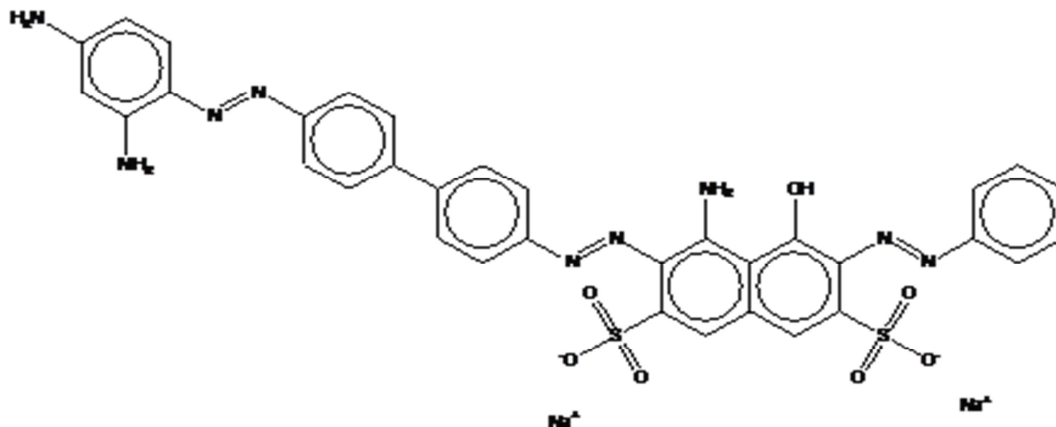
1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	217-710-3
EC name:	C.I. Direct Black 38; Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] - 5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate
CAS number (in the EC inventory):	1937-37-7
CAS number:	1937-37-7 (Deleted CAS numbers: 61701-15-3, 220970-37-6)
CAS name:	2,7-Naphthalenedisulfonic acid, 4-amino-3-[2-[4'-[2-(2,4-diaminophenyl)diazenyl][1,1'-biphenyl]-4-yl]diazenyl]-5-hydroxy-6-(2-phenyldiazenyl)-, sodium salt (1:2)
IUPAC name:	Disodium 4-amino-3-({4'-[(2,4-diaminophenyl)azo](1,1'-biphenyl)-4-yl}azo)-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate
Index number in Annex VI of the CLP Regulation	611-025-00-7
Molecular formula:	C ₃₄ H ₂₅ N ₉ Na ₂ O ₇ S ₂
Molecular weight range:	781.7 g/mol
Synonyms:	<i>Ahco Direct Black GX; Airedale Black ED; Aizen Direct Deep Black EH; Aizen Direct Deep Black GH; Aizen Direct Deep Black RH; Amanil Black GL; Amanil Black WD; Apomine Black GX; Atlantic Black BD; Atlantic Black C; Atlantic Black E; Atlantic Black EA; Atlantic Black GAC; Atlantic Black GG; Atlantic Black GXCW; Atlantic Black GXOO; Atlantic Black SD; Atul Direct Black E; Azine Deep Black EW; Azocard Black EW; Azomine Black EWO; Belamine Black GX; Bencidal Black E; Benzanil Black E; Benzo Deep Black E; BenzoLeather Black E; Benzoform Black BCN-CF; Black 2EMBL; Black 4EMBL; Brasilamina Black GN; Brilliant Chrome Leather Black H; C.I. 30235; C.I. Direct Black 38, disodium salt; Calcomine</i>

Black; Calcomine Black EXL; Carbide Black E; Chloramine Black C; Chloramine Black EC; Chloramine Black ERT; Chloramine Black EX; Chloramine Black EXR; Chloramine Black XO; Chloramine Carbon Black S; Chloramine Carbon Black SJ; Chloramine Carbon Black SN; Chlorazol Black E; Chlorazol Black EA; Chlorazol Black EN; Chlorazol Burl Black E; Chlorazol Leather Black ENP; Chlorazol Silk Black G; Chlorazol Black E; Chrome Leather Black E; Chrome Leather Black EC; Chrome Leather Black EM; Chrome Leather Black G; Chrome Leather Brilliant Black ER; Coir Deep Black; Columbia Black EP; Coranil Direct Black F; Diacotton Deep Black; Diacotton Deep Black RX; Diamine Deep Black EC; Diamine Direct Black E; Diaphtamine Black V; Diazine Black E; Diazine Direct Black E; Diazine Direct Black G; Diazol Black 2V; Diphenyl Deep Black G; Direct Black A; Direct Black BRN; Direct Black CX; Direct Black CXR; Direct Black E; Direct Black EW; Direct Black EX; Direct Black FR; Direct Black GAC; Direct Black GW; Direct Black GX; Direct Black GXR; Direct Black JET; Direct Black Meta; Direct Black methyl; Direct Black N; Direct Black RX; Direct Black SD; Direct Black WS; Direct Black Z; Direct Black ZSh; Direct Deep Black E; Direct Deep Black E Extra; Direct Deep Black E-EX; Direct Deep Black EA-CF; Direct Deep Black EAC; Direct Deep Black EW; Direct Deep Black EX; Direct Deep Black WX; Enianil Black CN; Erie Black B; Erie Black BF; Erie Black GAC; Erie Black GXOO; Erie Black JET; Erie Black NUG; Erie Black RXOO; Erie Brilliant Black S; Erie Fibre Black VP; Fenamin Black E; Fibre Black VF; Fixanol Black E; Formaline Black C; Formic Black C; Formic Black CW; Formic Black EA; Formic Black MTG; Formic Black TG; Hispamin Black EF; Interchem Direct Black Z; Kayaku Direct Deep Black EX; Kayaku Direct Deep Black GX; Kayaku Direct Deep Black S; Kayaku Direct Leather Black EX; Kayaku Direct Special Black AAX; Lurazol Black BA; Meta Black; Mitsui Direct Black EX; Mitsui Direct Black GX; Nippon Deep Black; Nippon Deep Black GX; Paper Black BA; Paper Black T; Paper Deep Black C; Paramine Black B; Paramine Black E; Peeramine Black E; Peeramine Black GXOO; Phenamine Black BCN-CF; Phenamine Black CL; Phenamine Black E; Phenamine Black E 200; Pheno Black EP; Pheno Black SGN; Pontamine Black E; Pontamine Black

	<i>EBN; Sandopel Black EX; Seristan Black B; Telon Fast Black E; Tetrodirect Black E; Tetrodirect Black EFD; Tetrazo Deep Black G; Union Black EM; Vondacel Black N</i>
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Structural formula:**1.2 Composition of the substance**

Name: C.I. Direct Black 38; Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate

Description: benzidine-based dye

Substance type: mono-constituent

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate 217-710-3	≥80%		

1.3 Physico-chemical properties

Very limited physical and chemical data is available for this substance. A read-across approach using data from selected analogues was used to estimate physical and chemical properties, given that they too are disulfonated dyes.

Table 3: Overview of physicochemical properties

Property	Value	Remarks	Literature
Physical state at 20°C and 101.3 kPa	Grey-black powder	At 25°C	Environment Canada, 2009
Melting/freezing point	>360°C		Environment Canada, 2009
Boiling point	>200°C	Not experimentally determined, read across	Environment Canada, 2009
Vapour pressure	No data		
Water solubility	93 000 mg/L	15-25°C	Environment Canada, 2009
Partition coefficient n-octanol/water (log value)	< 3	Azo dyes at 25°C, read-across value	Environment Canada, 2009
Dissociation constant	No data		

2 HARMONISED CLASSIFICATION AND LABELLING

Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphtalene-2,7-disulphonate is listed by Index number 611-025-00-7 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

Table 4: Harmonised classification according to part 3 of Annex VI, Table 3.1 of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	Classification		Labelling	
		Hazard Class and Category Code(s)#	Hazard statement code(s)##	Pictogram, Signal Word Code(s)	Hazard statement code(s) Suppl.
611-025-00-7	disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphtalene-2,7-disulphonate; C.I. Direct Black 38	Carc. 1B Repr. 2	H350 H361d ***	GHS08 Dgr	H350 H361d ***

Hazard Class and Category Code: Carc 1B
Repr. 2 Presumed to have carcinogenic potential for humans
Suspected human reproductive toxicant

Hazard statement Code: H350: May cause cancer
H361d: Suspected of damaging the unborn child
***: In order not to lose information from the harmonised
classifications for fertility and developmental effects
under Directive 67/548/EEC, the classifications have
been translated only for those effects classified under
that Directive.

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant for the identification of the substance as SVHC in accordance with Article 57a.

4 HUMAN HEALTH HAZARD ASSESSMENT

See section 2 on harmonised classification and labelling.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for the identification of the substance as SVHC in accordance with Article 57a.

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 CMR assessment

C.I. Direct Black 38; Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] - 5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate is listed by Index number 611-025-00-7 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as carcinogen, Carc. 1B (H350: “May cause cancer”).

The classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for the identification as SVHC in accordance with Article 57 (a) of REACH.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

INFORMATION ON MANUFACTURE, IMPORT/EXPORT AND USES –CONCLUSIONS ON EXPOSURE

MANUFACTURE, IMPORT/EXPORT

The substance is not registered under REACH, despite the relevant registration deadline having passed. The extent of EU manufacture and use of the substance and mixtures containing the substance may therefore be relatively limited. According to Environment Canada (2009), manufacturers began phasing out the use of benzidine-based dyes such as C.I. Direct Black 38 in the mid to late 1970s and replacing them with other dyes due to human health concerns. However, an internet search for the substance indicates that it is still marketed for use based on chemicals suppliers' websites. Several companies supplying Direct Black 38 have been consulted. Two companies confirmed that the substance is not manufactured in the EU but imported to the EU, with the total amount less than 500 kg. Potential for consumer exposure to this substance primarily relates to the potential for import of consumer products containing the substance, such as imported textiles or leather. The extent of the presence of the substance in imported articles, and the associated potential for exposure of consumers is unknown.

USES

Direct Black 38, a benzidine-based dye, can be used to: (1) dye cellulose, wool, silk, bast, and hog's hair; (2) print cellulose, wool and silk; (3) dye leather, plastics, vegetable-ivory buttons and wood flour used as a resin filler; (4) stain wool, silk, acetate, nylon, wood and biological materials, and (5) produce aqueous inks. It has reportedly been used in hair dyes.

Direct Black 38 has a high affinity for cellulose and has historically been used for the dyeing of textiles, leather and paper (HSDB, 2012). It is a benzidine-based dye; such substances are known to be cleaved metabolically to benzidine, a carcinogenic substance (Carc 1A by harmonized classification). Data obtained from the Dutch Food and Product Safety Authority (NVWA; see table 5) show that even after 1998, aromatic amines have been detected in textile and leather consumer articles, indicating azodyes are still used. Additionally, nearly all articles for which RAPEX alerts were issued in 2009-2012 because of too high levels of benzidine, came from China or India (table 6). This underpins the general expectation that azodyes are mostly used in countries outside the EU (e.g. Dapson, 2009), from where products are then imported into the EU. It is noted that current use of the substance in consumer products is relatively limited. Direct Black 38 is prohibited from use in cosmetics products under Regulation (EC) No 1223/2009. Furthermore, benzidine based azo dyes including Direct Black 38 are covered by the entry 43 ("Azocolourants and Azodyes") of Annex XVII of the REACH Regulation, according to which azodyes which, by reductive cleavage of one or more azo groups, may release one or more of 22 listed (in Appendix 10 of REACH) aromatic

amines, in concentrations above 30 mg/kg (0.003 % by weight) in the articles or in the dyed parts thereof shall not be used in textile and leather articles which may come in direct and prolonged contact with the human skin or oral cavity (additionally, such articles shall not be placed on the market). In the ECHA classification and labelling inventory 30 notifications of Direct Black 38 are indicated (i.e. notifications on behalf of 30 legal entities), all reporting the harmonised classification and labelling. This illustrates that the substance is used by a considerable number of European companies, but in volumes below 1 ton per year.

Table 5: Overview of results of analyses of consumer products for the aromatic amines indicative of azodye presence over the last 18 years (kindly provided by the Dutch Food and Product Safety Authority (NVWA)).

Year of study	Type of products analyzed	Country of sampling	No. of products	No. of products with aromatic amines	% of products with aromatic amines	No. of products with benzidine	% of products with benzidine	Maximum detected level of benzidine (mg/kg)	Ref. ²
1995	Clothing	NL	132	6	5%	n.a.	n.a.	n.a.	KvW, 1995
1996	Clothing	NL	200	15	8%	n.a.	n.a.	n.a.	KvW, 1996
1997	Clothing	NL	116	13	11%	n.a.	n.a.	n.a.	KvW, 1997
1999	Textile and leather products, toys	NL	160	4	3%	n.a.	n.a.	n.a.	Consumentenbond, 1999
2000	Clothing	NL	141	n.a.	n.a.	n.a.	n.a.	n.a.	KvW, 2000
2001	Leather clothing and other leather products	NL	70	9	13%	n.a.	n.a.	n.a.	KvW, 2001
2003	Leather working gloves	NL	31	6	19%	n.a.	n.a.	< 30	VWA, 2003
2003	Leather working gloves	NL	109	17	16%	n.a.	n.a.	1403	VWA, 2004a
2004	Toys with textile and leather, that are expected to be mouthed	NL	54	4	7%	n.a.	n.a.	< 30	VWA, 2004b
2004	Textile and (artificial) leather consumer products, e.g. wallets, bags, belts, gloves and watchstraps	NL	65	12	18%	n.a.	n.a.	1857	VWA, 2004c
2004	Textile products that come into contact with the skin, mainly brightly coloured ones	NL	341	11	3%	n.a.	n.a.	47	VWA, 2005a
2005	Underwear	NL	83	10	12%	1	1,2%	21	VWA, 2005b
2005	Clothing from third world shops	NL	59	23	39%	17	28,8%	2746	VWA, 2005c
2006	Textile products from army and navy dump shops	NL	99	8	8%	5	5,1%	552	VWA, 2007a
2006	Textile (and leather) articles from big chins of stores with cheap articles + 1 expensive bed store	AT	48	0 ¹	0% ¹	0	0,0%	< 30	CLEEN, 2007
2006	Textile and leather articles, wide range, and 2 colouring agents	DK	40	0 ¹	0% ¹	0	0,0%	< 30	CLEEN, 2007

2006	Textile and leather articles from companies importing cheap products, mainly from China	EE	17	0 ¹	0% ¹	0	0,0%	< 30	CLEEN, 2007
2006	Textile and leather articles, mostly imported	GR	105	2 ¹	2% ¹	n.a.	n.a.	n.a.	CLEEN, 2007
2006	Textile and leather articles from low-price stores or shops with direct import from Asia	NO	40	0 ¹	0% ¹	0	0,0%	< 30	CLEEN, 2007
2006	Textile and leather articles, mostly from Poland itself	PL	30	1 ¹	3% ¹	0	0,0%	< 30	CLEEN, 2007
2007	Sports clothing	NL	141	2	1%	2	1,4%	1515	VWA, 2007b
2008	Childrens clothing	NL	181	0	0%	n.a.	n.a.	n.a.	VWA, 2008
2009	Leather clothing	NL	44	2	5%	1	2,3%	2229	VWA, 2009
2011	Scarfs and jeans	NL	108	7	6%	5	4,6%	1170	VWA, 2011

n.a. = not available;

¹ = only levels >30 mg/kg legal threshold were considered

² References:CLEEN (Chemical Legislation European Enforcement Network), 2007, “Eurazos. Final report”.

Dutch Food and Product Safety Authority (Voedsel en Warenautoriteit, VWA), 2003, report ND03r015-02.

Dutch Food and Product Safety Authority (VWA), 2004a, “Handhavingsactie azo-kleurstoffen in werkhandschoenen [Enforcement action azodyes in working gloves]”, report ND03r015-03.

Dutch Food and Product Safety Authority (VWA), 2004b, “Handhavingsactie azo-kleurstoffen in speelgoed [Enforcement action azodyes in toys]”, report ND04o052-02.

Dutch Food and Product Safety Authority (VWA), 2004c, “Handhavingsactie azo-kleurstoffen in textiel en lederwaren [Enforcement action azodyes in textile and leather articles]”, report ND04o052-01.

Dutch Food and Product Safety Authority (VWA), 2005a, “Azo-kleurstoffen in textiel [Azodyes in textile]”, report ND04o052-03.

Dutch Food and Product Safety Authority (VWA), 2005b, “Azo-kleurstoffen in onderkleding [Azodyes in underwear]”, factsheet dated april 2006 (confidential).

Dutch Food and Product Safety Authority (VWA), 2005c, “Handhavingsactie azo-kleurstoffen in 3e wereldwinkel kleding [Enforcement action azodyes in 3d world shop clothing]”, report ND05o502.

Dutch Food and Product Safety Authority (VWA), 2007a, “Azocolourants in textile. Dutch contribution to the CLEEN project Eurazos”, factsheet dated February 2007.

Dutch Food and Product Safety Authority (VWA), 2007b, report ND071915.

Dutch Food and Product Safety Authority (VWA), 2008, report ND08191B.

Dutch Food and Product Safety Authority (VWA), 2009, report ND09191D-3.

Dutch Food and Product Safety Authority (VWA), 2011, report PHNT1106.

Dutch Food and Product Safety Authority (Keuringsdienst van Waren, KvW), 1995, report TX 12.

Dutch Food and Product Safety Authority (KvW), 1996, report TX 18.

Dutch Food and Product Safety Authority (KvW), 1997, report TX 19.

Dutch Food and Product Safety Authority (KvW), 2000, report ND TEX 002/01

Dutch Food and Product Safety Authority (KvW), 2001, report ND TEX 002/02

Dutch Union of Consumers [Consumentenbond], 1999, [Consumentengids april 1999, p. 48 – 50.](#)

Table 6. Cases where benzidine was found in consumer articles in the EU in 2009-2012 (RAPEX)

Year	Notifying country	Product	Country of origin	Benzidine level
2009	Germany	Baseball cap	China	598 mg/kg
2009	Finland	White scarf with print	China	180 mg/kg
2009	Finland	Green scarf	India	880 mg/kg
2009	Finland	Red scarf	India	880 mg/kg
2009	Finland	Red scarf	India	210 mg/kg
2009	Germany	Work gloves	Unknown	208 mg/kg
2009	Germany	Red silk scarf	China	124 mg/kg
2009	Germany	Black silk scarf	Unknown	617 mg/kg
2009	Germany	Black leather gloves	China	1.504 mg/kg
2009	Finland	Red-black scarf and blue-green scarf	India	44 and 240 mg/kg
2009	Finland	Red part of striped bedspread	China	740 mg/kg
2009	Finland	Dark blue scarf and orange scarf	India	590 mg/kg and 210 mg/kg
2009	Finland	Scarf with pattern	China	460 mg/kg
2009	Finland	Turquoise and blue colours in 2 scarves	India	100-230 mg/kg
2010	Germany	Pink silk scarf	India	130 mg/kg
2010	Denmark	Red scarf	India	196 mg/kg
2010	Finland	Scarf	India	660 mg/kg
2010	Germany	Black leather gloves	China	344 mg/kg
2010	Germany	Black leather purse	India	390 mg/kg
2010	Germany	Decorated floral scarf	India	96.7 mg/kg
2010	Finland	Grey scarf	India	100 mg/kg
2010	Germany	Red dress	China	88.9 mg/kg
2010	Finland	Red silk scarf and purple silk scarf	India	77 and 96 mg/kg
2010	Finland	Black scarf	China	400 mg/kg
2010	Finland	Navy blue T-shirt and red T-shirt	India	1100 and 910 mg/kg
2010	Germany	Black blouse	China	1571 mg/kg
2011	Finland	Black scarf	India	4500 mg/kg
2011	Bulgaria	Sports shoes	China	52.1 mg/kg
2011	Germany	Jeans	China	48 mg/kg
2011	Greece	Ladies dress	India	59 mg/kg
2011	The Netherlands	Black scarf	India	1170 mg/kg

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2011	Germany	Towel	India	1 501 mg/kg
2011	Finland	Bed spreads and cushion cover	India	130-210 mg/kg
2011	Greece	Men black T-shirt	Syria	4118 mg/kg
2011	Cyprus	Blue childrens' s T-shirt	China	100 mg/kg
2011	Germany	Black hat	China	189 mg/kg
2011	Spain	Denim dress	Bangladesh	1 183 ppm
2011	Cyprus	Black dress	Greece	500 mg/kg
2011	Hungary	Black scarf	India	3730 mg/kg
2011	Cyprus	Red scarf and blue scarf	India	Both 400 mg/kg
2011	Denmark	Green cardigan	China	1248,7 mg/kg
2011	Denmark	Children's sweatshirt	India	219,21 ppm
2012	Hungary	Leather bracelet	India	590 mg/kg
2012	Hungary	Men's leather wrist band	China	48.9 mg/kg
2012	Hungary	Black leather wristband	China	801.6 mg/kg
2012	Poland	Jeans	Germany	84.5 mg/kg

CURRENT KNOWLEDGE ON ALTERNATIVES

Relatively little information on specific alternatives to Direct Black 38 has been identified following a rapid review of the literature. However, it is clear that the substance has and can be replaced by alternative dye products for EU (and North American and Japanese) textile dyeing products.

It is important to note, however, that there are indications that benzidine-based dyes such as Direct Black 38 are still widely used in other parts of the world, including amongst countries that are significant exporters of textile products to the EU (Dapson, 2009).

One source indicates that the cost of Direct Black 38 was around \$US3 per kg whereas the cost of Direct Black 22 (which does not contain benzidine) is around \$US8-10 per kg (OECD, 2005).

RISK-RELATED INFORMATION

No EU risk assessments for the substance have been identified for Direct Black 38. A screening risk assessment related to the environment has been developed by the Canadian Government (Environment Canada, 2009). Based on reported use patterns and certain assumptions related to dyes in general, potential releases of Direct Black 38 to the Canadian environment during the formulation and consumer use of products containing this substance are estimated to be 15% to sewers and 85% transferred to waste disposal sites. Direct Black 38 is an azo dye with two sulfonic acid groups, which dictate its adsorption characteristics and impart high water solubility. Dyes have an inherently high affinity to substrates, and a potentially large proportion can be removed during sewage treatment as a result of such substances being adsorbed to sludge. A conservative exposure scenario was selected in which an industrial operation discharges this substance into the aquatic environment through a single sewage treatment plant. While there were no reports of Direct Black 38 being in commerce, the reporting threshold of 100 kg was used to conservatively estimate release and exposure levels. The predicted environmental concentration in water of this substance was below the predicted no-effect concentration for sensitive aquatic organisms, resulting in a risk quotient of much lower than one. It is concluded that Direct Black 38 is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

In order to assess potential risks associated with this substance, information on physicochemical properties was used to derive estimates of potential worst case consumer exposure using ECETOC-TRA and Consexpo software. This “indicative” risk characterisation then considered the exposure assessments and the DNEL or DMEL values obtained from the literature. No DNEL/DMEL values were found in the literature for Direct Black 38. Instead, a NSLR (No Significant Risk Level) from the California OEHHA Toxicity Criteria Database of 1.5×10^{-6} mg/kg bw/day (oral) was used as a basis for comparison with the exposure estimates. The “indicative” worst-case exposure estimates and risk characterization ratios derived using ECETOC-TRA and Consexpo software are:

- Clothing: 37 mg/kg/day (dermal) and 0.16 mg/kg/day (oral) with an RCR of 2.5×10^7
- Leather furniture: 5.5 mg/kg/day (dermal) with an RCR of 3.7×10^6
- Printed paper: 3.3×10^{-4} mg/kg/day (dermal plus oral) with an RCR of 220

Based on the above, it is clear that this screening level risk assessment indicates potential exposure significantly higher than established no significant risk levels. However, the above should be treated with caution given that NSRL values are based on a risk level of 1 in 10^5 , so the RCRs could never in practice be as high as those calculated here. This suggests that, if there is a real indication that the substance is still used in the EU, further refinement of the exposure and potentially hazard data would be required before any robust conclusions could be drawn on the likely scale of such risks.

The risk characterisation ratios noted for some of the uses are very high, at least in part due to the high default values used in the models, particularly in cases where little or no information was available on, for example, typical use concentrations. Very low no/minimal effects levels reported in the literature also leads to high risk characterisation ratios.

Overall, taking a worst case screening level exposure assessment, it appears that there could be some potential for unacceptable risks related to the use of the substance in consumer products. However, it should be noted that there is minimal information available on current uses in consumer products, and that the exposure and hazard elements of the risk characterisation have not been refined.

Furthermore, the exposure assessment approaches used are generally based on worst-case default assumptions in relevant models used in the context of REACH. There is considered to be significant potential to further refine the estimated levels of exposure, which would in turn provide additional information on the potential risks.

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