

Substance Name: 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: 217-710-3

CAS Number: 1937-37-7

SUPPORT DOCUMENT FOR IDENTIFICATION OF

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)

**AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS
CMR¹ PROPERTIES**

¹ CMR means carcinogenic, mutagenic or toxic for reproduction

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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

The substance is 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 1272/2008² 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.

² 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.

JUSTIFICATION

1. Identity of the substance and physical and chemical properties

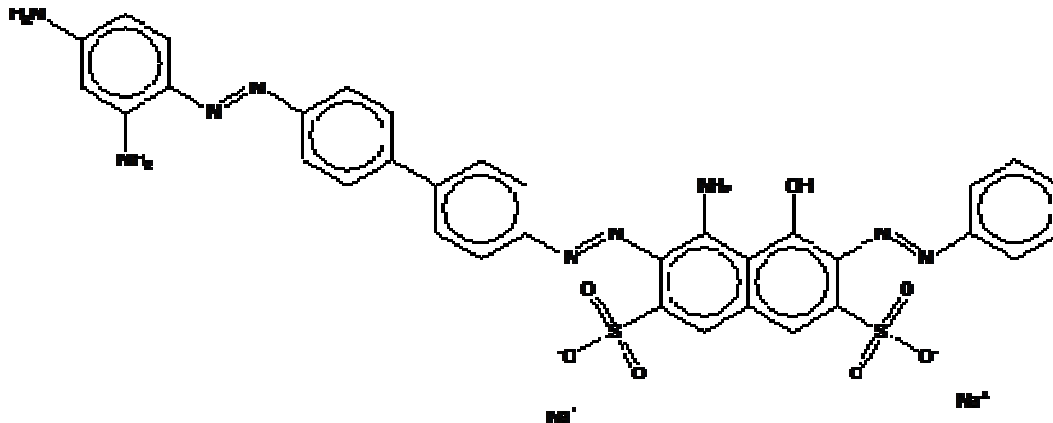
1.1. Name and other identifiers of the substance

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; Benzofom 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; DirectBlack 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 Calcomine 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;</i>

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 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 EBN; Sandopel Black EX; Seristan Black B; Telon Fast Black E; Tertrodirect Black E; Tertrodirect Black EFD; Tetrazo Deep Black G; Union Black EM; Vondacel Black N

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:

Repr. 2

Carc 1B Presumed to have carcinogenic potential for humans
Suspected human reproductive toxicant

Hazard statement Code:

H350:
H361d:
child
***:

May cause cancer
Suspected of damaging the unborn

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.

REFERENCES

Environment Canada (2009): Screening Assessment for the Challenge – 2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt (Direct Black 38), Environment Canada and Health Canada, November 2009.

OECD (2005): Environmental requirements and market access.