

Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 4 March 2021

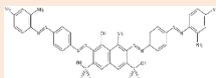
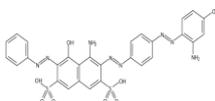
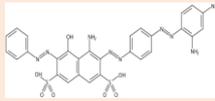
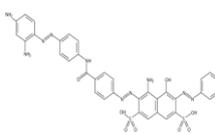
Group Name: Diazo amino hydroxyl naphthalenedisulfonic acid dyes

General structure: -

Revision history

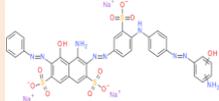
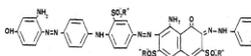
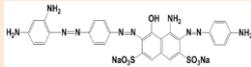
<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	4 March 2021	

Substances within this group:

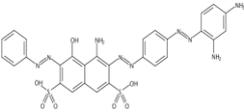
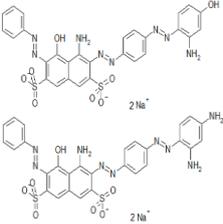
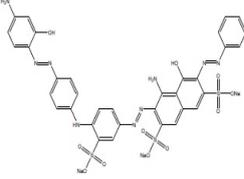
EC/List number	CAS number	Substance name [Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
229-208-1	6428-31-5	disodium 4-amino-3,6-bis[[4-[(2,4-diaminophenyl)azo]phenyl]azo]-5-hydroxynaphthalene-2,7-disulphonate/ [Direct Black 19]		Full, 10-100
270-629-5	68460-07-1	Disodium 4-amino-3-[[4-[(2-amino-4-hydroxyphenyl)azo]phenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate [Direct Black 155]		C&L notification
272-559-0	68877-33-8	disodium 4-amino-3-[[4-[(2,4-diaminophenyl)azo]phenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate [Direct Black RBB]		Full, not (publicly) available
276-529-8	72245-56-8	4-amino-3-[[4-[[[4-(2,4-diaminophenyl)azo]phenyl]amino]carbonyl]phenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonic acid, sodium salt [Direct Black 166]		Full, not (publicly) available

¹Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

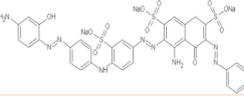
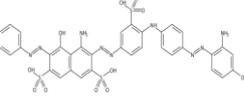
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EC/List number	CAS number	Substance name [Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
297-025-4	93281-13-1	2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-, coupled with 3-aminophenol, diazotized 5-amino-2-[(4-aminophenyl)amino]benzenesulfonic acid and diazotized benzenamine, sodium salts Direct Black 168		Full, 10-100
406-000-0	173939-66-7	A 2:1 mixture of: tris(3,5,5-trimethylhexylammonium)-4-amino-3-(4-(4-(2-amino-4-hydroxyphenylazo)anilino)-3-sulfonatophenylazo)-5,6-dihydro-5-oxo-6-phenylhydrazononaphthalene-2,7-disulfonate; tris(3,5,5-trimethylhexylammonium)-4-amino-3-(4-(4-(4-amino-2-hydroxyphenylazo)anilino)-3-sulfonatophenylazo)-5,6-dihydro-5-oxo-6-phenylhydrazononaphthalene-2,7-disulfonate [Direct Black 184]		NONS, not (publicly) available
812-037-7	1793011-72-9	reaction products of diazotized 4-amino-6-[(4-aminophenyl)diazenyl]-3-[(4-aminophenyl)diazenyl]-5-hydroxynaphthalene-2,7-disulfonic acid, coupled with benzene-1,3-diamine, sodium salts		Full, not (publicly) available

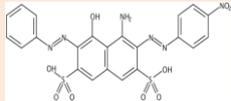
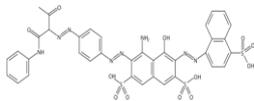
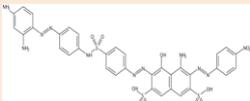
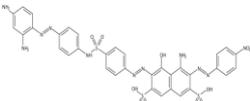
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EC/List number	CAS number	Substance name [Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
		WLBK191L (Direct type)		
824-263-3	2196165-14-5	[x Sodium, y Potassium, z Lithium, x+y+z =2] 4-amino-3-[[[(2,4-diaminophenyl)diazenyl]phenyl]diazenyl]-5-hydroxy-6-(phenyldiazenyl)naphthalene-2,7-disulfonate		Full, 10-100
916-632-3		reaction mass of disodium 4-amino-3-[[4-[(2,4-diaminophenyl)azo]phenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate and disodium 4-amino-3-[[4-[(2-amino-4-hydroxyphenyl)azo]phenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate [Aluminium Black CRO (Direct type)]		Full, not (publicly) available
925-141-3		Reaction mass of trisodium 4-amino-3-[[4-[[4-[(2-amino-4-hydroxyphenyl)azo]phenyl]amino]-3-sulphonatophenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate and trisodium 4-amino-3-[[4-[[4-[(4-amino-2-hydroxyphenyl)azo]phenyl]amino]-3-sulphonatophenyl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate [DirectBlack 168]		Full, not (publicly) available

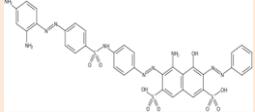
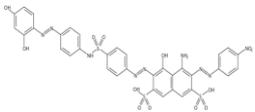
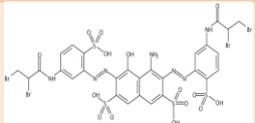
ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name [Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
941-211-6		<p>Reaction mass of trisodium; (6E)-4-amino-3-[[4-[4-[(2E)-2-(4-amino-6-oxocyclohexa-2,4-dien-1-ylidene)hydrazinyl]anilino]-3-sulfonatophenyl]diazenyl]-5-oxo-6-(phenylhydrazinylidene)naphthalene-2,7-disulfonate and trisodium;(6E)-4-amino-3-[[4-[4-[(2E)-2-(2-amino-4-oxocyclohexa-2,5-dien-1-ylidene)hydrazinyl]anilino]-3-sulfonatophenyl]diazenyl]-5-oxo-6-(phenylhydrazinylidene)naphthalene-2,7-disulfonate and trisodium 5-amino-6-((E)-(4-(4-((E)-(4-amino-2-hydroxyphenyl)diazenyl)phenylamino)-3-sulfonatophenyl)diazenyl)-4-oxo-3-((E)-(4-((E)-phenyldiazenyl)phenyl)diazenyl)-1,4-dihydronaphthalene-2,7-disulfonate</p> <p>[Direct Black RC]</p>		Full, not (publicly) available
411-890-9	108936-08-9	<p>A mixture of: trilithium 4-amino-3-((4-((4-((2-amino-4-hydroxyphenyl)azo)phenyl)amino)-3-sulfophenyl)azo)-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulfonate; trilithium 4-amino-3-((4-((4-((4-amino-2-hydroxyphenyl)azo)phenyl)amino)-3-</p>		NONS, not (publicly) available N/A

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name [Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
		sulfophenyl)azo)-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulfonate [Direct Black 168 (3Li)]		
213-903-1	1064-48-8	sodium 4-amino-5-hydroxy-3-(4-nitrophenylazo)-6-(phenylazo)naphthalene-2,7-disulphonate [Acid Black 1]		Full, 1-10
279-093-7	79135-92-5	trisodium 4-amino-5-hydroxy-3-[[4-[[[2-oxo-1-[(phenylamino)carbonyl]propyl]azo]phenyl]azo]-6-[(4-sulphonato-1-naphthyl)azo]naphthalene-2,7-disulphonate [Acid Green 111]		Full, 1-10
286-384-2	85223-29-6	4-amino-6-[[4-[[[4-[(2,4-diaminophenyl)azo]phenyl]amino]sulphonyl]phenyl]azo]-5-hydroxy-3-[(4-nitrophenyl)azo]naphthalene-2,7-disulphonic acid, potassium salt [Acid Black 210]		C&L notification
421-880-6	201792-73-6	disodium 4-amino-6-((4-((4-(2,4-diaminophenyl)azo)phenylsulfamoyl)phenyl)azo)-5-hydroxy-3-((4-nitrophenyl)azo)naphthalene-2,7-disulfonate [Acid Black 210 Na]		Full, 100-1000

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EC/List number	CAS number	Substance name [Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
605-104-5	157577-99-6	2,7-Naphthalenedisulfonic acid, 4-amino-3-[2-[4-[[[4-[2-(2,4-diaminophenyl)diazenyl]phenyl]sulfonyl]amino]phenyl]diazenyl]-5-hydroxy-6-(2-phenyldiazenyl)-, sodium salt (1:2) [Acid Black 234 RC]		Full, 100-1000
940-267-9	1397283-80-5	disodium 4-amino-6-{[4-({4-[(2,4-dihydroxyphenyl)diazenyl]phenyl}sulfamoyl)phenyl]diazenyl}-5-hydroxy-3-[(4-nitrophenyl)diazenyl]naphthalene-2,7-disulfonate [Acid Green 068]		Full, 1-10
403-940-3		[Reactive black 47]		Full, not (publicly) available

This table contains also group members that are only notified under the CLP Regulation. However, the list is currently non-exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website².

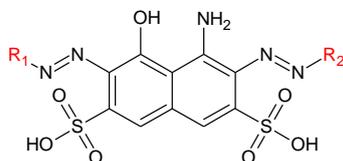
² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

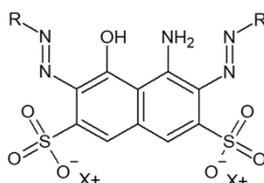
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the Diazo amino hydroxyl naphthalenedisulfonic acid moiety shown in the figure below.



The substituents of the azo groups include in most cases several azo bonds (Figure 1 below). The group covers three classes of azo dyes³ which are characterised by different ways to create bonds with the fibres. The different classes are described below together with relevant information on their uses, based on what was reported in the respective REACH registration dossiers.



Direct	Acid	Reactive
<p>R=</p> <p>X= Na, K</p>	<p>R=</p> <p>X= Na, K, Li</p>	<p>R=</p> <p>X= Na, K</p>

Figure 1- Structure of the substances of the different dyes classes present in the Diazo amino hydroxyl naphthalenedisulfonic acid dyes group.

³ https://www.ec.gc.ca/ese-ees/9E759C59-55E4-45F6-893A-F819EA9CB053/Azo_Technical%20Background_EN.pdf

- **Direct azo dyes** (11 substances): Large molecules with multiple azo bonds that attach to fibres mostly via van der Waals forces and hydrogen bonding between e.g amine, hydroxy groups in the dye and the fibre, in alkaline or neutral conditions. Principal uses of direct dyes are the colouring of paper, cellulosic textile fibres (e.g. cotton and rayon) and leather. All direct dyes are used by professionals, consumers and/or are present in articles, with a high potential for exposure to the parent compound and their breakdown products via cleavage of the azo bonds.
- **Acid azo dyes** (7 substances): Like direct dyes, but bond with fibres not only via hydrogen bonding, but also through ionic bonds of one or more sulfonic functional groups with amide groups of the fibres, in acidic pH conditions. Creating stronger bonds to the fibres, as compared to direct dyes. Acid dyes are used in dyeing of nylon, wool, silk and modified acrylic fibres. To a lesser extent, acid dyes may also be used in paints, inks, plastics and leather. Also these substances are used by professionals, consumers and/or are present in articles, with a high potential for exposure to the parent compound and their breakdown products via cleavage of the azo bonds.
- **Reactive azo dyes** (1 substance): Contain reactive groups (e.g. -Cl, -Br, -SH, -OCH) that bond covalently to hydroxyl, sulfhydryl and amino groups in fibres, in alkaline conditions. This type of dyes creates the strongest bonds with fibres and result in brighter and longer lasting colours. The principal uses are in dyeing of cellulosic textile fibres (e.g. cotton and rayon). The only reactive azo dye of the group is used by professionals and is present in textile articles. Due to the strong bonds with the textile material, the potential for exposure to humans and the environment from those textiles is lower than for the other types of dyes, however it cannot be excluded.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release/exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the (no) need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction for potential Mutagenicity, Reproductive toxicity, and PBT/vPvB hazards due to the potential for exposure and release to the environment from article use for most substances in the group.

Based on the current data, the group members do not seem to have significantly different patterns in their toxicity and are assessed as one group. Due to its particular situation (NONS registration and lack of information), the reactive azo dye (Reactive black 47) will be treated separately.

The azo functional group present in azo dyes is easily broken, particularly by intestinal microorganisms. The cleavage of the azo bond results in the production of the corresponding amines, therefore, it is possible to predict the potential metabolites expected to be released from the azo dyes.

From the screening assessment of the potential metabolites released by the dyes in this group of substances, it can be concluded that most are of concern due to the presence of aromatic amines.

For one substance and for the impurity of another substance (above the generic concentration limit of 0.1 %), one of the potential breakdown products is listed under Restriction entry 43 (Annex XVII of REACH), which restricts the use in textile or leather application, of azo dyes that, by cleavage of the azo groups, may release the aromatic amines listed in appendix 8 to that entry.

For many substances, two potential breakdown products are classified as carcinogenic and/or STOT RE under Annex VI of CLP.

Additionally, for most of the substances, some of the potential breakdown products are listed under an inventory of substances compiled by ECHA that are likely to meet criteria for category 1A or 1B carcinogenicity, mutagenicity, or reproductive toxicity according to Annex III to REACH.

Carcinogenicity and genotoxicity are considered critical health effects of concern for all the substances of this group, due to potential azo bond cleavage and release of aromatic amines. Therefore, consideration of potential azo bond cleavage products is a key element in the human health assessment. All the substances of this group have the potential to break down to at least one predicted products of concern (Aniline (Carc 2/STOT RE1); 4-nitroaniline (STOT RE 2); 4-aminoazobenzene (Carc. 1B); substances likely Carc., Muta., Repro.; para substituted aromatic amines; p-Phenylenediamine (Skin Sens. 1)).

The substances are currently not classified (with exception of EC 213-903-1 self-classified as Skin Sens 1 and few others with acute toxicity).

Based on ECHA's assessment of currently available hazard information, all substances in the group (with the exception of EC 403-940-3) fulfil the screening PBT criteria⁴. The substances have also potential aquatic toxicity. PBT would appear more probable than vPvB given that there is some evidence of degradation in the inherent biodegradability studies available however neither can be ruled out at present. Data generation is nevertheless needed to clarify the potential PBT/vPvB and aquatic toxicity properties of the substances.

⁴ As defined in REACH Annex XIII and R11 Guidance on PBT assessment (https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f)

The proposed regulatory risk management action is the restriction of the placing on the market of articles containing the substances in this group or that might release relevant breakdown products. As the substances of the group are exclusively used as dyes with the purpose to be incorporated in an article, such a restriction would likely also address any preceding steps (i.e. industrial and professional uses).

Further assessment of industrial uses with a view to export is envisaged when developing further the restriction which should also support clarifying what are those industrial uses in need for EU RRM action.

The first step would be to open compliance checks (CCH) to clarify mutagenicity, reprotoxicity, STOT RE and PBT/vPvB hazards.

Though the available data on the substances and the classification of some of the breakdown products (as Carc. 1B or 2) indicate that these substances are also potential carcinogenic, the clarification of this hazard would require substance evaluation at a later stage. Such generation of data could be avoided if the CCH provides sufficient data to classify the substances as Muta. 1B and/or Repr. 1B.

A harmonised classification as Muta. 1B and/or Repr. 1B i) will trigger company level risk management measures (RMM) under OSH legislation for workers, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures (i.e. dyes, inks and toners, paints and coatings), by means of the restriction entry 29 and 30, or in clothing, other textiles and footwear articles, by means of the restriction entry 72. However, this would still not address potential exposure to humans and release to the environment from the use of various types of articles containing the substances of this group.

Should the PBT/vPvB hazard exist, the confirmation of hazard via SVHC identification will be pursued. This will trigger supply chain communication obligations. The restriction conditions for the substances in articles should be designed to also tackle such hazard.

It is proposed that the two substances in the group that only have C&L notifications (EC 270-629-5 and 286-384-2) as well as the unclaimed NONs (EC 406-000-0) will be treated the same way, to avoid regrettable substitution.

The substance Direct Black RC (EC 941-211-6) releases 4-aminoazobenzene (EC 200-453-6) which has a harmonised classification as Carc. 1B and is on the list of aromatic amines as specified in Appendix 8 to entry 43 in Annex XVII to REACH, referring to substances restricted if released from textiles or leather products that come in close contact with skin.

Similarly, the substance EC 824-263-3 contains an impurity above the generic concentration limit of 0.1 % that releases 4-aminoazobenzene.

Therefore, Direct Black RC is under the scope of restriction entry 43 and correct application of the restriction conditions should limit the exposure to the carcinogenic break-down product potentially released from textiles or leather products placed on the EU market. The same applies to the substance EC 824-263-3.

Based on currently available information, it is not possible to assess the need for regulatory risk management as information on hazard is not sufficient to conclude on any hazards of the substance Reactive black 47 (EC 403-940-3).

The substance is a NONS for which it is not possible to generate further hazard information via compliance check.

Identified breakdown products are not classified (except for one which is potential Carc., Muta., Repr.) and the current tonnage is low. The substance is used by professionals and is present in textile articles. However, due to the strong bonds with the textile material, the potential for exposure to humans and the environment while not excluded, is expected to be lower than for the other types of dyes.

If the registration status changes for this substance subject to NONS registration, data generation and actions will be re-considered when the assessment will be revisited.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited

EC number, substance name (acronym)	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
229-208-1 Direct Black 19 272-559-0 Direct Black RBB 276-529-8 Direct Black 166 297-025-4 Direct Black 168 411-890-9 Direct Black 168 (3Li) (NONs) 812-037-7 WLBK191L (direct type)	Known or potential hazard for carcinogenicity for mutagenicity for reproductive toxicity for STOT RE	Known or potential hazard for PBT/vPvB for aquatic toxicity	Widespread professional and consumer uses, including at article service life stage as dyes in textiles, leather, paper, inks and toners, paints and coatings. High exposure potential for workers and consumers.	Need for EU RRM: Restriction of articles containing the substances <u>Justification:</u> Specific restriction for use in articles as potential exposure from articles cannot be excluded. Industrial and professional uses will be consequently limited.	First step: CCH Next steps (if hazard confirmed): <ul style="list-style-type: none"> • CLH for Muta., Repr. and STOT RE • PBT assessment • SVHC identification to confirm PBT/vPvB • Restriction

ASSESSMENT OF REGULATORY NEEDS

EC number, substance name (acronym)	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>824-263-3</p> <p>916-632-3 Aluminium Black CRO (direct type)</p> <p>925-141-3 Direct Black 168</p> <p>941-211-6 Direct Black RC</p> <p>213-903-1 Acid Black 1</p> <p>279-093-7 Acid Green 111</p> <p>421-880-6 Acid Black 210 Na</p> <p>605-104-5 Acid Black 234 RC</p> <p>940-267-9 Acid Green 068</p>					

ASSESSMENT OF REGULATORY NEEDS

EC number, substance name (acronym)	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
<p>406-000-0 Direct Black 184 (NONs)</p> <p>270-629-5 Direct Black 155 (only C&L notification)</p> <p>286-384-2 Acid Black 210 (only C&L notification)</p>					
<p>403-940-3 Reactive black 47 (NONs)</p>	<p>Inconclusive hazard</p>	<p>Inconclusive hazard</p>	<p>Professional use and article service life as dye in textiles with potential exposure for</p>	<p>Currently not possible to assess the regulatory needs</p> <p><u>Justification:</u> Available information is not sufficient to conclude on any hazards of the substance</p>	<p>No action</p>

Annex 1: Harmonised and self-classifications

Data extracted on 1/12/2020

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
213-903-1	Acid Black 1	-	Skin Sens. 1B	STOT Re 1(blood) STOT SE 3 (resp. syst) Skin Irrit 2 Eye Irrit2 Acute Tox 4
229-208-1	Direct Black 19	-	-	Skin Irrit. 2 Eye Irrit. 2 STOT SE 3
270-629-5	Direct Black 155	-	-	Aquatic Chronic 3
272-559-0	Direct Black RBB	-	-	-
276-529-8	Direct Black 166	-	-	-
279-093-7	Acid Green 111	-	-	Skin Sens. 1 Eye Irrit. 2 Resp. Sens. 1
286-384-2	Acid Black 210	-	-	Eye Dam. 1 Eye Irrit. 2 Aquatic Chronic 3
297-025-4	Dye_Direct Black 168 (UVCB)	-	Eye Irrit. 2 Aquatic Chronic 3	Eye Irrit. 2 Aquatic Chronic 3
403-940-3	CI REACTIVE BLACK 47	-	-	-
406-000-0	CI Direct Black 184 (Multi)	Eye Dam. 1 Aquatic Chronic 2 H318 H411	Eye Dam. 1 Aquatic Chronic 2	Eye Dam. 1 Aquatic Chronic 2
411-890-9	Direct Black 168 (3Li)	Acute Tox. 4 * Eye Dam. 1 Aquatic Chronic 3 H302 H318 H412	-	Acute Tox 4 oral Eye Dam. 1

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
421-880-6	Acid Black 210 Na	Eye Dam. 1 H318	Eye Dam. 1 Aquatic Chronic 3	Eye Dam. 1 Aquatic Chronic 3
605-104-5	Acid Black 234 RC	-	-	Skin Irrit. 2 H315 Eye Irrit.2 H319
812-037-7	WLBK191L	-	-	-
824-263-3	[x Sodium, y Potassium, z Lithium, x+y+z =2] 4-amino-3-[[[(2,4-diaminophenyl)diazenyl]phenyl]diazenyl]-5-hydroxy-6-(phenyldiazenyl)naphthalene-2,7-disulfonate	-	Eye Dam. 1 H317 Skin Sens. 1 H318	-
916-632-3	Aluminium Black CRO (Direct type)	-	Aquatic Chronic 3	-
925-141-3	Direct Black 168	-	Eye Irrit. 2 H319 Aquatic Chronic 3 H 412	-
940-267-9	Acid Green 068	-	-	-
941-211-6	Direct Black RC	-	Eye Irrit. 2 Aquatic Chronic 3	Eye Irrit. 2 Aquatic Chronic 3

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 1/12/2020

EC/List number	Dying of paper products	Dying of textiles	Ink and toners	Leather dying	Polymers	Coating and Paints	Dyeing of Aluminium	Dyeing of wood	Fuel	Lubricants
229-208-1	F, I, P, A	F, I, P, A	F, I, P	F, I, P, A	I					
272-559-0	I, P, A	I, P, A		I, A						
276-529-8	I, A	I, P, A	F, I	I, A	I					
297-025-4	F, I, P, A	F, I, P, A		F, I, A		I, P		I, A		
406-000-0	I, A									
812-037-7	A		I, P, C							
824-263-3	F, I, P, A	I, P, A		I, A						
916-632-3							I, A			
925-141-3	F, I, A	I, P, A	I	F, I, A	F, I					
941-211-6	F, I, A	F, I, P, A		F, I, A						
213-903-1	F, I, A	F, I, P, C, A	I	F, I, A	F, I					
279-093-7	F, I, A	I, P, A	F, I	F, I, A	F, I	I, P, C				
411-890-9	I, A		I, P, C							
421-880-6	F, I, P	F, I, P, C, A	F, I	F, I, P, A	F, I, A	F, I, C		I, A		F
605-104-5		F, I, P, C, A		F, I, A						
940-267-9	F, I, A	F, I, P, C, A	F, I	F, I, A	I	F, I, P, C		I, A	P	
403-940-3		I, P, A								

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 1/12/2020

No relevant completed or ongoing regulatory risk management activities for the substances in this group.