



REACH & Colours

Sustaining the future

September
2014

The REACH and the colours

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours





THE REACH REGULATION

- The pre-registration
- The registration
- Non phase-in substances
- ECHA numbers
- SVHC
- The polymers
- The mixtures
- The value of the registration
- How to check

CLP REGULATION

- The notification

MSDS

- Sanctions and penalties

REACH&Colours

The REACH Regulation EU 1907/2006

Registration, Evaluation, Authorisation of Chemicals

REACH is a European Regulation that is applied to each single European company producing and/or importing a chemical substance above 1000 kg/year.

Since the 1^o of June 2008 following REACH Regulation, each company in order to keep its business, is obliged to submit a REGISTRATION DOSSIER to the European Chemicals Agency (called ECHA and located in Helsinki) that contains a huge amount of information (i.e. time and costs).

As to facilitate companies in the dossier preparation without stopping import and production , the Regulation allows some extra time, by submitting a **pre-registration**.



THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: *the pre-registration*

The pre-registration postpones the deadlines for the dossier preparation as follows:

30th of November 2010:

- substances > 1000 ton/year
- substances R50/53 > 100ton/ year
- substances CMR Cat 1 e 2 > 1 ton/year

31st of May 2013:

- substances 100-1000 ton/year

31st of May 2018:

- substances 1-100 ton/year

From the 31^o of May 2018, this pre-registration period will cease and any company willing to produce and/or import will have to immediately submit a registration dossier (*no data, no market*).

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours

The REACH Regulation: *the pre-registration*

The PRE-REGISTRATION is easy to fulfill and completely different from a registration preparation

When:

- Companies could pre-register between the 1st of June and the 1st of December 2008
- Companies can still pre-register (to allow brand new business) and this fulfillment is called **late pre-registration** and is characterised by well defined conditions. However, from the 31^o of May 2017 the pre-registration possibility will no longer exist.

What:

ONLY the so-called “**PHASE-IN**” substances, i.e. those substances defined by an **EINECS NUMBER (2XX-XXX-X, 3XX-XXX-X, 5XX-XXX-X)** could have been/could be pre-registered. ELINCS substances (**4XX-XXX-X**) or those substance without EINECS number cannot be pre-registered.

NOTE: the **CAS** number **IS NOT** AN European identifier.



THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: *THE REGISTRATION*

What is a Registration Dossier?

1. Detailed description of the produced/imported substance (molecule): detailed analytical characterisation (i.e. identification and quantification of each single component /impurity of the substance)
2. Data purchase: the data inserted in the common dossier come from animal testing, eco-toxicological testing and physical-chemical testing. As high is the tonnage volume of the dossier as more expensive and time consuming are the data required:
 - 1-10 ton/year requires an average of 40.000-80.000€ of tests
 - 10-100 ton/year requires an average of 200.000-400.000€ of tests
 - 100-1000 ton/year requires 600.000-1.000.000 € of tests
 - >1000 ton/year requires in some cases more than 1.500.000€ of tests

(continues)

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: *THE REGISTRATION* *What is a Registration Dossier?*

3. Data sharing: SIEF and CONSORTIA (legal, administrative and technical aspects)
4. Dossier preparation: technical and administrative costs for the dossier preparation ranging from 100.000 to 400.000€
5. ECHA fees

Substances registration requires a lot of investment in terms of internal companies resources and an economical burden for many different activities.

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: non-phase in substances

NON PHASE-IN: those substances could NOT/CANNOT be pre-registered and, unless notified before, they had to be registered REACH in 2008 as to import/produce them in Europe. Some examples:

- **Acid Black 210:** the EINECS describes the potassium salt and could be pre-registered. The sodium salt form is described by an ELINCS number which has to be registered.

Acid Black 234: this substance does not have an EINECS number nor an ELINCS number. It has to be registered.

- **Acid Brown 432 or 434**

- **Direct Blue 299, etc.**

ONLY THOSE COMPANIES THAT HAVE DULY REGISTERED THOSE SUBSTANCES CAN LEGALLY IMPORT/PRODUCT THEM IN EUROPE. IT MUST RESULT WITHIN THE MSDS OF YOUR SUPPLIERS, PLEASE CHECK!

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: *ECHA numbers*

- Pre-registration number: **05-xxxxxxx-0000**
- Late pre-registration number: **17-xxxxxxx-0000**

Pre-registration numbers do not have legal value for the downstream users since they cannot be verified and it is better not to communicate them

- **REGISTRATION NUMBER** **01-xxxxxxxx-xxxx**

Registration numbers are absolutely legal, they can be verified on the ECHA website and **have to be communicated within the SDS**

- Notification number **02-xxxxxxxx-xxxx**

THE REACH REGULATION

The pre-registration
The registration
Non phase-in substances
ECHA numbers
SVHC
The polymers
The mixtures
The value of the registration
How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: *SVHC*

SVHC stands for Substances of Very High Concern

In particular: CMR (Carcinogenic, Mutagenic, Reprotoxic cat. 1 e 2)
 PBT e vPvB (Persistent, Bioaccumulative and Toxic)
 Endocrine disruptors

SVHC is a list of substances really dangerous that are considered in depth by the Agency to be candidate for an Authorisation for their import/production.

The list of **SVHC** is published on the ECHA website and constantly updated at the following link:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

FULFILLMENT

For the dyes (mixtures) the suppliers have to update their MSDS in case these **SVHC** substances are present over the 0,1%.

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The REACH Regulation: *polymers*

- ✓ Polymers are exempted from the registration however their constituting monomers are not
- ✓ Some dyes have been identified as polymers, like Direct Yellow 11, Direct Orange 15, Sulphur Black 1.
- ✓ Also some additives present in the commercial dyes are polymers and their monomers have to be registered
- **In case of polymers, it is better to have a correct and complete declaration from your suppliers that along the supply chain the monomers have been duly registered.**

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



REACH: commercial dyes= mixtures

- ✓ The dyes placed on the market are usually MIXTURES, i.e. they contain a lot of different substances together with the dye itself, and they are all subjected to REACH registration
- ✓ Some examples are the standardising salts (e.g. sodium sulfate), the antidusting oils, the dispersing agent, the stabilizers, solvents (as acetic acid) etc.
- ✓ At the end of the REACH registration a commercial dye will be sold by means of **different registration numbers**, one for each substance present in the mixture (an open cooperation with the suppliers is fundamental!)
- NOTE: for each single substance contained in the commercial dye also the pre-registration had to be fulfilled. Therefore, a dye placed on the market is characterised by different pre-registration numbers, not only one!

The CLP Regulation

CLP is the new European Regulation that describes Classification and Labeling and it is different and complementary to REACH.

CLP indicates HOW to COMMUNICATE the danger of a substance, by identifying the symbols and phrases that have to be used and the criteria for the danger classification.



Symbols, phrases and criteria changed with respect to the old Directive and the classification and labeling of mixtures that we import are already implemented following CLP Regulation.

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The CLP Regulation: *notification*

Since 01/12/2010 , all substances placed on the market in a quantity >1 to/year have to notified to the Agency within 30 days, independently of their classification.

If a substance is classified, it has to be always notified independently of the quantity, i.e. even below 1 to/year.

For instance, a sample of classified dye imported by you from China or Switzerland have to be duly notified to the Agency by yourself.

The notification of a substance is a fulfillment technically more complex than the pre-registration. The classification (or non classification) of the substance has to be notified with consequent full responsibility of the declaration.

Very few companies are fully aware of this notification obligation and acted correctly. Always check with your suppliers!

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



Safety Data Sheets

Safety Data Sheets have to be compliant to a new Regulation N. 453/2010 that replaces Annex II of the REACH Regulation

Key changes are:

- 1) Exhaustive information about physical-chemical, toxicological and ecotoxicological properties as reported in the registrations
- 1) Update of the Classification and Labeling following CLP
- 2) Update (when required) with the exposure scenarios

The SDS of a registered and classified substance can have up to 100 pages. This is a very important instrument for the downstream user. Check your suppliers!

THE REACH REGULATION

The pre-registration
The registration
Non phase-in substances
ECHA numbers
SVHC
The polymers
The mixtures
The value of the registration
How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



Sanctions and penalties

Each Country fixed the sanctions and penalties for REACH, CLP and MSDS.

They are generally strict and costly.

Please check what it is foreseen in your Country and take the appropriate measures to be compliant and to be properly granted by your suppliers.

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

[The value of the registration](#)

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The economical value of the registration: *the company costs*

Average costs for a single substance per single company:

| | |
|--|--------------------------|
| • Data sharing: SIEF and CONSORTIA | 2000-5000 EURO |
| • Substance characterisation: ANALYTICS | 3000-5000 EURO |
| • Data purchase: Letter of Access | 30000-150000 EURO |
| • Dossier preparation: IUCLID and CSR | 10000-15000 EURO |
| • ECHA fees | 1000-7000 EURO |
| <u>TOTAL PER SUBSTANCE PER COMPANY:</u> | 50.000-180.000 EU |

For 100 SUBSTANCES EACH COMPANY WILL HAVE TO SPEND BETWEEN 5 AND 18 MILLIONS OF EURO → FEW COMPANIES WILL REGISTER!

MOREOVER, INTERNAL COSTS (HUMAN RESOURCES) AND EXTERNAL CONSULTANTS HAVE TO TAKEN INTO ACCOUNT FOR A REGISTRATION!

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

[The value of the registration](#)

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours

COMPANY ROLES: *ECONOMICAL VALUE OF REACH*

It is fundamental that you are fully aware of the deep value of your REACH compliance as to valorise it economically

- **Sales departments have to take advantage over different aspects:**
 - **To give added value to your products**
 - **To justify potential prices increase**
 - **To monitor the market and define competitors**



THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

[The value of the registration](#)

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The value of the registration: visibility among competitors

Few companies can bear the registration of the substances since it requires

- Economical involvement
- Culture, knowledge, competence
- Managing expertise
- Technical expertise

The number of competitors in line with REACH will be very small and you can identify, check and monitor it starting from now.

All the other companies will be ILLEGAL and they will disappear from the market.

Start selecting your suppliers!

THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

[The value of the registration](#)

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



The value of the registration: *ethical commitment and consumer care*

A dossier registration requires the deep analysis of the substances and the identification of possible dangerous impurities.

Products safety is really studied and the potential risks are defined and controlled

The risk management measures are well studied and communicated

THEREFORE

A REGISTERED SUBSTANCE IS SAFER FOR THE WORKER AND THE CONSUMER



THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

[REACH&Colours](#)



REACH&Colours Kft

REACH&Colours KFT (R&C) was born in 2007, with legal entity in Hungary, and has fixed exclusive agreements with a restricted and well-defined numbers of European distributors.

Under the Regulation, R&C is the producer/importer that have been/will register a high number of colorants, pigments, optical brighteners and additives that resell ESCLUSEVELY to its producers/distributors. These last companies are exempted from the registration duties, but guaranteed that their supplier will register all the dye present in their portfolio.



THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

How to check

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours



REACH&Colours Italia

REACH&Colours Italia is the legal entity that **TECHNICALLY** prepare and finalise the registration dossiers **ON BEHALF OF REACH&Colours Kft.**

REACH&Colours Italia does not import nor register anything but works as technical consultant.

Moreover, during the years, REACH&Colours Italia was appointed by big dye companies as technical and administrative manager of the three European Dyes Consortia (refer to ETAD website www.etad.com for leather, paper and textile dyes) and has therefore a complete view of the state of the registration of dyes.



ETAD

The Ecological and Toxicological Association
of Dyes and Organic Pigments Manufacturers

REACH Dyes Consortia

ETAD members (together with other interested parties) formed between 2008 and 2011 three organic dyes REACH consortia based on the experience gathered in the ETAD working groups. The consortia successfully registered more than 30 dyes up to the second REACH phase which ended in June 2013. Already under preparation for 2018 are 125 dossier (ideally to be submitted during 2013-2014).

For any specific information about the already registered dyes and those which will be registered within the last deadline of May 2018, please contact the company REACH&Colours Italia S.r.l., which is managing all the SIEF communication. The contact details are:

REACH&Colours Italia S.r.l. - Via Locatelli, 6 - 20124 - Milan (Italy)
Phone +39026700319
Fax +390267386811
e-mail facilitator@reachcolours.it

Organic Dyes REACH Consortia:

EPCG Paper Colourants REACH Consortium – manager Mr. Peter Ungeheuer Ungeheuer@VCI.de
Established during 2008, about 100 substances covered.

Textile Dyes REACH Consortium – manager Mrs. Michela Kahlberg michela.kahlberg@reachcolours.it
Established during 2010, about 300 substances covered.

Leather Dyes REACH Consortium – manager Mrs. Michela Kahlberg michela.kahlberg@reachcolours.it
Established during 2011, about 200 substances covered.

THE REACH REGULATION
The pre-registration
The registration
Non phase-in substances
ECHA numbers
SVHC
The polymers
The mixtures
The value of the registration
How to check

CLP REGULATION
The notification

MSDS

Sanctions and penalties

[REACH&Colours](#)



How to verify registrations on the ECHA website

- It is possible to check whether a substance has been registered together with the names of the registrants on the ECHA website at the following link: <http://echa.europa.eu/it/information-on-chemicals>

Informazioni sulle sostanze chimiche

The 'Information on Chemicals' section is the 'gateway' to ECHA's public databases on chemical substances, which contain a plethora of information about chemicals in Europe.



Ricerca sostanze chimiche

Ho letto e accetto le [condizioni dell'avviso legale](#)

Nome, num. EC o num. CAS

- As an example, EC: 232-380-0 for Acid Brown 75.
- If a substance has been registered, by entering the EC or CAS number the following window will appear:
- By clicking on "Registered Substances"

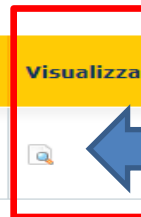
Results

Category

[Registered Substances \(1\)](#)



| EC / List No. | CAS No. | Name | Registration type | Submission type | Tonnage band | Visualizza |
|---------------|-----------|---|-------------------|------------------|-------------------------|------------|
| 232-380-0 | 8011-86-7 | 2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-, diazotized, coupled with diazotized 2-amino-4,6-dinitrophenol, diazotized 4-nitrobenzenamine and resorcinol, sodium salts | Full | Joint Submission | 1 - 10 tonnes per annum | |



How to verify registrations on the ECHA website

The dossier opens up with all the tox, ecotox and physical chemical properties together with the registrant name:

> Home page

- General Information
- Classification and Labelling
- Manufacture, Use & Exposure
- PBT assessment
- Physical and chemical properties
- Environmental fate and pathways
- Ecotoxicological Information
- Toxicological information
- Guidance on safe use
- Reference substances

Identification Registration data Administrative data

Identification

Substance identification

2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-, diazotized, coupled with diazotized 2-amino-4,6-dinitrophenol, diazotized 4-nitrobenzenamine and resorcinol, sodium salts

EC Number 232-380-0

EC Name 2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-, diazotized, coupled with diazotized 2-amino-4,6-dinitrophenol, diazotized 4-nitrobenzenamine and resorcinol, sodium salts

CAS Number 8011-86-7

Description This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 34905.

IUPAC Name 2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-, diazotized, coupled with diazotized 2-amino-4,6-dinitrophenol, diazotized 4-nitrobenzenamine and resorcinol, sodium salts

structural formula

Type of substance

Composition UVCB

Origin organic

Total Tonnage Band

1 - 10 tonnes per annum

Registrants / Suppliers

REACH&Colours Kft Petofi Sandor utca 11 I Em. 4, 1052, Budapest, Hungary

Registration Numbers

01-2119967790-26-0000



THE REACH REGULATION

The pre-registration

The registration

Non phase-in substances

ECHA numbers

SVHC

The polymers

The mixtures

The value of the registration

[How to check](#)

CLP REGULATION

The notification

MSDS

Sanctions and penalties

REACH&Colours

SIEF MANAGER

R&C coordinates the registrations of every dye by its software on line
<http://siefmanager.reachcolours.it/>

Any company that has pre-registered a dye can have, for free, the most updated information on: consortium, lead registrant, tonnage, Classification and Labeling, substance definition (sameness) costs of the Letter of access etc.



**THANK YOU FOR YOUR
ATTENTION**



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