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REACH regulation
Main features and implications for Release Papers

July 2018

What is REACH?

Registration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals is a European Union regulation dated 18 December 2006.

REACH addresses the production and use of chemical substances, and their potential impacts on both human health and the environment.

Effect on companies

- **Manufacturer**: If you make chemicals, either to use yourself or for export, you will probably have some important responsibilities under REACH.

- **Importer**: If you buy anything from outside the EU/EEA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures or finished products.

- **Downstream users**: Most companies use chemicals, sometimes even without realising it; you need to check your obligations if you handle any chemicals in your industrial or professional activity. You might have some responsibilities under REACH.

- **Companies established outside the EU**: If you are a company established outside the EU, you are not bound by the obligations of REACH, even if you export their products into the customs territory of the European Union. The responsibility for fulfilling the requirements of REACH, lies with the importers established in the European Union, or with the only representative of a non-EU manufacturer established in the European Union.

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Favini and REACH

Favini S.r.l. – Crusinallo Plant is a Manufacturer of Speciality Paper for Graphical and Industrial use.

Paper, according to art.3 of Regulation (EC) No 1907/2006 of 18 December 2006 is an article […] : "*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*".

The obligations established for manufacturers of articles are indicated in art.7

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Favini and REACH

In particular, concerning the Papers produced in our plant:

- they don't contain substances with intentional release of dangerous components in normal or reasonably foreseeable conditions;

- they don't contain substances which comply to the criteria included in art.57 (carcinogenic, mutagenic, toxic for reproduction, persistent and bioaccumulative) and which have been identified in art.59, paragraph 1:
  - in quantities > 1 ton per year.
  - in concentration > 0,1% weight by weight (w/w).

- as per today, they don't contain substances for which the agency undertook decisions which prescribe the presentation of a registration, according to the norms in the present regulation.

Moreover, Favini – Crusinallo Plant needs all Suppliers of Raw Materials who are subject to the European Community Regulation to supply all indications and information required by REACH.
The main tool is the Safety Data Sheet, managed within our Certified Quality management System ISO 9001:2008 with the scope to preserve health and environment.

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Favini and REACH

Extracted from our SDS:

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Safety Data Sheet

FAVINI safety production profile according to Regulation (EC) 1907/2006 and (EC) 453/2010
Date / revision: 29/05/2015 Version: 4.0
Product: **PETALO**

2. Possible hazard

The product is not classified among dangerous substances according to EU criteria and does not need specific precaution during normal use.
The product is not labelled according to EU guidelines.

3. Composition and information on ingredients

This product does not meet the criteria for classification as hazardous as defined in the Regulation EC 1272/2008 (and in Directive 67/548/EEC).

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Solvent based PU Manufacturer

Polymers are exempted from the provisions on registration of Title II of REACH. Therefore, the manufacturer or importer of a polymer is generally not required to provide to the Agency any information related to the intrinsic properties of the polymer itself.

According to Article 6, the manufacturer or importer of a polymer must submit a registration to the Agency for the monomer substance(s) or any other substance(s) that have not already been registered by another party up the supply chain, if both the following conditions are met:

- In concentration ≥ 2% w/w of the polymer
- In quantity ≥ 1 ton per year

Solvent based PU

Most of the PU used in the worldwide production of Manmade leather is obtained using DMF (dymethilformamide) solvent based synthesized polymers.

Barrels of PU containing DMF are classified as toxic substances.

REACH stipulates that this substance, classified as **SVHC** (substance of very high concern, criteria in art.57) is registered by the producers and not by the users.

It has recently been included in the **candidate list** for authorization, **so in the case of future approval of this list, users will have to require an authorization for using DMF**.

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Water based PU

WB PU can reach a very high concentration of polymers (typically 60% PU and 40% water), so the amount of water to be evaporated is lower than Solvent Based PU.

That means:

- Lower energy consumption
- Lower weights
- Higher efficiency in manufacturing processes

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Solvent based PU

PROS

- Appearance, touch and breathability similar to genuine leather
- Extended shelf life in case of 2-components PU
- Quality perceived by end users to be higher than PVC
- Lighter than genuine leather

CONS

- Production costs higher than PVC
- Limited shelf life in case of mono-component PU
- Coating equipments different and more expensive than PVC
- Solvent based (DMF)

Water based PU

PROS

- Compliant with the EU regulations
- Appearance, touch and breathability very similar to genuine leather
- Extended shelf life
- High abrasion resistance
- Wide range of finished products
- High quality level perceived by end users

CONS

- Production costs higher than traditional PVC and PU resins
- Traditional coating equipments must be updated to cope with WB PU

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Water based PU tests on our papers

- Samples tested
  - On our pilot machine
  - In collaboration with PU manufacturers

- For a good level of resistance to water aggression, a high weight is preferred

- The final coating quality does not depend on the type of solvent used in the PU formulation

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Water based PU tests on our papers

- **Coated papers**:

Generally, standard coated papers don’t work well with WB PU due to water absorption.

Starting from our R&D laboratory we have developed and industrialized a special coated paper for this application

Water Resistant 2

available in Plain or Embossed version.

Currently the embossed version is under testing with our customers and PU manufacturers.

- **Extruded Papers**:

These papers also have good interactions and are suitable for WB PU applications.

FOR MORE INFORMATION YOU CAN DIRECTLY CONTACT US

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REACH articles – art.7

Registration and notification of substances in articles
1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
b) the substance is intended to be released under normal or reasonably foreseeable conditions of use
A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59, if both the following conditions are met:
a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4. The information to be notified shall include the following:
a) the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;
b) the registration number(s) referred to in Article 20, if available;
c) the identity if the substance as specified in sections 2.1 to 2.3.4. of Annex VI;
d) the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI.
e) a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s)
f) the tonnage range of the substance(s), such as 1-10 tonnes, 10-100 tonnes and so on.

5)The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
a) the substance is present in those articles in quantities totalling over 1 tonnes per producer or importer per year;
b) the Agency has grounds for suspecting that:
i) the substance is released from the articles, and
ii) the release of the substance from the articles presents a risk to human health or the environment;
c) the substance is not subject to paragraph 1.
A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6) Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7) From 1 June 2001 paragraphs 2,3 and 4 of this Article shall apply 6 months after a substance is identified in accordance with Article 59

8) Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133.

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REACH articles – art. 57

(Article 57: Substances to be included in Annex XIV)

a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex III of this Regulation;

e) substances which are very persistent and very bioaccumultive in accordance with the criteria set out in Annex III of this Regulation;

f) substances – such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) – for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.