

Regulatory Landscape for UV/EB Printing Inks in Europe

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Supplying UV/EB¹ curable formulations from North America into other regions requires the US formulators to become familiar with the respective regulations for import and applications their products should be supplied into.

The paper focuses on the import into the European market regulated by EU REACH² and on requirements for printing inks used in food packaging applications.

A short outlook on regulatory developments in other European regions will be given as well.

Export UV/EB printing inks out of North America into Europe

Transport of materials overseas into other countries has been, is and will be challenging; however challenges have changed, in early times there have been physical challenges like stormy weather, navigation, diseases of the boat crew on the long way to other continents, nowadays we have to manage business related challenges like lead time, minimize cost, we have to be compliant with many different regulations for import/export, need to be familiar customs, free trade agreements, chemical inventories just to name a few of them. This paper will outline challenges in exporting chemicals into Europe and will focus on relevant chemical legislations for import and application of UV/EB curable formulations.

1. Transportation

For physical transport of your products you have to consider the mode of transport either sea or air freight and find a good balance of time, cost and requirements to be met. The product safety data sheets and labels need to match with local regulations in North America, with international regulations applicable during transport and with local regulations at the port of entry. Format, content and language might be parameters to be adjusted; for the same product the hazard classification might be different, because for certain endpoints e.g. reprotoxicity the thresholds given in the US OSHA³ and the EU CLP⁴ are different. Therefore a product might be classified reprotoxic in one jurisdiction but not in the other and product labels have to be changed and match with the respective safety data sheets. Depending on the mode of transport the packaging might have to be

adjusted e.g. certain classes of dangerous good are not allowed on airplanes in larger packagings than small (25kg) pails;

Once arriving in the destinations entry point custom clearance needs to be done. Here logistic providers have the best know how to assist;

2. Chemical legislation relevant for import and use of UV/EB printing inks in EUROPE

When importing chemicals into a foreign country one has to check if a chemical legislation in this jurisdiction exists and if all components of the UV/EB printing ink are compliant with the specific regulation and chemical inventory;

Shipping UV/EB printing inks to Europe a company has to be aware that there might be several chemical inventories to manage: the European Union (EU)⁵ with its REACH regulation does not include Switzerland, Norway, Iceland and Liechtenstein, these countries have own regulations set up; UK might drop out of EU REACH in the near future; Turkey and the EURASIA⁶ region will be one of the next chemical inventories to be added on the European continent.

2.1 EU member states , REACH and CLP

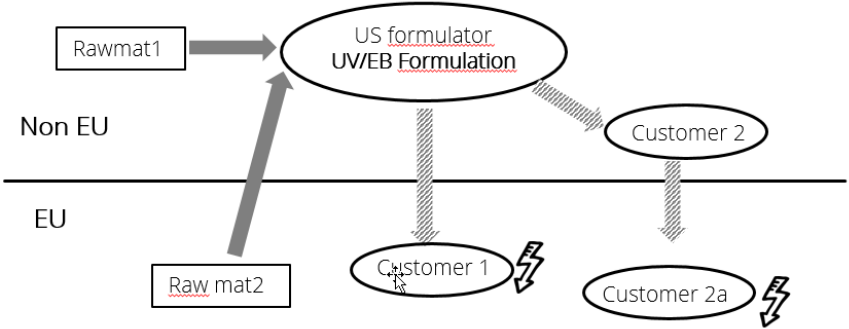
Relevant for imports into EU member states is the chemical inventory regulated by the REACH regulation EC 1907/2006 and the regulation on classification labelling and packaging CLP EC1272/2008.

All substances imported into the EU with volumes >1t/year/legal entity require a registration under REACH and additionally classification, labelling and packaging has to meet the requirements laid down in the CLP regulation; Polymers as such are exempt, however the respective monomers have to be registered.

In contrast to TSCA⁷, REACH is NOT a positive list of substances identified by CAS numbers. A positive list inventory allows everybody to import substances which are on the list, in contrast to that, a REACH registration is only valid for the respective notifier and only covers this specific supply chain. EU REACH registrations can only be submitted by legal entities located in the EU, like manufacturers and importers located in the EU;

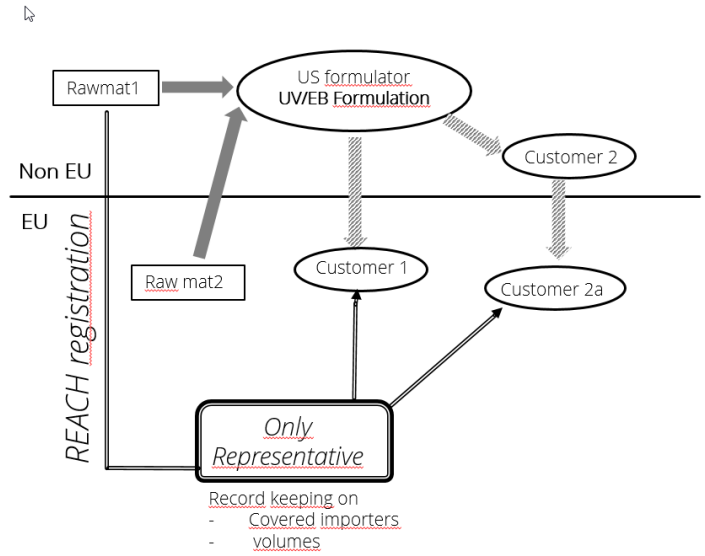
In case a North American formulator supplies printing inks to affiliates and/or customers in the EU, these entities would be the responsible legal entities which need to register all substances of the formulation under REACH if the raw materials have not been registered by the supplier.

Fig. 1a: **No** only representative appointed by non EU manufacturer of Rawmat 1, which is part of the UV/EB formulation; Customer 1 & customer 2a are importers of Rawmat1 into the EU and as consequence have registration obligations



However, if the components in your formulation are not purchased from an EU source, the non EU manufacturer of these substances can appoint an only representative (OR) to submit the registration on his behalf and by doing so he can cover your customers located in the EU and release them from their registration obligations.

Fig. 1b: Only representative **is** appointed by non EU manufacturer of Rawmat1, which is part of the UV/EB formulation; Customer 1 & customer 2a are now downstream users and have **no registration obligation**



OR concept in a nutshell:

The only representative is a legal entity located in the EU acting on behalf of the non EU manufacturer; the OR submits registration dossiers on behalf of the manufacturer and is legally responsible for tracking the imported volumes to make sure the total imports covered by that registration stays within the tonnage band covered by the respective registration; therefore the OR needs information about the volume of the registered substance imported from the non EU company to the EU and another OR obligation is to know which legal entities (=Importers of the UV formulation) he is covering with his activity; if an OR is appointed by a non EU manufacturer and the volumes and the respective importers are covered by the registration of the OR these importers do no longer have registration obligations under REACH; in case of inspections the importer has to demonstrate that he is covered by an OR and the OR has to demonstrate that he indeed covers that importer and that the tonnage imported by this legal entity is covered by the registration.

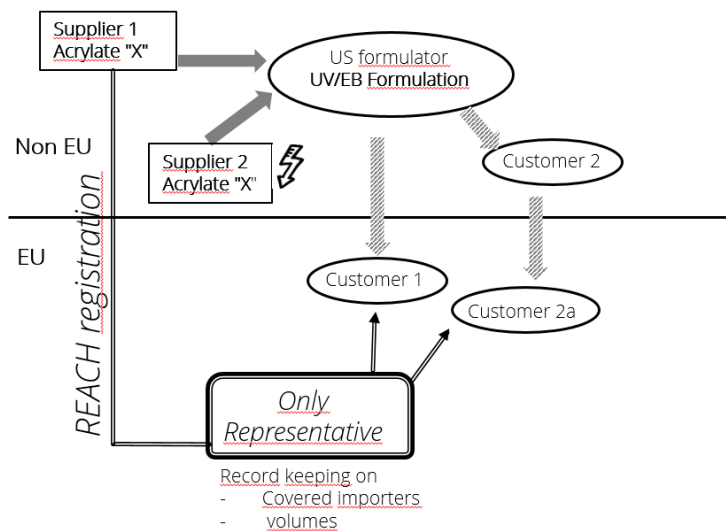
You have to know your supply chain!

With regards to REACH the same chemical, e.g. an acrylate "X" coming from two different sources might be different in its REACH status: one is registered by the supplier the other one might not.

Purchasing the acrylate "X" from the supplier holding a REACH registration and covering your customers with that, neither your company nor your importing affiliates or customers in the EU do have a registration obligation.

Using the not registered acrylate "X" of the second supplier will place registration obligations on your customers/importers located in the EU.

Fig. 2: Same acrylate "x" purchased from 2 suppliers with different REACH status One releases EU customers from registration obligation, the other does not



If your market is the EU you have to manage your supply chain accordingly to release your EU customers from registration obligations. Some options:

- a) purchase from a supplier located in the EU (he can easily cover your clients with his registration activity)
- b) Purchase from a non EU supplier having an OR appointed (this supplier can cover your clients as well)
- c) Use an own affiliate in the EU to submit REACH registrations for all relevant substances and supply your EU customers from this affiliate

2.2 Other European countries having a REACH like system

There are other European countries (not EU members) with existing or emerging chemical legislations and inventories.

Turkey and the Eurasian economic union (Russia, Belarus, Kazakhstan, Armenia and Kyrgyzstan) are building new systems which are more or less in line with the requirements of REACH, however not covered by a REACH registration. UK might drop out of REACH as well and set up an own UK REACH legislation;

These chemical inventories are or will be EU REACH alike systems, where only legal entities located in the respective country have registration obligations and can act; the respective registration activity is only valid for the respective notifier; a preregistration is followed by final registration and usually the tonnage band triggers a stepwise registration and data requirements.

Like EU REACH these inventories are not CAS number lists; your specific supply chain has to act! You need to have close contact to the regulatory department of your supplier and verify if your customers in these specific countries are regarded as downstream users covered by the regulatory activity of your supplier or not; Your company might also consider to set up an affiliate in these countries importing the formulations and comply with the respective registration obligations

Tonnage bands and data requirements for a registration are in line with REACH, so once data are generated for REACH one can go into data sharing and make use of these data to prepare a registration for these countries.

Switzerland has a long standing inventory system⁸, which is a mix of a positive list and notifier specific part.

With the positive list Switzerland fully accepts already existing REACH registrations, provided these are former EINECS⁹ substances (existing substances) and puts them on the existing chemicals inventory, which is a CAS number positive list and valid for every legal entity importing these substances

However for new substances (EC number starting with 4, 5, 6, 7, 8) a standalone Swiss notification has to be submitted to the Swiss authorities by a legal entity located in CH, importer or sole representative of the respective supply chain. This is the REACH alike part of the Swiss chemical inventory.

3. Use of your formulation in the final application

Several applications of UV/EB curable formulations are regulated within the EU or other European countries, either by law, trade association rules or brand owners policy.

3.1 Printing inks for food packaging

An example for a regulated application is the use of printing inks for food packaging.

Currently there is no EU regulation on printing inks for food packaging. There is a directive for plastic in contact with food (EC 10/2011)¹⁰ but this is not specific for UV/EB curable printing inks and most of the raw materials used in our industry, for example photoinitiators are not addressed at all. Some of the European countries have taken own initiative on regulating printing ink materials in food packaging.

Switzerland, although not an EU member has taken first initiative and although being a Swiss legislation this "Swiss Ordinance"¹¹ is currently the only and accepted "quality proof" for printing inks used in food packaging; Germany has taken action as well some years ago, but this has been stopped due to an EU initiative to regulate printing inks used in food packaging been started. Preparing this regulation only slow progress is made on EU level and stakeholders anticipate that Germany will restart the German ordinance to regulate printing inks in food packaging which will then be a national piece of legislation but might be taken as a template for a future EU level legislation;

Brand owners do also strongly influence the raw material selection in order to avoid any potentially critical materials which might endanger their reputation at the final consumer.

Known brand owners strongly influencing the choice of raw materials for food packaging are Nestlé and Tetrapak. The Nestlé guidance on packaging materials¹², updated every second year is a negative list, materials listed are prohibited or restricted to be used in food packagings for Nestlé.

3.2 UV curable formulations in Cosmetics

The cosmetics regulation in EU (EC 1223/2009)¹³ is regulating which materials can be used for example in nail gel formulations; it is a negative list pointing out

prohibited and restricted materials; UV curable material supplied into this application have to match the requirements.

3.3 other regulated applications

There are other regulated applications, either regulated by legal obligations or regulated by brand owners;

Just to name a few regulated applications: electronics, automotive, special wood coatings and brand owner requirements like IKEA, Sony, APPLE all these stakeholders have their own requirements for materials used in their articles.

When your company is going to supply a UV/EB curable formulation into a regulated application it is recommended to first of all know the requirements (ask your customer what he has to comply with) and know your raw materials; are they compliant with the respective regulations?

4. Summary

Knowing your supply chain and your markets is crucial for managing the challenging European landscape of inventories. Inventory status is a property of a chemical substance the same as viscosity, reactivity etc. The raw material supplier needs to be chosen according to business needs taking into account the regulatory requirements of the market your company wants to enter.

Several questions need to be answered before choosing a specific raw material from a specific raw material supplier: where are my customers? Does my raw material supplier register in these countries? Can my company submit a registration? Does business justify the cost for registration?

Looking into the end use of your formulations you have to be aware that some of the uses are regulated by specific pieces of legislation, by company policies or by brand owners. It is crucial to know the use of your product and the regulations related to that to ensure having sustainable business.

Globally acting raw material suppliers, like RAHN can help you to manage these challenges! Globally acting raw material suppliers are familiar with these regulations, have legal entities in the respective countries and a good network with experts and authorities. Managing this complex environment is our daily business.

References

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