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Registration of Polymers – Adhesives and Sealants Industry Perspective

FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European adhesive and sealant industry. Today's membership stands at 15 National Association Members, 24 Direct Company Members and 19 Affiliate Company Members. The European market for adhesives and sealants is currently worth more than 17 billion euros. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard, FEICA works with all relevant stakeholders to create a mutually beneficial economic and legislative environment.

Background

Polymers are currently exempted from registration under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). However, Article 138(2) of REACH foresees a possible further review of REACH to extend the registration requirements to polymers. If the risk posed by certain polymers can be proven, and practical and cost-efficient ways of selecting polymers requiring registration (PRR) can be established, registration requirements under REACH will be extended to polymers.

To establish sound technical scientific criteria for the identification of polymers requiring registration and to define the most efficient registration process, the CARACAL Sub-Group on Polymers was created. Two FEICA representatives have been accepted as members of the subgroup. FEICA would like to express its gratitude to the European Commission for the opportunity to contribute to the development of a regulatory framework for the registration of polymers under the REACH Regulation that will help to protect human health and the environment without the loss of the competitiveness and innovativeness of the European industry.

While strongly supporting CEFIC and DUCC positions about the registration of polymers for which there is a concern in terms of human health or the environment, FEICA would appreciate the consideration of the following issues with respect to the impact of polymer registration on adhesives and sealants formulators.

Singularities of the adhesives and sealants industry

The use of polymers within the adhesives and sealants industry is very widespread. In general terms, polymers are the chemicals which enable adhesives and sealants to work. FEICA would like to summarise some concepts and facts that will illustrate how polymers are structured, and which are the parameters of relevance within adhesives and sealants products.

Multiplicity of polymers

The number of polymers used in the manufacture of adhesives and sealants is very large. For example, it is estimated that a single manufacturer of polyesters may have to register between 500 and 1,500 polymers if no robust grouping approach is available. For other polymer classes used in the adhesives and sealants industry, such as polyurethanes, the numbers can be even greater.

Such a registration burden will be challenging to medium-sized companies, but even more so for small enterprises. Some examples to illustrate the complexity of the challenge for the adhesives and sealants industry are provided in **Annex 1**.

Customised polymers

Formulators at the end of supply chains, such as adhesives and sealants manufacturers, often customise polymers, the result being new polymer species. Thus, those formulators, which are currently downstream users (DUs) under REACH legislation, may become potential polymer registrants in the future if the new polymer is subject to the obligation of registration. Such customisation is required in order to fulfil technical feasibility and customer requirements as well as regulatory needs. Without such customised polymers, end users would be left with products of higher hazard profile and/or insufficient performance. Customising polymers may result in a huge number of new polymers to be potentially registered while the total production volume of each individual polymer may be comparatively low.

More examples of customised polymers were shared in the FEICA paper 'Manufacturers of low-volume customised polymers at the end of the supply chain'.¹

Costly and complex registration requirements would be a disproportionate economic, technical and organisational burden, especially for small and medium-sized companies. This could destroy the established technology in adhesives and sealants widely used and their absence would be a problem for many final-use sectors.

An example of why customisation is required can be found in the engineered wood industry. Here customized one component PU replaces less environment friendly formaldehyde-based resins.

'Life expectancy' of polymer formulations

While the total production volume of an individual polymer can be comparatively low, the customised life cycle of a single customised polymer may often be less than three years depending on customer demands, market developments and changes in regulatory requirements.

Even if in some areas or market segments there are many polymers utilized in well-established adhesives that can have a long lifespan, customer requirements for tailor-made solutions change frequently due to the demands of new processes or application equipment. This means that some

¹ FEICA paper 'Manufacturers of low-volume customised polymers at the end of the supply chain' is available at:

<https://www.feica.eu/information-center/all-information-centre/preview/1214/manufacturers-low-volume-customised-polymers-end-supply-chain?id=f13c103e-f4ab-477a-b0db-2f4a4a64e775&filename=Manufacturers+of+low-volume+customised+polymers+at+the+end+of+the+supply+chain.pdf> and <https://www.feica.eu/information-center/all-information-centre/preview/1214/polymers-scope-prr-examples?id=c3d69e5b-f19d-4293-943f-b47bce4440ca&filename=Polymers+in+the+scope+of+PRR+examples.pdf>

customised polymers may be short-lived. Only simple and pragmatic grouping solutions will allow such short-lived polymers to be commercially viable.

What such polymers in our adhesives with a short lifespan have in common is that they are used for products in highly competitive market sub-segments whereas the value depends heavily on the efficiency in the production process of our customers so they can achieve a profitable business. On top of non-adhesive related measures, our customers gain efficiency, e.g., with measures like increase in machine speed, reduction in adhesive coating weights (cost), faster adhesive cure times for faster further processing as well as cost pressure on the adhesive itself. In many cases, the adhesive suppliers are forced to modify the existing polymer or even change the overall composition to fulfil such requirements.

For example, in the area of flexible packaging, there are many highly competitive sub-segments utilizing 2-component PU laminating adhesives. Converters compete for high-volume snack and pasta packaging, and even if they have gained business, they constantly optimise their efficiency as described above. This means that the lifespan of the polymers used in the two component PU-laminating adhesive industry has reduced from 10 years to 3 to 5 years.

In the area of the wood and furniture industry, the adhesive manufactures are facing a strong competitive pressure with the need to optimise their products (e.g., reactive polyurethane hotmelts) in regard to cost as well as performance to meet the continuous improvements in the manufacturing process of the industry as well as to address changes in design of the finished article, e.g., lamination of kitchen doors and panels. Therefore, polymers utilised for adhesives have to be modified or even completely reformulated. In a way similar to that of the flexible packaging industry, the adhesives industry has faced over the last 10 years a reduction in the lifetime of polymers from more than 10 years to 3 to 5 years.

The electronics industry is well known for the very short life cycles of its products. In the case of handheld devices (HHDs) (mobile phones), new models are released every 1 to 2 years, and adhesives (mainly reactive acrylic- and polyurethane-based adhesives) play a crucial role in the assembly. Such adhesives are developed and manufactured in Europe for export to Asian countries where electronic devices are mainly assembled. Wherever possible, manufacturers of HHDs utilise the adhesive over multiple models, but changes in design or in the way the products are assembled will require reformulation of the adhesive, often combined with a new polymer as backbone to meet the specification of the new model. For such cases, the lifetime of polymers utilised in such adhesives can be as short as 1 to 2 years. On top of that, we need to consider the new requirements for repair and recyclability of electronic devices. These must be considered in the design of the adhesive itself with a high degree of customisation of the polymer backbone and continuous improvement needs over a longer period to optimise efficiency.

Beside efficiency improvements, adhesive suppliers are also confronted with changing requirements, e.g., resistant properties due to changes in the food composition whereby the adhesive no longer resists specific food components. To address such requirements, adhesive suppliers need the flexibility to modify existing polymers as well as to change the overall polymer composition to meet customer expectations in a timely manner.

In addition, the adhesives industry is facing an increased demand for bio-based adhesives to address the requirements of the new EU circular economy initiative.

If the costs of registering customised adhesives and sealants in Europe are not affordable or customisation is no longer possible, companies might move their manufacturing sites out of the European industry and import the final products instead.

Proposed approach

With all this in mind, FEICA proposes to have a viable solution, with pragmatic grouping criteria to balance the economic impact on the industry. FEICA is working on a proposal for a set of grouping rules to further support the grouping concept and would be happy to share the results of such an exercise with the Commission and other stakeholders.

Grouping should be as wide as possible, to allow customising inside this framework.

In addition, an exemption for polymeric precursors should be granted. In the case of industrial uses with no or minimal exposure, where precursors subsequently cure on application, such transient species should not be considered within the Exposure Scenario. Registration of such functional polymers should not be required.

Manageable exposure should be considered when defining polymers requiring registration.

The data requirements for registration of polymers should be tiered according a tonnage band approach.

Conclusion

The members of FEICA are thankful for all the efforts of the CARACAL Polymers subgroup in trying to identify polymers requiring registration and will continue contributing to the global discussion.

However, from all that has been said, it is easily understandable that the adhesives and sealants industry is confronted with some particular issues that may differ from the issues chemical suppliers face. We hope that the practical examples we are providing with this paper will illustrate those issues to the rest of the stakeholders.

The customisation of polymers implies, for their manufacturing and for the achievement of the technical properties required, a high degree of flexibility and considerable knowledge. For the purpose of the present discussion, as customised polymers are manufactured in many cases by SMEs, it is evident that such companies will be unable to support the burden of multiple registrations.

Therefore, FEICA is convinced that grouping concepts, sameness and similarity approaches, and the affording of exemptions for polymeric precursors are of utmost relevance and should be reflected in any polymer regulation in a pragmatic and robust manner.

We would also like to express our willingness to discuss the abovementioned issues with any interested stakeholder or provide more practical examples if necessary.

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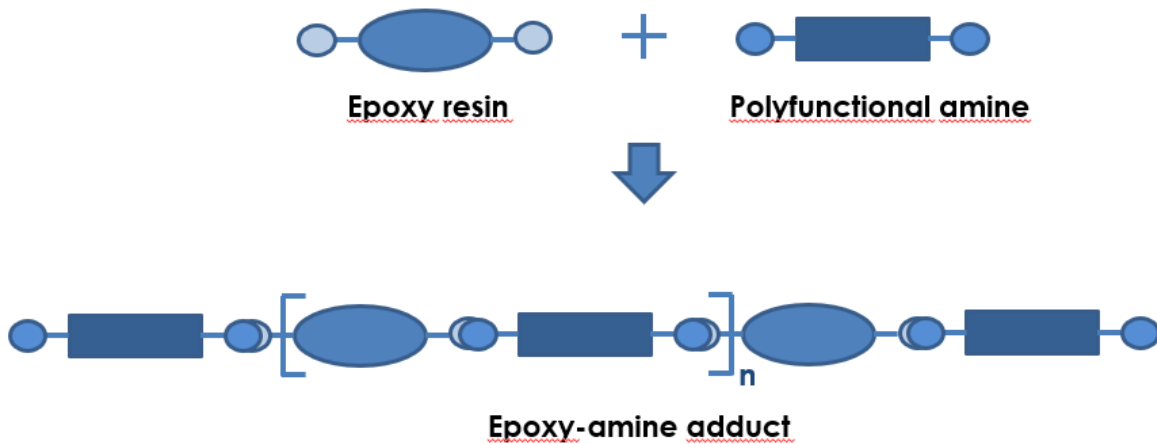
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Annex 1 Multiplicity of polymers

EPNHA–Customised Polymeric Precursors

Epoxy-Amine Adducts (EPNHAs) are customised precursors in many tailor-made epoxy products, such as adhesives, coatings and construction materials. They are produced by the reaction of epoxy resins with di- or polyfunctional amines. The EPNHA can be either polymeric or non-polymeric, depending on the use.

Epoxy A resin is the most common epoxy component for these precursors, while on the amine side, a large variety of amines can be used, e. g., aliphatic, cycloaliphatic and araliphatic amines, which may have two or more amino groups as the functional group. Amines can be used on their own (single amine), or several amines can be combined to alter properties.



There are more than 100 amines on the market that could be used for EPNHAs. Most EPNHAs for commercial applications, however, are produced with a set of approximately 15 to 20 amines. Combinations of these amines give a large number of possible EPNHAs. The table below illustrates how two (or more) amines can be combined in an EPNHA.

	Amine 1	Amine 2	Amine 3	Amine 4	Amine 5	...
–	Adduct 1	Adduct 2	Adduct 3	Adduct 4	Adduct 5	...
Amine 2	Adduct 1-2	–	Adduct 3-2	Adduct 4-2	Adduct 5-2	...
Amine 3	Adduct 1-3	–	–	Adduct 4-3	Adduct 5-3	...
...

The reason for using such a large variety of different EPNHAs is to formulate tailor-made epoxy products which meet customer demands and allow staying competitive and flexible in changing market environments. EPNHAs allow formulations to be tailored, e. g., to improve application

properties, durability or longevity, but also to improve efficiency in production (e.g., faster line speed in assembly operations) and to reduce the hazard profile of the product.

Most SME manufacturers of EPNHA are under the current REACH regulation for typical downstream users of raw materials without registration obligations. If customised polymers will require registration, these SMEs will find themselves in the unfamiliar role of registrants.

Epoxy-amine adducts are used in reactive, 2-part epoxy products, such as adhesives, in industrial applications (e.g., wind turbines), in construction applications (concrete and steel structures) and in automotive applications. Other uses include coatings (e.g., corrosion-protection coatings, marine coatings and heavy-duty coatings), flooring materials (e.g., in industrial facilities, warehouses or car parks) and construction chemicals, injection materials (for reinforcing cracks in concrete) and tile adhesives. The epoxy products cure after application into crosslinked high molecular weight resins.

One-Component Foam (OCF) Example

The number of polymers in an OCF formulation is incalculable. The actual polymer, which is contained in the foam can and cures to the insulation material after application by reaction with water or humidity, is formed by a reaction of the main components polyol and isocyanate in the packaging (pressurised can) immediately after filling (prepolymer). Since a chemical reaction takes place here, this composition could be different for each batch, depending on, e.g., the respective temperature of the raw materials and other process-related parameters, such as the shaking process after filling, and gassing.

The starting raw materials themselves already consist of a variety of polymers, as they are of technical quality. Due to the permutation of these components during the chemical reaction in the can (pre-polymerisation), the number of possible polymers is already enormous. This multiplicity is further enhanced by the fact that the formulations usually consist of several different polyols, which can combine with the various isocyanate molecules in any arrangement and chain length.

Polyols are defined by a few parameters that make them appear identical at first glance. In practice, the specification is only an average; e.g., the molar mass may consist of a narrow distribution with very similar chain lengths (molar masses) or the average of widely differing molar masses. Thus, one would have different polymers with the same specification.

One-component PU foams are very popular insulation and filler materials among craftsmen and do-it-yourselfers because they are very high-performing on the one hand and very economical on the other. Because of the self-expansion of the curing foam, they are also safe to use and contribute significantly to reducing CO₂ emissions. A registration obligation would increase the costs of these products and hinder their further development. As a consequence, alternative but less efficient insulation and filling materials could be preferred since they are not based on polymers and would therefore not be affected by this registration. Examples would be mineral wool or concrete.

The PU Example

The versatility of polyurethanes is derived in large part from the wide selection of building blocks available to materials designers. In principle, there is as much potential for design of isocyanate structures as there is for alcohol and amine coreactants. Thus, for the purpose of obtaining any

particular outcome, varying the polyol and the chain extender components is the most straightforward way to begin.

The polyols in urethane formulations tend to provide softness and flexibility, while isocyanates and low-molecular-weight chain extenders provide hardness and stiffness to the resulting polymer structures. Polyols are produced with a range of backbones and hydroxy functionalities that can be tailored to best meet application processing and property requirements. The most industrially significant polyol backbones are ether- and ester-based, while a number of specialty backbones including carbonate, acrylic, and ethers derived from tetrahydrofuran (THF) are used in high-performance coating, adhesive, and elastomer applications.

Non-exhaustive examples are polyether polyols based on propylene oxide and ethylene oxide, aliphatic polyester polyol, aromatic polyester polyol, polyether polyols based on tetrahydrofuran, polycarbonate polyols, acrylic polyols and polybutadiene polyol.

Isocyanates represent a class of chemicals that are characterised by high reactivity and versatility. Since additional polymerisation requires that monomers be able to propagate a chain by undergoing multiple reactions, polymerisable isocyanate monomers have at least two isocyanate functionalities.

The two highest volume diisocyanates are based in one case on toluene to make toluene diisocyanate (commonly referred to as TDI) and methylene diphenyl diisocyanate (commonly referred to as MDI).

Polyurethanes also function in any number of applications requiring good weatherability that can be hindered by aromatic ring structures, and entirely aliphatic polyisocyanates have been developed for these uses.

Non-exhaustive examples of commercially available monomeric diisocyanates are 2,4-TDI and 2,6-TDI, 2,2'-MDI, 2,4'-MDI and 4,4'-MDI, HDI, IPDI, H12MDI, TMXDI, XDI, PPDl, and naftalen diisocyanate.

The chain extender has a significant effect on the kinetics and extent of phase separation. There are a huge number of potential chain extenders that can be employed to alter hard segment structure, polymerisation kinetics and polymer properties.

Non-exhaustive examples are water, ethylene glycol, 1,2-propylene glycol, 1,3-propylene glycol, diethylene glycol, neopentyl glycol, butanediol, hexanediol, cyclohexane dimethanol, 4,4'-methylenebis (2-chloroaniline), glycerin, trimethylolpropane, 1,6-hexane diamine, 1,3-diamino pentane, diethanolamine and triethanolamine.

Furthermore, the isocyanate group can undergo at the same time other reactions besides urethanisation, for example, allophanation, urea and biuret formation, and isocyanuration.

Combinations of these monomers and coreactants, and different types of reactions give an astronomical number of possible polymer combinations. Obviously not all such possibilities are exploited, but thousands of formulations (as monomer compositions) exist commercially. This number needs to be further increased because each of these may be produced with different molecular weights (there can be 2 to 3 grades for each single monomer composition). If no grouping is applied at all, or if a restrictive grouping criterion is implemented, the number of potential registrations may be 5,000 (if a group contains 2 to 3 members) or up to 15,000 (with no grouping at all).

Also, from this short enumeration, which, incidentally, actually applies only to a polyurethane moiety, it is clear how many customised polymers are not only possible but also necessary in order to get the needed technical properties.

The Polyester Example

Polyesters are a very versatile class of polymers, that can be used as such or in combination with other chemicals in order to get many different properties and technological effects. Practically speaking, any real, medium-sized company might use around 27 monomers (dibasic acids, monobasic acids as terminating parts, diols, polyols, etc.), not counting other polyester-like polymers like alkyds. Combinations of these monomers give an astronomical number of possible polymer combinations. Obviously not all such possibilities are exploited, but approximately 500 formulations (as monomer compositions) exist commercially, and this number needs to be further increased because each of these 500 formulations may be produced with different molecular weights (There can be 2 to 3 grades for each single monomer composition). If no grouping at all is applied, or if a restrictive grouping criterion is implemented, the number of potential registrations may be 500 (if a group contains 2 to 3 members) or up to 1,500 (with no grouping at all).

Also, from this short enumeration, which, incidentally, actually applies only to a polyester moiety, it is clear how many customised polymers are not only possible but also necessary in order to get the necessary technical properties. It is worth recalling that, in addition to polyester, polyethers are used, complicating the picture, as well as diisocyanates of different natures (aliphatics, like hexamethylene diisocyanate, isophorone diisocyanate, H12MDI and others; aromatics, like toluene diisocyanate (TDI), methylene diphenyl diisocyanate (MDI), etc.; or even araliphatics, like m-xylylene diisocyanate (XDI).

In addition to those chemicals, in some cases it is necessary to use chain extenders (usually amines), which further complicate the matter.