FEICA The European voice of the adhesive and sealant industry

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FEICA comments after fourth CASG Polymers meeting

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

The 'Thought Starter on substance identification and joint submission obligations of Polymers Requiring Registration' developed by the European Chemicals Agency (ECHA) was discussed during the fourth CARACAL Subgroup polymers meeting held on 22 June (Agenda item 4: CASG-Polymers/05/2021).

FEICA submitted some initial comments[1] regarding the paper in advance of the CASG meeting.

We would like to further comment on the paper in line with the discussions held during the meeting.

Polymer substance ID

FEICA supports ECHA's proposal, as stated in Annex II of the Thought Starter:

It is recognised that according to REACH definitions, polymer substances consist of two parts which are both considered: the polymerised part and a part that does not result from the monomer(s) polymerisation reaction. Based on the current practices under REACH, differences in the impurity profile are not a reason as such for registering substances separately. The same applies to substances stabilised with different additives. Where a differentiation between substances displaying different impurity profiles is relevant, several boundary compositions can be specified in the registration. As there is no manifest reason why polymers should be treated more restrictively than substances currently registered under REACH, it is proposed not to include these elements among the criteria to assess compositional similarities for the purpose of defining the polymers to be registered jointly.

[1] FEICA comments on ECHA's Thought Starter on SID polymers.

Chemical components that are necessary for the stability of the polymer should be included in the substance ID. However, components not relevant for the stability of the polymer should not affect the substance ID. FEICA considers, therefore, that almost all impurities, catalysts, additives, processing aids, solvents, performance-related components or appearance improvers and residual starting materials should have no impact on the substance identity. These chemical combinations shall be regarded as mixtures.

Solvents and catalysts are often changed when polymers are reformulated. The amount and choice of solvent can also vary. The same polymer can be formulated with different catalysts and solvents and change over time, and that would not have an effect on the identity of the polymer.

Unreacted and residual monomers should not be differentiated. Monomers are registered substances and should not be part of the polymer identity. The concentration of a monomer in a polymer does not change the identity of the polymer and, therefore, should be excluded from the polymer ID.

The hazard classifications of these kinds of mixtures can be calculated separately.

Grouping

We consider that hazard similarity should be the central element and the goal to define and justify polymer grouping in order to ensure safety of human health and the environment.

We acknowledge that CAS numbers (or other available identifiers, such as EC numbers) can be useful to identify polymers. However, chemistry-based grouping criteria should be broader and not based solely on one identifier, e.g., the CAS number. In addition to CAS numbers, other chemistry-based identifiers could be used, such as polymer classes and functional groups.

CAS numbers can be used in different types of polymers.

We would also like to highlight that those chemical names of polymers can be very lengthy. For practical terms it might be more suitable to describe the polymer as a reaction product of a set of monomers.

Grouping of polymers should be as wide and flexible as possible to allow the formulation of customised polymers inside this framework.[2]

At FEICA, we think options should be kept open. Chemical grouping should be applied first. In case additional data (physico-chemical or hazard data) is available, a merging of different PRR substances could be possible.

Different grouping approaches could be used depending on the data available. The grouping approach as described in the ECETOC paper 'ECETOC considerations on grouping of polymers' should be favoured if available data would allow for it. If that data is not available, a chemistry-based grouping could be adopted instead.

FEICA also supports the 2% rule as referred to in Annex II of the ECHA paper. Constituent monomers or reactants at equal to or less than 2% at the polymer should not be considered for grouping or registration of the polymer.

[2] Further information about the customisation of polymers.

The 2% rule is also applied in other jurisdictions; therefore, its implementation in Europe would facilitate global regulatory harmonisation.

For polymers with > 2% of a different monomer, the approach proposed in the ECETOC paper would be much more practical as it would allow starting with the assumption that a certain group of similar polymers, even based on different monomers, might have similar physico-chemical properties and could be grouped together. Evaluating the hazard profile of representative polymers of such a group will prove or disprove the original assumption.

Grouping should be done in a practical way to avoid an unnecessarily high number of groups, each to be registered separately. Identical polymers made from different starting materials should be able to be grouped together. However, in certain cases, using the same starting materials, different polymers are formulated.

For example, Polyamide (PA) hotmelts are made from a set of different carboxylic acids and aliphatic diamines whereas dimer fatty acid is a key component. The composition can be different, but all PAs have in common a Mw > 10000 dalton, FGEW > 5000 dalton, solidity at room temperature and high hydrophobia resulting in a non-measurable low water solubility. They can be amine or carboxylic end group terminated, and by evaluating the hazard profile of the lowest Mw amine and carboxylic term PA, we will be able to determine if both have a comparable (same PRR substance) or different (separate PRR substance) hazard. On the contrary, lower Mw weight (<<10000) PAs based on a comparable chemistry are liquids and are expected to behave differently in a toxicological test.

Annex III 'Molecular and Structural Information' suggests the provision of ranges for values that are relevant for the characterisation of molecular weight and molecular weight distribution to display the variations in the manufacturing process. We consider that, if such ranges are to be provided, it should be kept in mind that continuous process improvement in the direction of energy and material efficiency is a steady task, and there is the possibility that these steps will lead to changes in the values - without affecting hazard profiles at all.

In any case, opting out of joint registration should be allowed when there are sufficient reasons (for example, for situations when it is not clear if the polymers belong to the same group).

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