

Exposure Scenarios intended to be covered in the Vinyl Acetate Monomer REACH registration dossier

"Manufacturing of the Monomer Vinyl Acetate" and

"Use of Vinyl Acetate Monomer in Polymer Production ((co)polymerization processes of vinyl acetate monomer)"

Rationale for not including additional Exposure Scenarios in the Registration Dossier for Vinyl Acetate Monomer

The European Court of Justice adopted on July 07, 2009, its judgement in the case of monomers in polymers, confirming the main points of the advisory opinion of Advocate General J. Kokott (Case C-558/07)¹.

According to the adopted Advocate General's opinion, the life cycle of a monomer ends when it is reacted into a polymer (para 48).

Para 48 further details" Under point 0.3. of Annex I to the REACH Regulation, the life cycle of a substance covers its manufacture and identified uses. *A polymer is not a use but a separate substance within the meaning of the definition of a substance in Article 3(1) of the REACH Regulation. It therefore has a life cycle of its own.*" (emphasis added)

Exposure Scenarios are defined to be covering the life cycle of a substance (REACH Art. 3(37)). For this reason, the REACH registration dossier for Vinyl Acetate Monomer will only include the Exposure Scenarios for production of the monomer and (co)polymerisation processes.

The above also provides the rationale for the deviation from scenarios developed in the EU Risk Assessment for Vinyl acetate²: The scenarios "Manufacturing of Formulations and Products containing VAM-based (co)polymers (formulation step)" and "Use of formulations and products containing residual vinyl acetate monomer" can be excluded from the REACH registration dossier as they relate exclusively to (co)polymers which are regarded to have life cycles of their own.

In case of polymers or polymer preparations, application of REACH Art. 14(2) may be considered: A Chemical Safety Assessment (CSA) is not required if the concentration of a substance in a preparation is lower than the concentration limit (cut off limit) for classification and labelling.

The data collected for the EU Risk assessment show that residual vinyl acetate monomer levels in the polymers manufactured in the EU are considerably lower than the highest relevant classification and labelling concentration limit (cut off limit) of 1 wt.-%.

Any other components in the polymers manufactured by downstream users need of course be evaluated separately whether or not they fulfill the criteria specified in REACH Art. 14(2).

¹ Full document: http://curia.europa.eu/jcms/jcms/j_6/, Case no. C-558/07

² EU Risk Assessment document:
http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/vinylacetatereport059.pdf