

Position Paper

Prioritisation with a sense of proportion: Anhydrides MHHPA and HHPA under the REACH Regulation



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German Electrical and Electronic Manufacturers' Association

Anhydrides MHPA and HHPA under the REACH Regulation

The REACH authorisation process pursues three equivalent targets: the smooth functioning of the European internal market, the sufficient control of the risks from Substances of Very High Concern (SVHC), and the successive substitution of SVHC by appropriate alternative substances or technologies, if they are economically and technically feasible.

Altogether, it aims to ensure a high level of protection for human health and for the environment. This target shall promote innovations and improve production conditions by preventing harmful consequences of SVHC on human health and the environment applying appropriate risk management measures.

Considering this background, the electro industry rejects the prioritisation of the two anhydrides MHPA and HHPA and their subsequent inclusion into Annex XIV following the REACH authorisation procedure:

- The electro industry supports the target of the REACH regulation to replace SVHC successively by appropriate substances or technologies as far as they are economically and technically feasible. The electro industry has the strong opinion that the REACH regulation will improve production conditions and encourage innovations provided that a risk management option analysis (RMOA) is performed before under the involvement of industry expertise.
- With respect to the risk management of SVHC, decisions concerning adequate and proportionate risk management options have to be taken as early as possible (even before the preparation of an Annex XV dossier) and in a transparent way under industry involvement. It has to be ensured that decisions and requirements are adjusted to the actual risks and that for the concerned substance and its applications the necessity of risk management actions is investigated (“case-by-case”). If this is the case, the most appropriate action has to be chosen.
- The electro industry raises biggest concerns against the prioritisation of the two anhydrides MHPA and HHPA in the frame of the REACH regulation, as the possible risk already is under control and furthermore no technical alternatives are known at time being. Out of this reason, we argue in favour of a risk management option analysis (RMOA) with involvement of industry expertise before the prioritisation of the two substances. A hasty prioritisation of the anhydrides MHPA and HHPA and the disregard of a risk management option analysis (RMOA) within the prioritisation procedure would inevitably result in the migration of whole economic branches and the import of finished products from non-EU countries.
- The electro industry supports therefore the position of BDI¹ that for each substance and its applications an investigation should be performed whether risk management actions are required and if so, to choose the most adequate action.

¹ See publication by BDI: “Positionspapier zur Anwendung des risikobasierten Ansatzes bei der Auswahl von Instrumenten zur Stoff-Reglementierung unter der REACH-Verordnung, um Benachteiligungen der europäischen Erzeugnishersteller zu vermeiden“; http://www.bdi.eu/download_content/KlimaUndUmwelt/BDI-Positionspapier_SVHC_20140404_final.pdf

Introduction

Anhydrides MHHPA (Methylhexahydrophthalicacidanhydride²) and HHPA (Hexahydrophthalicacidanhydride³) are key building blocks for the production of insulating materials based on epoxy resin, which are mainly used in electrical equipment devices. Their proper function depends on insulations made out of epoxy resin.

Electrical equipment devices are main components of a successfully operating infrastructure for energy generation and distribution. Efficient electricity networks require equipment such as electrical switchgear, switching devices and transformers for voltage transformation and energy distribution as well as for the connection and disconnection of parts of the supply network (substations). Electrical machines are applied for energy generation, conversion and distribution and therefore are absolutely essential for the achievements of the political targets concerning the energy transition ('German Energiewende') as well as energy and resource efficiency.

Beyond these main applications, epoxy resins are also used extensively for insulation in automotive electrics and shipbuilding as well as for encapsulations in lighting technology (LEDs) and IT equipment (fibre optics).

Economic and technical importance

Epoxy resins utilising MHHPA and HHPA are key enablers for powerful, cost-effective and energy-efficient insulations. They are applied, among others, in motors, generators, electrical switchgear and transformers in the field of renewable energies and electro mobility since years.

These insulating materials are in use since decades.

Within the process of manufacturing of the electro-technical products, the anhydrides react chemically with the epoxy resin so that no free anhydrides are present in the finished product. In this sense, anhydrides can be described as intermediates in the production process.

Technically and economically feasible substances as substitutions are currently not known. Although other curing agents are available for epoxy resins, they do not provide the required process capability, the required combination of mechanical, thermal and electrical resistance, as well as the required durability for outdoor use. Also, insulating materials based on other chemical substances do not fulfil all these requirements.

A possible ban of the use of anhydride hardeners will put a large burden on the concerned enterprises in the EU and creates a considerable competitive disadvantage compared with producers outside the EU. Even with a possible ban of anhydrides, finished products could be imported into the EU. The elimination of the production of epoxy resin components and the aforementioned electro technical products within the EU would constrain the innovation ability of Europe targeted by REACH and the development of new components and applications in

² Different spellings are in use, see EC Number (247-094-1, 243-072-0, 256-356-4, 260-566-1)

³ Different spellings are in use, see EC Number (201-604-9, 236-086-3, 238-009-9)

Europe. Therefore, seen in the long term this would threaten the technological leadership of Europe concerning electrical equipment, and massively impact the renewal of energy generation plants and the extension of power distribution.

Even if alternatives are found, it has to be kept in mind that in central industrial competence areas, for example in aerospace, shipbuilding, automotive engineering, energy generation and distribution, as well as mining industry (explosion protection), specific certifications and standards for materials have to be fulfilled with respect to safety aspects. Such special approvals based on vast technical investigations may require many years, if not decades.

The technology leadership in the field of epoxy resin insulation has drawn considerable research efforts in Europe over decades and was established as worldwide standard over the years.

Unless a long term security of supply of the electro industry with the aforementioned anhydrides is guaranteed, the threat is already today real, that developments will migrate outside Europe.

Safety aspects and risk management

Anhydrides are exclusively used as monomers and therefore as intermediates within the production chain in industrial appliances. There are no consumer applications; there is no sale to non-industrial customers according to the chemical industry.

The finished insulation products based on cured epoxy resins do not contain free anhydrides and therefore are safe to use⁴. In the last decade, large effort was applied in the area of occupational safety and risk reduction in addition to the optimization of technical properties and processing technology. Processing is carried out in accordance with the requirements established by safety data sheets, following work protection regulations, including workers medical surveillance.

The respiratory tract sensitizing properties⁵ are known since the investigations during the 1990s. As a consequence, the manufacturing industry had introduced safety precautions for the handling of anhydrides (as requested by the safety data sheets). In today's epoxy processing facilities, technical, organisational and personal protective measures have to be applied (local exhaust ventilations and personal respiratory protections, etc.). All used materials are processed, whenever possible, in closed systems.

The proper execution of occupational health, safety and environmental protection measures are reviewed periodically by the Professional Association⁶ and by the Labour Inspectorate⁷.

As a result, the risk of an unintentional exposure was taken under control.

⁴ Laboratory tests are available and can be provided on request

⁵ See also: „Conclusion on the identification of equivalent level of concern“: „Therefore, it is concluded that MHHPA fulfils the criteria of being of an equivalent level of concern as CMR (cat 1 or 2) substances. Therefore, MHHPA can be regarded as a Substance of Very High Concern (SVHC) according to Article 57(f) of the REACH legislation (Regulation (EC) No 1907/2006) and may be included in Annex XIV.“

⁶ See BG/BGIA Report, Arbeitsschutzlösungen für ausgewählte Stoffe und Verfahren, 2006, Abschnitt 3.19

⁷ Labour Inspectorate monitors compliance with §§ 14 and 15 of BetrSichV

In cases, in which sensitisation (asthma, rhinitis or conjunctivitis) occurred in spite of the aforementioned health and safety measures, it is industrial practice since years to offer alternative jobs to affected workers, so that contact to the substances does no longer occur. In verifiable cases (see dossier from ECHA⁸), resolution of all symptoms has been reported.

About the ZVEI

The ZVEI is committed to the common interests of the electrical industry in Germany and at the international level. Over 1,600 companies have opted for membership of the ZVEI. They employ around 90 percent of the employees and staff of the electrical industry in Germany.

With its 26 divisions and corporate members, the ZVEI represents a sector with revenue in 2013 of Euro 167 billion and almost 841,000 employees. With the over 665,000 employees outside of Germany, the value addition of the electrical industry is the most highly networked of all sectors worldwide.

About 40 percent of its turnover comes from novel products and systems. Every third innovation of manufacturing industry is based on solutions of the electrical industry. The basis of this power of innovation is the high expenditure on research and development: year by year, the companies of the electrical industry invested nearly Euro 14.7 billion for R&D, Euro 6.6 billion on Investments and two billion on education and training.



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⁸ Annex XV Dossier HHPA and MHPA (2012)