Prioritization with a Sense of Proportion: Anhydrides MHHPA and HHPA under the European REACH Directive

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Introduction

Members of the European Committee of Manufacturers of Electrical Machines and Power Electronics (CEMEP) and the National Electrical Manufacturers Association (NEMA) in the US supply the majority of motors, generators, transformers, switchgear, and other critical electrical products placed in operation in the EU market. The two groups respectfully offer the following comments with regard to ECHA's proposal to add the anhydrides MHHPA and HHPA to the SVHC Candidate List under REACH.

Background

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

Altogether, REACH aims to ensure a high level of protection of human health and the environment. By doing so, it is intended to promote innovation and improve production conditions that prevent harmful consequences of SVHCs through appropriate risk management measures.

Position Statement

Considering this background, the electro-product industry objects to the prioritization of the two anhydrides MHHPA and HHPA and their subsequent inclusion into Annex XIV following the European REACH authorization procedure. While manufacturers of electrotechnical products support the goal of replacing SVHCs successively through appropriate substitution and technological innovation, we strongly believe that ECHA's decision on anhydrides is premature and lacks a sound scientific basis. We recommend that a risk option management analysis (RMOA) be conducted with technical guidance from experts within the manufacturing industry.

Decisions concerning adequate and proportionate risk management options for SVHCs must be made as early as possible through a transparent process in association with industry. This analysis should be performed ***prior to*** the preparation of an Annex XV

dossier to ensure that the dossier properly assesses the actual risks associated with differing applications of the substance under review. Only in this way can the most appropriate risk management options be defined.

The undersigned organizations further contend that potential risks associated with the two anhydrides MHHPA and HHPA are already mitigated and that no commercially available alternatives exist for their critical applications. A decision to prioritize the anhydrides MHHPA and HHPA at this time would inevitably result in the economic disruption of main industrial suppliers.

In summary, the undersigned organizations recommend that a more detailed analysis of the particular applications of these substances be conducted to accurately determine risks and appropriate mitigation actions. A broad-based "blanket" prioritization is premature and does not reflect the reality of how these compounds are used in the production arena.

Substance Information

Anhydrides MHHPA (Methylhexahydrophtalicacidanhydride2) and HHPA (Hexahydrophtalicanhydride3) are key building blocks in the production of epoxy resin-based insulating materials, which are widely used in electrical equipment. The proper function as well as the electrical safety of this equipment is largely dependent on the insulating material containing the epoxy resin.

Electrical products and systems in turn are key 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 motors and generators that control energy conversion and generation are absolutely essential to achieving policy objectives related to energy transition and resource efficiency and are backbones of the worldwide industry.

In addition to their use in electrical infrastructure, epoxy resins are used extensively for insulation in automotive electrics and shipbuilding as well as for encapsulations in lighting technology (LEDs) and IT equipment (fiber optics).

Economic and technical importance

Energy efficient insulating materials containing MHHPA and HHPA have been used successfully for decades in the aforementioned applications. Within the manufacturing process, 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.

Epoxy resin insulation has been the focus of considerable research activity for many years and long term security of supply of the electro industry with the aforementioned anhydrides is necessary to be guaranteed. At this time, industrial manufacturers have tested and found out, that no technically reliable and economically feasible substitutes for MHHPA and HHPA are available for their applications in the electrical sector. Although other curing agents are available for epoxy resins, they do not provide the process capability or required combination of mechanical, thermal and electrical resistances, nor are they sufficiently durable for outdoor use. Furthermore, insulating materials based on other chemical substances also fail to meet these requirements.

Restrictions on the use of anhydride hardeners will impose a large burden on companies that manufacture insulating materials for critical electrical products. This would constrain innovation among companies and thus adversely affect energy generation plants and the extension of power distribution.

Even if alternatives to anhydrides will be discovered, they must be proven to meet rigorous safety requirements and quality certification standards before approved for widespread use in power generation and distribution, not to mention other central industrial competence areas such as aerospace, shipbuilding, mining, and automotive engineering. Attaining special approvals for these applications require vast technical investigations that may last many years, if not decades.

Safety aspects and risk management

Anhydrides are exclusively used as monomers and therefore as intermediates within the production chain for industrial appliances.
Moreover, finished insulation products based on cured epoxy resins do not contain free anhydrides and therefore are safe to use. In the last decade, manufacturer initiatives and regulatory requirements have led to advancements in the area of occupational safety and risk reduction as well as optimization of technical properties and processing technology. Processing is carried out in accordance with the requirements established by safety data sheets, following worker protection regulations, including medical surveillance.

The respiratory tract sensitizing properties of anhydrides have been recognized since the 1990s. As a consequence, the manufacturing industry had introduced safety precautions for the handling of anhydrides (as requested by the safety data sheets). Extensive technical, organisational, and personal protective measures (e.g. local exhaust ventilations and personal respiratory protections) are universally present in today's epoxy processing facilities. All used materials are processed, whenever possible, in closed systems. The proper application of occupational health, safety and environmental protection measures are reviewed periodically by national dedicated authorities and by the Labour Inspectorate.

As a result of these procedures and regulatory requirements, the risk of unintentional exposure to anhydrides in state of the art production facilities is minimal.

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

The National Electrical Manufacturers Association (NEMA)
The National Electrical Manufacturers Association (NEMA) represents nearly 400 electrical, medical imaging, and radiation therapy manufacturers. Our combined industries account for more than 400,000 American jobs and more than 7,000 facilities across the U.S. Domestic production exceeds $117 billion per year. Our industry is at the forefront on electrical safety, reliability, resilience, efficiency, and energy security.

About CEMEP
CEMEP is the European Committee of Manufacturers of Electrical Machines and Power Electronics, representing an industry with a market value of € 6.3 billion and 130,000 employees. The members of CEMEP are the National Associations in Europe, representing manufacturers of electric motors, variable speed drives and uninterruptible power supplies. This organization allows industry to co-ordinate actions at the European and International level, with the main topics being: market evolution, standardization, regulation, promotion and connection with other products & professional groups.

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