VCI Information on

Preservation of Chemical Products

Legal Requirements

Preservatives serve to protect substances, mixtures or articles in containers and packs against microbial attack. The use of preservatives means that the products treated with them have longer shelf-lives and remain fit for their intended use also after prolonged storage or even after the container or pack has been opened. Preservatives are used in a large number of highly diverse systems (aqueous solutions, emulsions, dispersions, pastes): Both DIY (do it yourself) and professional products as well as intermediates used in industry or research & development must be preserved with preservatives (examples: see annex 2).

Preservatives are regulated under “Product-type 6: Preservatives for products during storage” (PT 6) in the Biocidal Products Regulation (EU) No 528/2012 (BPR). According to the BPR, mixtures treated with a preservative are called “treated articles”. Beside any product-specific provisions, possibly existing labelling rules have to be applied as described in Article 58 BPR. Furthermore, suppliers need to meet information requirements.

However, the BPR rules on product preservation do not comprise all products. For example, the preservation of food and feeding stuffs and cosmetics is exempted from the BPR. Here, sector-specific provisions apply for use and labelling.

Reasons for using preservatives

The industry constantly works to improve its products in terms of functionality and durability and also regarding environmental and health protection.

- For many years, great efforts were made in product development away from organic solvents to water-based products.
- Readily biodegradable substances are increasingly used in formulations, partly also because of regulatory requirements.[1]
- The content of remaining residual monomers[2] e.g. in polymer dispersions was reduced significantly.

[1] For example, the Detergents Regulation (EC) No 648/2004 demands for detergents and cleaning products that input surfactants must have complete aerobic biodegradability.

[2] Residual monomers can remain in many products, with negative impacts on these products as regards their technical functions and toxicological properties. Therefore, the residual monomer content should be as low as possible.

This progress only was made possible by the use of preservatives, as organic substances in aqueous media are often an ideal breeding ground and form the basis of life for micro-organisms such as bacteria, moulds and yeasts that decompose them. Therefore, organic components in water-based products inevitably require protection against attack by micro-organisms, in order to safeguard their durability.

The essential protection of organic substances against attack by micro-organisms concerns not only end products but also starting materials and intermediates, i.e. the whole production chain. In many cases without preservation, water-based intermediates and end products could not be supplied in a non-perished state along the value chain or to end consumers. Although an excellent plant hygiene is very important, a complete microbial protection cannot be ensured along the whole production and supply chain. Also, many mixtures must remain stable after their containers or packs have been opened. Some examples are wall paints or liquid detergents and cleaning products whose total volume is usually not consumed totally at once. Early microbial spoilage would not only result in large amounts of waste and unnecessary resource consumption; it would also have effects on the health of consumers.

Alongside improved formulations, the industry has also optimised and targeted the use of preservatives. Different active substances have different activity spectrums (see below, "*Different active substances are needed"*) and micro-organisms vary depending on the end product and the location. In extensive tests, a suitable preservative is identified for the respective product, and the active substance concentration is optimised. In this exercise, especially for industrial use quite often the real germ load is determined and monitored. Health and environmental protection as well as economic aspects are taken into account. The following motto applies: "As much as necessary, as little as possible."

Certain products need no preservatives to be added. This is the case where mixtures are present in a medium that per se does not permit excessive growth of micro-organisms.

- In very acidic or very basic mixtures or in solvent-containing formulations, there usually is hardly any or no growth of micro-organisms. Examples are silicate paints, solvent-containing coatings and acid cleaners.
- Products without water or with very low bioavailable water (lowered water activity), e.g. powder or gel detergents, usually do not additionally require preservation.

According to the current state of the art for most uses or products (annex 2) preservatives are indispensable and will be in the foreseeable future, too.

Different active substances are needed

Due to highly diverse products on today's market and the different uses, there are lots of different requirements to preservatives for the large number of different products. This calls for a wide range of active substances:

- Not every active substance is compatible in every product. Oxidation sensitivity, odour, formation of discolouration or limited stability at certain pH values are aspects that need to be taken into account for use in the respective products.

  Example: Active substances that cause discolouration are unsuitable for use in coatings intended to improve the optical appearance of articles. Craft adhesives should not contain any active substances with strong or unpleasant odour.

- Micro-organisms can vary in different systems and also at different locations/ production sites. They can be controlled in a targeted manner by using suitable active substances. The required quantity of a biocidal product can be minimised through the use of active substances that are precisely tailored to the specific setting.

  Example: Gaps in effect can be closed by using active substances that complement each other. A complementary effect is achieved, for example, through a combination of the active substances MIT and BIT[3].

Decreasing number of active substances for preservation

Since 1998, preservatives have been regulated in the biocides legislation. Thus, they are subject to a two-tier authorisation system where, as a first step, the active substance is evaluated. Approval of the active substance is followed by the evaluation of the biocidal product. This evaluation relies on concrete and highly extensive data that applicants have to submit to the evaluating authorities. The authorisation for a biocidal product only is granted in a given use if the evaluating authority based on the risk assessment concludes that the product is effective and sufficiently safe for humans, animals and the environment.

The number of active substances available for preservation (PT 6) has dropped significantly in recent years from over 140[4] "existing active substances" to 48[5] currently available active substances. This development has several causes:

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[3] MIT = 2,methyl-1,2-thiazol-3(2H)-one

BIT = 1,2-benzoisothiazol-3(2H)-one

[4] Review-Regulation (EC) No 2032/2003, Annex II

[5] ECHA database, accessed on 16 October 2018

- **Active substances from the first review programme Regulation (EC) No 2032/2003 – Mainly economic reasons**

  Many of the active substances listed in the 2003 review programme are no longer supported. This is largely due to economic reasons: Costs and workload for active substance approval are extremely disproportionate to the market and economic viability. For example, preservatives for the food and feeding stuffs sector or for cosmetic products do not fall under the rules of the biocides legislation. However, for preservation in chemical products the same preservatives would have to undergo the complex and expensive authorisation procedure according to the BPR. Therefore, many manufacturers limit themselves to markets outside the BPR scope for economic reasons.

- **Active substances in the current review programme – Impacts of a harmonised classification**

  The CLP Regulation envisages a harmonised classification of biocidal active substances.[6] In many cases, the classification leads to restrictions in the use of the substances. On one hand the statutory exclusion criteria[7] play a role here. On the other hand there are also consequences[8] beyond the text of the BPR that are reflected in specific provisions in active substance approvals. Problems arise, in particular, for products where there is no clear borderline between products for professional users and end consumers.
  A classification also impacts the criteria for eco-labels, such as the “Blue Angel” or the “EU Ecolabel”. Many sector-specific regulations take up the classification, too.

- **New active substances – Uncertainty and costs**

  The approval of new active substances involves an enormous effort. One aggravating point is the uncertainty of whether the active substance will finally be approved as applied for. Generally, the use or the placing on the market of a new active substance are only possible after completion of the authorisation procedure for the relevant biocidal products.[9] The previously made high investment starts to amortise not before this period of time. Other active substances which are not covered by the current review programme need to go through the approval procedure for new active substances, too.

  Where substances are intended to be used for the first time as new active substances in biocidal products, there is the possibility of a provisional

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[6] CLP Regulation (EC) No 1272/2008

[7] BPR, Articles 5 and 19(4)

[8] Example: Classification as skin sensitiser can lead to restrictions through special rules in active substance approval

[9] Ideally: 4 years for performing the necessary tests for data gathering
1-2 years for dossier preparation
2 years for the evaluation process

authorisation.[10] By this means the use of an active substance in a biocidal product can be allowed prior to active substance approval. However, the provisional authorisation procedure cannot be applied for active substances already known as biocidal active substances.

Starting points for solutions – for the future availability of preservatives

From the VCI's viewpoint, fully abandoning preservatives is not target-oriented for consumer and environmental protection. Giving up the use of suitable preservatives would obliterate the progress achieved in the past decades: For reasons of environmental and health protection, we reject a return to solvent-containing systems or the use of active substances which, due to their critical properties, were substituted by active substances with better properties but lower efficacy. The positive developments of the past decades – both in occupational health and safety and waste avoidance –must not be counteracted for regulatory reasons by steps backward in preservation. The BPR with its two-tier assessment system decisively contributes to a sustainable use of biocidal products. With its extensive data requirements, tests and risk-based assessment of the respective uses by the competent authorities, the BPR ensures that only those biocidal products are placed on the market and used which have no unacceptable impacts on humans, animals and the environment.

With the advancing harmonised classification (CLH process), the expected limitations can be well-forecasted. Due to high hurdles in the approval of new active substances and in the authorisation of biocidal products, the reduction in the number of available active substances cannot be countered. Although various points of the BPR define facilitations for the authorisation of certain biocidal products – e.g. the option of a simplified authorisation[11] or a provisional authorisation[12] – these are hardly workable and mean a real facilitation only in very few cases. Therefore, it must be feared that suitable active substances and authorised biocidal products will be no longer available for all uses in the foreseeable future.

Against this backdrop, the VCI speaks for the following approaches for solutions in the existing regulatory framework:

- The real risk should be taken into account in the approval of active substances. Generally linking the active substance approval to the purely hazard-based classification in the CLH process does not serve the intended purpose.
- In order to meet the various requirements for preserving a wide range of different products, the hurdles in the authorisation procedure for biocides should be minimised as far as possible within the legal text. Existing tolerances/margin for data requirements and costs should be used in the framework of the legal

[10] BPR, Article 55(2)

[11] BPR, Article 25

[12] BPR, Article 55(2)

provisions, benefitting the availability of biocidal products. Furthermore, uncertainties should not be intensified but eliminated.

- A holistic approach[13] to all existing active substances for PT 6, which are currently still under review, would enable better comparability and an identification of really critical substances, while preventing a successive phase-out of all available active substances due to purely hazard-based considerations.

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- Identification no. in the EU Transparency Register: 15423437054-40
- The VCI is registered in the “public list on the registration of associations and their representatives” of German Parliament (Deutscher Bundestag).

The VCI represents the politico-economic interests of around 1,700 German chemical companies and German subsidiaries of foreign businesses. For this purpose, the VCI is in contact with politicians, public authorities, other industries, science and media. The VCI stands for over 90 percent of the chemical industry in Germany. In 2018 the German chemical industry realised sales of ca. 204 billion euros and employed 462,000 staff.

[13] “The need for a holistic Approach on in-can preservatives“ (CA-Nov14-Doc.4.6”

Annex 1: Explanation of the terms used in this information document

- (In-can) preservative:

  According to the BPR: biocidal product of product type 6 (PT 6) *"Preservatives for products during storage"*

- In-can preservation: Measure to prolong the durability of mixtures during storage by adding a preservative.

- Relevant definitions of the BPR and some explanations:

  "Biocidal product" [means] *any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.* […]

  This means: A preservative contains one or several active substances and is intended to have an effect against harmful organisms – e.g. fungi and bacteria – which are detrimental to the durability of a product.

  "Active substance" [means] *a substance or a micro-organism that has an action on or against harmful organisms.*

  "Treated article" [means] *any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.*

  This means: A preserved mixture intentionally contains a preservative, so it is a treated article.

Annex 2: Examples for various preserved end products and intermediates

In very many very different products for private end users as well as for professional users and intermediates preservatives are added. The utilised active substances and biocidal products have to be tailored to the respective uses and target pest organisms.

The following list contains examples for preserved products and should give an overview on the breath of product diversity.

- Washing and cleaning fluids for
  - floors and surfaces
  - cleaning in kitchens
  - cleaning in hospitals
  - bathrooms and toilets
  - washing up liquid
  - laundry washing fluids and conditioners
- Maintenance Products for
  - furniture
  - shoes
  - automotive
  - floors
- Paints, Coatings, and Inks
  - white and coloured paints
  - paints for outdoor use
  - wood protection products
  - coatings
  - children's finger paint
  - inkjet inks for private use, home office
  - printing inks for professional use (e.g. for newspapers, brochures, packaging, napkins, wall paper textile)
  - dyes
- Construction Chemicals
  - coatings for concrete protection
  - concrete admixtures and release agents
  - priming coats

- hydrophobic treatment
- sealings

- Glues and Adhesives
  - DIY glue and crafting glue
  - glue for wall paper
  - adhesives for floor coverings and parquet
  - adhesives for furniture
  - adhesives for packaging

- Products for Industrial or Professional Use
  - process chemicals in the production of textiles, leather and fur
  - pressroom chemicals
  - raw material for e.g. paper production
  - pre preserved intermediates

- Other Products
  - biodiesel
  - laboratory solutions
  - fluids used in medical devices
  - photo chemicals

This list of examples is not exhaustive. Furthermore there may be different uses within one group of products. E.g. there are professional and end consumer uses that might to be considered in preservation.

As a rule all water based products need preservation.