Background

Due to the high percentage of water and the absence of highly toxic ingredients, aqueous-based digital printing inks are subject to the growth of environmental bacteria and fungi. Therefore, they require the use of biocides as in-can preservatives, Product Type 6 (PT6), under the Biocidal Products Regulation (BPR). The most important group of biocides in the majority of these products is the Isothiazolinones, including MIT, CMIT/MIT, BIT, OIT and MBIT[1]. Biocides are also used within the Imaging and Printing Industry in press and pre-press mixtures as well as in certain photographic chemical mixtures, again for PT6 and also in some cases for liquid cooling and processing systems (PT11). This document focuses on aqueous digital inkjet inks for the sake of simplicity and relevance, while many of the arguments also apply to press, pre-press and photographic chemicals.

BIT biocide prevents microbial growth, especially fungal and bacterial. Without it, products will not function as intended. The growth of fungal spores or bacteria resulting from the absence of a biocide could also present an unnecessary risk to human health. Concerning printing device functionality, microbial growth will result in blocked inkjet printheads causing unacceptable printing results, not to mention production downtime to clear blockages and replacement of inks, resulting in more waste to treat. For commercial printers this is a significant economic factor since the aim is to reduce downtime to an absolute minimum in a highly competitive European market.

Increasingly, Isothiazolinones are classified as skin sensitisers under CLP with Specific Concentration Limit (SCL) values below those recommended by the rapporteur member states in some cases. Isothiazolinones are typically used in the 100-400 ppm range for adequate efficacy and are generally not effective as in-can preservatives at the 15 ppm SCL that has been set for several of them. As a result of the SCL, restrictions are being applied under the BPR that limit the use of these active substances. If this trend continues, the industry will find itself at risk of having to eliminate existing, effective biocides without viable alternatives to take their place.

The need and benefits of BIT for PT6 in the imaging and printing industry

Digital inkjet printing has several benefits in certain areas over traditional printing as well as being complementary to it. For example, within the industrial sector, variable data printing is very cost-effective with digital inkjet systems, resulting in low waste, low environmental emissions and therefore clearly supportive to an overall circular economy strategy.

Consumer inkjet printing is a standard household activity and without effective biocides to preserve aqueous inks, this whole consumer industry will cease to exist. For the home printing market there is no suitable alternative to consumer inkjet technology, and even if there were, forcing consumers to eliminate functioning printers would be a serious cost and waste issue and counterproductive to a circular economy strategy.

[1] MIT – CAS No. 2682-20-4, CMIT/MIT – CAS No. 55965-84-9, BIT – CAS No. 2634-33-5, MBIT – CAS No. 2527-66-4, OIT – CAS No. 26530-20-1

Regulatory risks to the industry

Several Isothiazolinones have entries in CLP Annex VI with a SCL that triggers classification of the mixtures as skin sensitiser at levels below which they are not effective as in-can preservatives. If this also becomes the case for BIT, the risk of market deselection due to an excessively severe hazard classification is relevant and could reverse the transition from solvent- to water-based inks achieved over the past decades.

In the case of CMIT/MIT, the BPR PT6 restrictions[2] take this classification into account by restricting the use of the active substance in mixtures for consumer and professional use. For consumer use, this makes it essentially impossible to use CMIT/MIT as a biocide to preserve consumer inkjet inks. If the same or more stringent restrictions were applied to the other Isothiazolinones that can feasibly be used as alternatives, it will no longer be possible to place those consumer inkjet inks on the market in the EU.

Likewise, in the professional and industrial sectors, applying overly restrictive conditions means there is a significant risk of aqueous inkjet inks being removed from the market altogether. The only alternative printing technology for most applications is the traditional organic solvent-based ink analogue printing operations which are cost-effective at high volumes but not so at very small run lengths, resulting in very significant waste, emissions and cost consequences in comparison to digital inkjet solutions.

Health and environmental risks

Much emphasis is placed by regulators on eliminating risk to human health and the environment. The design of the digital printing system and the digital printing process with aqueous inks is such that inks are transferred to the substrate in very low quantities and the ink printhead is extremely close to the substrate. Hence during the intended and foreseeable use of aqueous printing inks there is almost no risk arising which would lead to skin sensitising effects.

Although the risk of accidental and limited exposure cannot be eliminated entirely, the likelihood that a consumer would exceed levels and frequency of exposure to BIT due to inkjet inks to trigger sensitisation is extremely low. Inks are supplied in purpose-built sealed cartridges which are designed for controlled release and to minimize exposure and spillage, while used cartridge recycling is an industry-standard, ensuring a low risk to public health and the environment.

For professional and industrial use, digital inkjet inks are properly managed and risk management measures are taken to avoid human and environmental exposure. Again, the likelihood of users exceeding exposure levels and frequency to BIT enough to trigger sensitisation is extremely low.

Additionally, in the absence of scientific data justifying an extremely low SCL for skin sensitisation, such as 15 ppm, reclassification processes are not regarded as the adequate regulatory tool to effectively reduce the allergic reactions to Isothiazolinones potentially observed. Such a limit would impact all uses, even those where the exposure can be regarded as negligible under foreseeable conditions of use, and therefore do not contribute to the problem of sensitization. Effectively limiting the use in products discussed here would result in a big impact on the industry while not reducing the exposure to these chemicals, which is already negligible from these uses.

Furthermore, reducing the list of biocides effectively available, for instance by setting an extremely low SCL for BIT, can have counterproductive effects. Effective exposure to consumers and professionals to the few biocides that would remain on the market will increase, potentially increasing the negative reactions in the population and the environment.

Therefore, considering the current safety information available and the potential exposure and risk of the use of BIT in inkjet inks, a regulatory action such as a reclassification with an extremely low SCL (e.g., 15 ppm) is regarded as not justified based on scientific data, nor proportional to the risk and can end up being counterproductive to the protection of human health and the environment.

Future state

Ink manufacturers are continually searching for less hazardous alternatives to existing biocides and other hazardous substances but are dependent on biocide suppliers to provide suitable biocidal products and on regulators to provide the appropriate regulatory environment. There are currently no viable substitutes for BIT in the imaging and printing industry and none is expected to be available in the foreseeable future. Per year, the imaging and printing industry represents billions of euros of business in Europe alone for the digital inkjet consumer and industrial sectors.

[2] REGULATION (EU) 2016/131 of 1 February 2016
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0131&from=EN