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# Insider

## DIGITAL PRINTING WITH LOW-MIGRATION INK ON PP FILM FOR IV BAGS

When printing packaging for the pharmaceutical and medical sectors, patient safety is paramount. Thus, low-migration inks play a crucial role. As part of a client project, Hapa worked intensively on the complex processes for the digital printing of polypropylene (PP) film with low-migration ink for IV bags.

The challenges of the project for an international company in the healthcare sector involved not only the development of low-migration UV LED ink. It was also necessary to develop a sustainable process for an industrial application that relied completely on digital direct printing. The switch from an existing industrial process to an entirely new one is a huge step that requires a great deal of patience and expertise. Mathias Theiler, Ink Department Manager, provides expert insight into the exciting project.

### Greater flexibility and lower cost with digital printing

Previously, the client labeled its IV bags using labels and thermal transfer printing. "Both processes require additional consumables, namely labels and heat transfer films, of which 80 to 90 percent remain as waste. Furthermore, due to their adhesive layer, labels constitute an additional migration risk," explains Theiler. During digital direct printing, on the other hand, the materials consumed are limited to the film and the ink. In addition, because of the growing variety of options – with up to 16 different color markings – the flexibility of digital printing convinced the company to switch to a fully digital process.

### Guaranteeing patient safety

As is mandatory in the pharmaceutical and medical industry, patient safety is paramount in this case as well. "Specifically, this means that at all times, it must be ensured that no limit value exceeding quantities of substances from the ink and the IV bag enter its content, i.e. migrate into it," explains Theiler.

Migration may result in substances entering the human body which could be unhealthy for the patient. What is relevant for the definition of migration limits is the scientifically determined quantity of foreign substances which the human body is able to break down and tolerate. In order to be able to correctly evaluate interactions

between the IV fluid, packaging, and ink, it is necessary to possess comprehensive knowledge of the ingredients of these components.

### A sustainable and safe process

"Considering that the client's new system will be designed for a service life of 20 to 25 years, the printing solution must function over a very long period of time and therefore be perfectly mature", emphasizes Theiler. "This requires a meticulous development and testing process in which we have considered all parameters for safe and reliable production." These parameters are:

- Substrate
- Pre-treatment of substrate
- Dispersion and ink
- Printing process
- Post-processing (polymerization)
- Extraction test (worse case test)
- Evaluation
- Migration test

The **substrate**, the PP film, had already been tested by the client and proven its suitability. "The fact that the film continues to remain an important influencing factor may not be apparent from the very beginning", Theiler points out. "However, it is extremely important that the material to be printed on is always available with a constant level of quality, and that it does not exhibit any fluctuations with regard to its properties, such as material thickness and density, as well as surface tension." The first step was to determine the correct **pre-treatment** of the film to establish a solid basis for the adhesion and scratch-proofing of the ink. "During our tests with various pre-treatment methods, the cold plasma process was identified as the best solution", says Theiler. In the next

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*Low-migration, fully cured inks provide the highest level of safety for patients.*

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phase, Hapa created a custom **dispersion** for the ink. "A stable dispersion makes or breaks the long-term quality of an **ink**. During the ink development, we analyzed each individual application carefully while considering the polymerization kinetics and the degree of curing. Based on this, we tailored the dynamic behavior of viscosity, surface tension, flow properties, adhesion, and opacity of the ink exactly to the client's printing process. We also paid particular attention to the print heads by optimizing what is called the jetability, which ensures the precise placement of the ink drops", says Theiler, describing the development process. One other major influencing

factor is the **polymerization**, which refers to the curing of the ink. This is because only fully cured inks provide the greatest degree of safety against migration; this also applies to low-migration inks. "We selected a polymerization with UV LED units, whereby the factors of performance and time played a decisive role. Thus, the question was: How much UV output is necessary and how long must the printed substrate remain in the curing unit when passing through it in order to achieve the chemical reaction for adequate curing of the ink?", says Theiler, explaining the challenge. After satisfactory curing results were achieved, the project was ready for



Comprehensive analyses and tests in Hapa Ink's in-house laboratory.



Mathias Theiler  
Manager Ink Department

Mathias Theiler, an Electronic Engineer, joined Hapa in 1980, where he served as R & D Director for thirteen years. In 2014, he was involved in the acquisition of an industrial ink organization to form the Hapa Ink department.

During his years at Hapa, he acquired extensive experience in UV DOD inkjet printing design and application, experience that helps him support customers in his role as the manager of Hapa's Ink Department.

Mathias Theiler made a name for himself as a pioneering speaker at the inkjet conference "TheIJC", which takes place in Germany and in the USA every six months, and is aimed at inkjet specialists.

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the **extraction test**. "It is also called the 'worst case test', because it investigates whether, in a worst case scenario, harmful substances which exceed the limits which the body is able to break down could migrate out of the ink." This stringent test is performed by an independent, certified institute and concludes with an **evaluation**. If it is within range, such that the ink is able to pass an elaborate **migration test**, the 'gold standard' of all tests, a huge milestone will have been reached on the path towards the

successful conclusion of the entire project. "The time spent on development and testing was definitely worth it. We have instituted a sustainably functioning overall process including ink for the digital printing of PP film for IV bags, and are currently in the migration test phase together with the client", says Theiler proudly.

The entire development process took place in Hapa's in-house laboratory; the extraction and migration test were performed with external partner institutes.