# Investigating the influence of various plasticiser on the properties of Kollicoat® SR 30 D based coats

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## INTRODUCTION

Plasticiser play a decisive role in the application of functional films, especially, if an aqueous dispersion containing a water insoluble polymer is used.

For the water insoluble sustained release film forming polymer PVAc, both elongation at break and minimum film forming temperature (MFFT) depend strongly on the type and amount of plasticiser used in the coating formulation. As MFFT is comparably low for PVAc (18°C) this physical characteristic is of minor interest [1]. However, the elongation properties are of huge importance, especially if coated particles are compressed to multiple unit pellet systems (MUPS).

This investigation is intended to consider the suitability of three different plasticiser: poly(ethylene glycol) 6000, 1,2-propylene glycol and triethyl citrate.

## MATERIALS AND METHODS

### Materials

Poly(vinyl acetate) (Kollicoat® SR 30 D, BASF SE, Germany) was used in combination with the following plasticisers:

- **a)** Poly(ethylene glycol) (PEG) 6000 (Lutrol® E 6000, BASF)
- **b)** 1,2-Propylene glycol (PG) (Propylene glycol pharma, BASF)
- **c)** Triethyl citrate (TEC) (Merck)

### Formulations

The isolated films were prepared with a plasticiser content of 10% (m/m) each, calculated on the polymer content of the dispersion. To assure homogeneously distribution and incorporation within the PVAc dispersion, the mixture was stirred for at least 2 hours.

### Preparation of isolated films

Isolated films were prepared by using a film caster (Coatmaster, Erichsen Testing Equipment) equipped with a 300 µm knife. The film caster allowed various temperatures to dry the cast films.

### Characterisation of isolated films

The film was examined visually as first indication for its quality. To determine the mechanical properties, a texture analyser (TA-XT2i HR, Stable Micro Systems) was used. The testing was performed under climatic controlled conditions of 23°C and 54% r.h. [2]

## RESULTS AND DISCUSSION

### Poly(ethylene glycol) 6000

Appraising the film visually, a clear dependency of homogeneity on the drying temperature was found. Forming the film at temperatures of about 30°C led to an inhomogeneous distribution of PEG 6000 within the film. As the white sections appearing in the film (Figure 1) could be dissolved in water, it could be concluded that the plasticiser was not properly incorporated in the PVAc matrix.

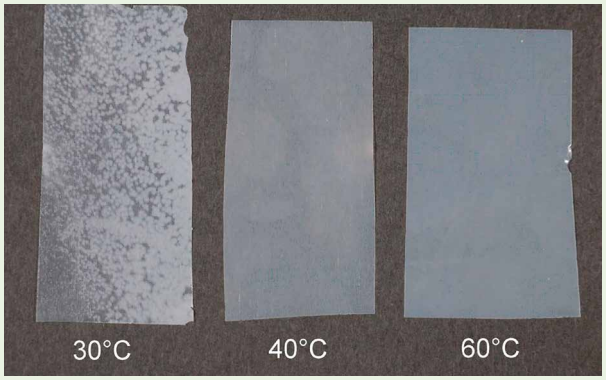


**Figure 1.**
**Isolated films obtained by different drying temperatures using PEG 6000.**

Using elevated temperatures of 40°C and higher, the distribution of PEG 6000 within the isolated film was visually more homogeneous.

Investigating this effect in detail, a temperature of 36°C could be determined as the necessary minimum temperature to achieve a film without any crystalline areas.

The inhomogeneous distribution of PEG 6000 in the film was also found to be indicated by the results of the texture analysis. In spite of the poor elongation properties of all films tested, differences could still be observed inbetween the films prepared at different temperatures (Figure 2).

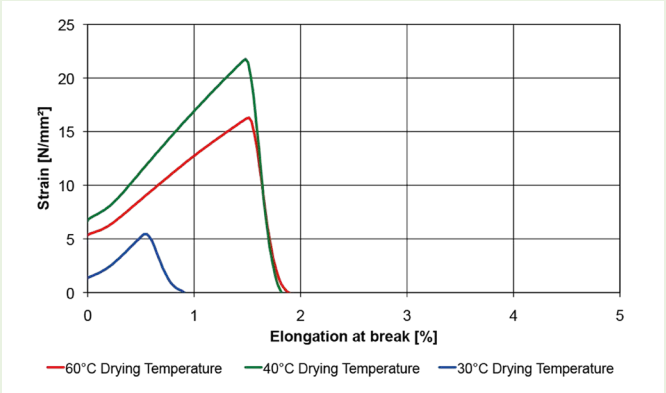


**Figure 2.**
**Elongation properties of isolated films prepared at different drying temperatures using PEG 6000.**

Drying temperatures above 30°C result in films showing a higher elasticity/plasticity compared with films dried at 30°C.

PEG 6000 can be considered as a film former on its own, but forming very brittle films. Hence, the elasticity of PVAc could not be increased by means of adding this plasticiser. However, physical properties such as tackiness or tensile strength can clearly be influenced [3].

Due to the poor elongation properties, even at elevated preparation temperatures, PEG 6000 cannot be regarded as a useful plasticiser for PVAc.

## Propylene glycol

MFFT of a PVAc film containing 10% of PG was found to be 14°C [1]. However, independent from the temperature used for the preparation of the isolated films, visually homogenous films could be obtained.

Skultety and Sims stated that huge amounts of PG do evaporate during the film coating process [4]. This effect was found for the test of elasticity and plasticity of the isolated films as well. Both characteristics were observed as extremely high on the day of preparation (Figure 3). However, storing the films openly for 48 hours under controlled conditions of 23°C/54% r.h., the elongation properties changed to a high extent. The film became more brittle. However, no alteration could be found for samples stored in a closed system.

Additional test on this phenomena showed that the intensity of the effect depends on the preparation method and the thickness of the film. Preparing the film with a spray gun led to a less pronounced reduction in elongation at break during storage. Anyhow, reductions of more than 20% could be found after 65 hours as well.

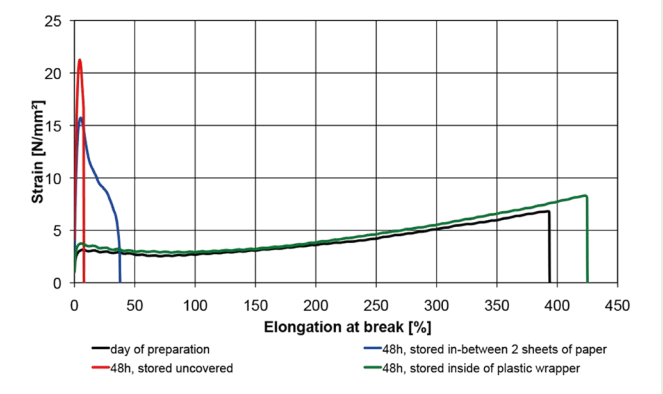


**Figure 3.**
**Elongation properties of isolated films prepared at different drying temperatures using PG.**

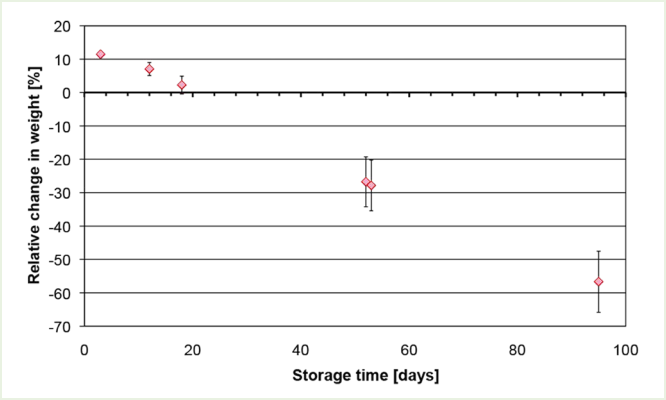


**Figure 4.**
**Loss of PG due to evaporation at 23°C/54% r.h**

To prove evaporation of the plasticiser as cause for the change of the films characteristics, a fabric filter wetted with PG was stored at 23°C/54% r.h. After taking up the equilibrium amount of water, a strong decrease in mass could be observed (Figure 4). This suggests that PG evaporates under these storage conditions.

From the solely process technology point of view, PG can be used as plasticiser for PVAc. Yet the potential risk of change in its elongation properties has to be closely monitored during stability tests.

### Triethyl citrate

TEC has a very high effect on MFFT of PVAc films [1]. An amount of 10% plasticiser lowers the MFFT to 1°C. Similar to PG, it was also found that for TEC, homogeneous films could be prepared, independent of the temperature used for the drying. The elongation properties were also found to be very high (Figure 5).

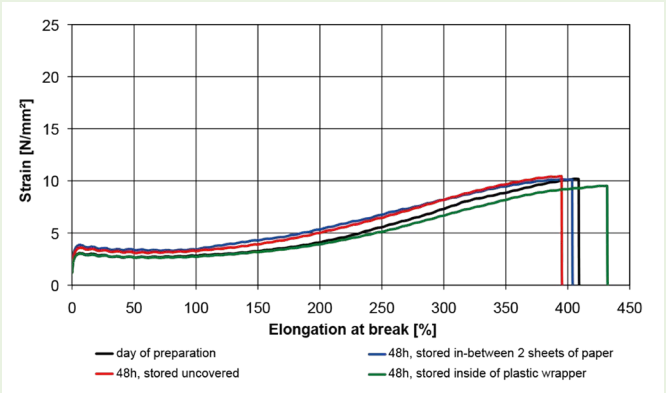


**Figure 5.**
**Elongation properties of isolated films prepared at different drying temperatures using TEC.**

The elongation properties of the isolated film remain at this high level, even during open storage of the films. This indicates that TEC is not as susceptible for both evaporation and migration effects as PG. Therefore,TEC is suggested to be the ideal plasticiser for PVAc. It offers a very low minimum film forming temperature and causes films with excellent elongation properties.

## CONCLUSION

The plasticiser showing the best results in regard to plasticizing effects and storage stability was triethyl citrate (TEC). This excipient is therefore recommended to be used as plasticiser for the aqueous dispersion of PVAc (Kollicoat® SR 30 D).

A previous investigation showed that the performance of triacetin (TAC) is quite comparable to TEC, except tackiness (TAC is less tacky than TEC) [3]. Therefore, TAC could be used alternatively to TEC in similar quantities.

## REFERENCES

[1] Kolter, K.; Ruchatz, F.; Kollicoat® SR 30 D – A new sustained release Excipient; CRS Annual Meeting and Exposition; 1999; Boston; U.S.A.

[2] DIN 53 455; Tensile strength at yield

[3] Kolter, K.; Ruchatz, F.; Influence of plasticisers on the physicochemical properties of Kollicoat® SR 30 D-films; AAPS Annual Meeting and Exposition; 1999; Louisiana; U.S.A.

[4] Skultety, P. F.; Sims, S. M.; Evaluation of the loss of propylene glycol during aqueous film coating; Drug Development and Industrial Pharmacy; 1987; Vol. 13; No. 12; Pages 2209–2219

Presented at:
Aurora Film-Coating Symposium, May 15, 2018; Kiev, Ukraine
Pharma Solutions Europe | G-ENP/ET556

# Kollicoat® SR 30 D

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