



German Ordinance on printing Inks

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German Ordinance for Printing Inks for FCM

No specific EU-Regulation for Printing Inks

- → German Ordinance for Printing Ink for Food Contact Materials (FCM) was issued on December 7, 2021
- Positive list of substances used in printing inks for printing on FCM
 Listing of substances in 5 different categories:
 Monomers/starting substance, colourant, solvent, additive, photo initiator
- Only substances for which the German Federal Institute for Risk Assessment (BfR) has issued a favorable opinion are included in this list
- If it is necessary for reasons of consumer health protection, the list of substances also contains corresponding limitations and restrictions

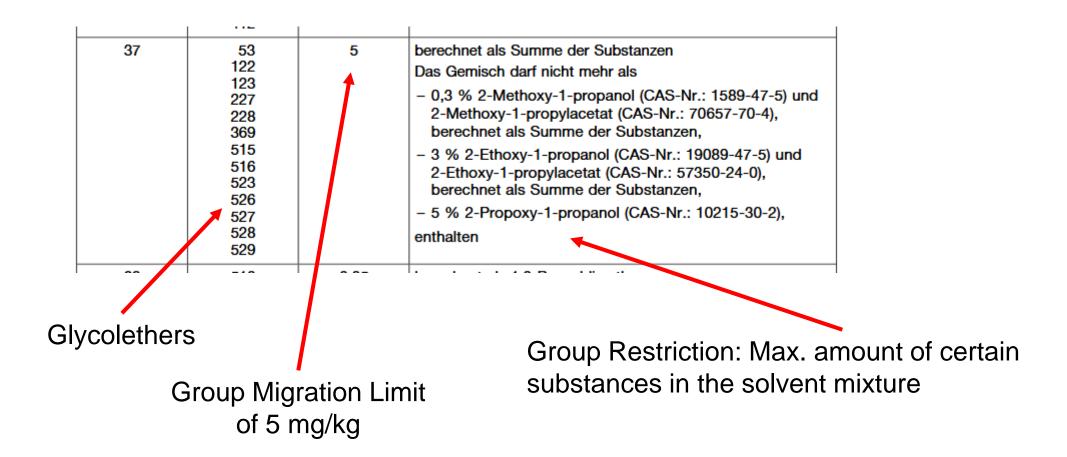
Transitional period: 4 years

Migration of the applied substance (including NIAS) under worst case conditions of the intended use

- Toxicological data depending on the level of migration is needed (see EFSA Note for Guidance)
- One substance is used for different applications What is the worst case application?
- → Mixtures of Substances (e.g. solvents)
- Substance characterization/characterization of mixtures
- What is the composition of the mixture?
- Is the composition always the same?
- Within what limits does the composition vary? What is the worst case composition?

Example

Group Restriction for Mixtures: Glycolethers used as solvents



- → Degradation of Substances (e.g. photo initiators)
- Degradation of the initial/listed substance is intended
- Toxicological data might only available for initial/listed substance
- What are the degradation products? What substance will migrate and in what amount?
- Degradation products might react with matrix → matrix varies widely
- → Different ways to produce the requested substance (e.g. natural vs. synthetic product)
- Impurity profile might vary
- What is the worst case product?

Conclusive or unconclusive?

- → Application for adding a new substance
- → BfR checks the data and asks for questions/ requests further data
- If data is sufficient (for the applied use) → substance will be listed as applied (if necessary with appropriate restrictions, limits...)



Thank you for your attention



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