



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

Challenges for Risk Assessment

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?

Challenges for Risk Assessment

Example

Group Restriction for Mixtures: Glycoethers used as solvents

37	53 122 123 227 228 369 515 516 523 526 527 528 529	5	berechnet als Summe der Substanzen Das Gemisch darf nicht mehr als – 0,3 % 2-Methoxy-1-propanol (CAS-Nr.: 1589-47-5) und 2-Methoxy-1-propylacetat (CAS-Nr.: 70657-70-4), berechnet als Summe der Substanzen, – 3 % 2-Ethoxy-1-propanol (CAS-Nr.: 19089-47-5) und 2-Ethoxy-1-propylacetat (CAS-Nr.: 57350-24-0), berechnet als Summe der Substanzen, – 5 % 2-Propoxy-1-propanol (CAS-Nr.: 10215-30-2), enthalten
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Glycoethers

Group Migration Limit
of 5 mg/kg

Group Restriction: Max. amount of certain
substances in the solvent mixture

Challenges for Risk Assessment

- 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?

Challenges for Risk Assessment

Conclusive or inconclusive?

→ 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



Identify Risks –
Protect Health

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