

Annex to Siegwerk's Statement of Composition (EMEA Version)

PART I – Regulatory Background

Siegwerk's Statement of Composition (SoC) provides information to support converters in fulfilling their compliance work. The demands are laid down in Annex IV of Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Plastics Regulation), and in section 12, Art. 33 of the Swiss Ordinance of the FDHA on Materials and Articles (817.023.21; „Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen“), with its Annex 10, „Liste der zulässigen Stoffe für die Herstellung von Druckfarben und Anforderungen an diese Stoffe“, in their up-to-date state.

Regulation (EC) No 1935/2004 and the Swiss Ordinance 817.023.21 require that materials and articles which, in their finished state, are intended to be brought into contact with foodstuffs, must not transfer any components to the packed food in quantities which could endanger human health or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

This means that the manufacturer of the finished article and the filler have the legal responsibility that it is suitable for its intended purpose.

Explanations to the tables provided in the SoC:

Regulated substances in the printed layer

Based on all up-to-date information retrieved from raw material suppliers, Siegwerk has made an individual Risk Assessment of all potentially migrating components.

A risk for a migration of concern does only apply if the substances in question are present in ink layers in amounts relevant for a potential non-compliance with migration thresholds and also have a molecular weight below 1000 Da (substances above 1000 Da, if ever ingested, are not absorbed by the gastro-intestinal tract and thus are not considered by the European Food Safety Authority (EFSA) to present a toxicological risk). Nonetheless, there are several kinds of substances that are not regarded as migrants. Among them are printing ink pigments, fillers and inorganic materials (such as white titanium dioxide pigment, calcium carbonate fillers, silica matting agents) as they are fully insoluble crystalline particles. Furthermore carbon black and organic pigments that are commonly used as colorants in inks intended for food packaging are also present as particles and generally not regarded as being migrants.

Consequently, Siegwerk provides information on potentially migrating substances of concern, which are present in the ink layer and are listed and/or restricted under the scope of the Plastics Regulation (EU) No 10/2011 and/or of the Swiss Ordinance 817.023.21.

Siegwerk strives for obtaining complete disclosure from all raw material suppliers of all intentionally and non-intentionally added substances, evaluated as well as non-evaluated ones, also including monomers of polymeric binders and additives, and even down to trace level. In fact, Siegwerk has implemented a longstanding and comprehensive raw material introduction process, which is based on a centrally coordinated approval via its Corporate Department Global PSR + Sustainability, and which is operating on a worldwide basis. With this process, Siegwerk aspires towards full knowledge of the identity, positive lists status, migration threshold and quantity of every potential migrant present in ink layers. This is important in particular for Siegwerk's risk management of non-evaluated substances, which must not be detectable in food (therefore default threshold 10 ppb).

Restrictions and migration limits in the Swiss Ordinance

Switzerland has amended the "Ordinance on Materials and Articles in Contact with Food" with provisions on food packaging inks. It came into force on April 1st 2008 and in this ordinance, the positive list principle was introduced ("list of permissible substances"). These Substances are defined as those which are listed in Annex 2 and in Annex 10. The positive list of Annex 10 contains in the actual valid version (V 2.1; 1st December 2020) about 5300 entries with a corresponding classification of the substances in Part A (toxicologically evaluated) or Part B (non-evaluated). Part A substances are listed with specific migration limits (SMLs) or without a specific limit, in which case the overall migration limit (OML) of 60 ppm applies. These substances may be used in the manufacture of inks, given that the SMLs are not exceeded for the final packaging. Part B substances are only permitted to use if they are not classified as "CMR" substances (carcinogenic, mutagenic, reprotoxic = classes 1A, 1B or 2 acc. to the CLP Regulation) and if their migration is not detectable with a detection limit of 10 ppb. It has to be pointed out, that the Swiss Ordinance is applicable only for Intentionally Added Substances (IAS) and that it does not cover direct food contact (DFC) inks.

Restrictions and migration limits in the Plastics Regulation

Until today, there is no European legislation specifically concerning printing inks for food packaging available¹. The main regulation dealing with food packaging materials pursuant to the "Framework Regulation" (EC) 1935/2004 is the "Plastics Regulation" (EU) No 10/2011. Underlying herein is an OML of 10 mg/dm² food contact material. In addition, specific migration limits, or group restrictions SML (T), or maximum contents in the material or article (QM) are set for individual substances.

Packaging inks are not in the direct scope of this regulation, so substances used only in the manufacture of printing inks are not listed. However, printed plastic packaging is covered as far as the positively listed substances in the ink are concerned. Therefore, the relevant restrictions such as specific migration limits or maximum content given in the Plastics Regulation have to be met by the final packaging.

For some substances, it may be allowed to use a Fat Consumption Reduction Factor (FRF), as indicated by Siegwerk in the column "Comments", for correction of test or calculation results before comparison with the SML.

Dual use substances (Regulation (EC) No 1333/2008 and Regulation (EC) No 1334/2008)

Dual use substances are those substances, according to Art. 11 (3) of Regulation (EU) No 10/2011, which are also authorized as food additives by Regulation (EC) No 1333/2008 or as flavorings by Regulation (EC) No 1334/2008.

¹ With the exception of the Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film, which states that the printed surface of regenerated cellulose film must not come into contact with food.

Maximum amount of non-volatile potential migrants in the dried ink film

The maximum amount of a potential migrant present in the dried ink film is given in percent. This value allows the printer to estimate or calculate with his own parameters (e.g. amount of ink applied per area, surface / volume ratio of the packaging, migrants from other sources) the risk to exceed a given SML.

Worst Case Calculation (WCC), S/V ratio 6:1

Comparing the result of the worst-case calculation with the specified SML of a substance provides a quick indication on the risk to exceed the given limit.

The maximum amount of a migrant that could migrate into food is calculated using the following underlying assumptions:

- ⇒ 100% transfer of the substance (via set-off or diffusion migration)
- ⇒ 100% area coverage of ink
- ⇒ Dry ink film weight of 3 g per m² of the packaging
- ⇒ Standard "EU-Cube" (6 dm² wrap 1 kg of food; S/V ratio 6:1).

If these assumptions do not meet your specific packaging parameters, please see "Worst Case Calculation" in Part II of this Annex.

For substances where the result of this WCC (S/V ratio 6:1) is above the limit, please refer to the column "Comments"; Siegwirk may provide information such as "Exemplary analysis indicate that printed substrates can fall below this limit".

Worst Case Calculation (WCC) for non-finished inks

Many Siegwirk products for NPH (Nutrition, Pharma and Hygiene) packaging applications are ready for printing when delivered to the customer or just need to be diluted to achieve printing viscosity. We consider such products to be finished inks/varnishes.

However, Siegwirk also offers "non-finished inks/varnishes". The converter combines in this case at least two of these non-finished inks/varnishes in order to obtain a finished ink/varnish. This procedure allows "production" of a variety of finished inks/varnishes with only a few non-finished inks.

Since the possible combinations of these products are manifold and under the control of the converter, Siegwirk can only provide Statements of Composition for the individual non-finished inks as delivered.

Usually, Siegwirk supports the product safety evaluation of our customers by providing a Worst Case Calculation (WCC) indicating the maximum potential migration for each migrant disclosed in our SoC. However, a WCC is based on the amount of the migrant in the dried ink film of the finished ink/varnish. Performing a WCC for non-finished inks/varnishes significantly overestimates the potential migration risk and thus may lead to a wrong product safety evaluation.

Consequently, Siegwirk provides a specific SoC for such non-finished inks/varnishes that does not include a WCC result, but indicates the solid content of the individual intermediate. Based on this information, the amount of the potential migrant given in the SoC and the mix ratio of the non-finished inks/varnishes, a WCC for critical migrants can be performed. In the generic example below, we will explain how this worst case calculation can be performed.

In addition, we offer a specific „**Worst Case Calculator non-finished inks**“ as well as detailed information on the legal background, Siegwirk standard assumptions, risk evaluation and migration testing to our customers at <https://www.siegwerk.com/en/our-responsibility/product-responsibility/safe-food-packaging.html>

Performing a WCC for a migrant “X” based on the information given in the SoC of two non-finished inks “A” and “B”:

The final liquid ink is obtained by addition of 10 parts of non-finished ink A to 100 parts of non-finished ink B. Thus, the final liquid ink consists of 9.1% A and 90.9% B.

In addition, the following information is given in the individual SoC's of A and B:

SoC of A:

In the migrant table, migrant X with an SML of 18 mg/kg is disclosed.

The amount of migrant X in the solid film is given with 62%.

The solid content of **A** is given with 44%.

Since the amount of migrant X seems to be quite high compared to the SML, performing a detailed worst case calculation is reasonable.

SoC of B:

Migrant X is not contained.

The solid content of **B** is given with 33%.

Step 1: Calculating the amount of migrant X in the liquid non-finished ink A:

$$\begin{aligned}\text{„Amount of X in liquid A“} &= \text{„Amount of migrant X in SoC of A“} * \text{„Solid content of A“} / 100\% \\ &= 62\% * 44\% / 100\% \\ &= \underline{27.3\%}\end{aligned}$$

Step 2: Calculating the amount of migrant X in the final liquid ink:

$$\begin{aligned}\text{„Amount of X in final liquid ink“} &= \text{„Amount of X in liquid A“} * \text{„Amount of A in final liquid ink“} / 100\% \\ &= 27.3\% * 9.1\% / 100\% \\ &= \underline{2.5\%}\end{aligned}$$

Step 3: Calculating the solid content of the final ink:

$$\begin{aligned}\text{„Solid content of final ink“} &= \text{„Solid content of A“} * \text{„Amount of A in final liquid ink“} / 100\% \\ &\quad + \text{„Solid content of B“} * \text{„Amount of B in final liquid ink“} / 100\% \\ &= 44\% * 9.1\% / 100\% + 33\% * 90.9\% / 100\% \\ &= \underline{34\%}\end{aligned}$$

Step 4: Calculating the amount of migrant X in the finally printed ink film:

$$\begin{aligned}\text{„Amount of X in printed final ink film“} &= \text{„Amount of X in final liquid ink“} * 100\% / \text{„Solid content of final ink“} \\ &= 2.5\% * 100\% / 34\% \\ &= \underline{7.4\%}\end{aligned}$$

This value is a lot more realistic than the one given for migrant X in the SoC of A and thus it can be used for a reasonable worst case calculation.

Final Step: Worst Case Calculation for migrant X

Based on the result of step 4, our online Worst Case Calculator can be used to obtain a WCC result based on the specific printing conditions. It can be accessed via: <https://ink-safety-portal.siegwerk.com/exposure-assessment/worst-case-calculation>

Alternatively, customers may just want to apply the Siegwerk standard worst case assumptions as this provides the WCC result, Siegwerk would give in our SoC if the “finished ink” would be delivered.

This WCC result is obtained by multiplying the “Amount of X in printed final ink film” with a factor of 1.8 [mg/kg] / [%].

$$\begin{aligned}\Rightarrow \text{Final WCC result for X} &= \text{„Amount of X in printed final ink film“} * 1.8 \text{ [mg/kg] / [\%]} \\ &= 7.4\% * 1.8 \text{ [mg/kg] / [\%]} \\ &= \mathbf{13.3 \text{ mg/kg}} \text{ (13.1 mg/kg without any rounding of intermediary results)}\end{aligned}$$

Comparing this result for the worst case migration of X with the SML of X (18 mg/kg), it can be concluded that even under the strict worst case assumptions of Siegwerk, the potential migration of X from the ink is below the SML and thus allows compliance with the Swiss Ordinance 817.023.21 as well as the Plastics Regulation (EU) No 10/2011.

Primary Aromatic Amines with Restrictions in the Plastics Regulation (EU) No 10/2011 Annex II (2)

Primary Aromatic Amine (PAA) are unavoidable impurities that may be present in certain types of pigments. Commission Regulation (EU) 2020/1245 stipulates, that adequate information regarding these substances should be given to downstream business operators to support their compliance work. In keeping with this new Commission Regulation (EU) No 10/2011 amendment, the EMEA version of the Siegwerk SoC now includes information in two tables about specific PAA that could possibly be present in the liquid ink.

Organic solvents

Organic solvents are in the scope of Swiss Ordinance 817.023.21. Organic solvents (including retarders) are not intended to become part of the printed layer. The drying conditions and thus, the residual content of solvents in the ink film are under control of the converter. Consequently, the converter has to ensure compliance with the migration limits for these solvents in the Swiss Ordinance. In order to support our customer’s compliance work, Siegwerk provides information on identity, Swiss Ordinance evaluation status and amount in liquid ink for these solvents in a separate table of our SoC.

PART II – Risk Evaluation and Migration Testing

Article 16 of the Regulation (EC) No 1935/2004 regulates that materials and articles covered by specific measures defined in Article 5 (e.g. specific limits on the migration of certain constituents into food), shall be accompanied by a written declaration stating that they comply with the rules applicable to them.

Concerning plastic materials and articles, this requirement is enforced by Article 15 of the Regulation (EU) No 10/2011 (Plastics Regulation). The required content of the Declaration of Compliance (DoC) is set out in the Annex IV of the Regulation.

Excerpt from Whereas No. 30 of the Plastics Regulation 10/2011:

“Coatings, printing inks and adhesives are not yet covered by a specific EU legislation and therefore not subject to the requirement of a declaration of compliance. However, for coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in this Regulation.”

However, the Plastics Regulation has no direct and legally enforceable effect on packaging made of other materials than plastics; therefore, any information given is to enable the printer to comply with industry standards, which are oriented to the Plastics Regulation as a guideline.

Siegwerk is actively supporting customers in making available in the SoC all appropriate information for the packaging chain to set up the Declaration of Conformity under the Plastics Regulation, and any other communication intended to safeguard compliance of the final packaging with Regulation (EC) No 1935/2004 and the Swiss Ordinance 817.023.21.

Evaluation of risk

Depending on the potential level of risk linked to migration across the layer(s) between the print and the food or to invisible set-off, the printer should conduct representative practical investigations, such as organoleptic testing, migration assessment via WCC, Migration Modeling or via practical analytical migration testing. Detailed guidance is provided in the Siegwerk brochure “Know How; Customer Guidance: Printing Inks for Food Packaging”, which is available in the Ink Safety Portal on <https://ink-safety-portal.siegwerk.com/regulatory-affairs/compliance.html>.

Based on the exposure data provided in Siegwerk’s SoC, the manufacturer of the packaging material is enabled to perform, with regard to the Siegwerk product, the initial check for compliance with Regulation (EC) No 1935/2004, the Plastics Regulation and/or the Swiss Ordinance.

The converter needs however to extend this initial check via consolidation of this data with data of potentially migrating substances provided by suppliers for other components of the NPH packaging application (example: inks from other suppliers, plastic films, paper, board, adhesives, and coatings). Food packaging intended for particularly sensitive consumer groups (such as infants and young children) requires formal qualification in any case, as a rule via practical analytical migration testing.

Worst Case Calculation (WCC)

With the Worst Case Calculator[®] provided by Siegwerk, the recipient of a SoC is able to easily calculate the maximum amount of a substance that could, under worst case conditions, end up in the packed food. It allows entering the specific packaging size (surface / volume ratio), the specific ink amount applied and the area coverage on the final packaging. Thus, for each of the substances, as consolidated from different applications,

the printer can easily calculate his risk to exceed the given maximum migration limits. The Worst Case Calculator® can be accessed in the Ink Safety Portal via: <https://ink-safety-portal.siegwerk.com/exposure-assessment/worst-case-calculation.html>

For detailed information on the rules governing the applicable surface / volume ratio, printers are advised to refer to Article 12 (overall migration) and 17 (specific migration) of the Regulation (EU) No 10/2011. Particular attention is due for the stringent provisions on food packaging for infants and young children therein.

For the possible application of a Fat Consumption Reduction Factor (FRF), see Annex V, chapter 4.1 of the Regulation No 10/2011.

A Group restriction is applicable for a number of substances used in inks, as indicated in the Column "Comments". In this case, printers are advised to refer to Annex 1, Table 1, Column (9), and Annex 1, Table 2 of Regulation (EU) No 10/2011 (i.e. for the SML (T) of Group restriction 32, of which some are ink plasticizers).

Migration Modeling (MM)

Numerous scientific investigations during the last two decades have demonstrated that migration from food contact materials into food and food simulants follow predictable physical processes. Hence, in addition to experimental methods an alternative tool based on theoretical migration estimations can be applicable for verifying the compliance of a migrant. The European Union introduced this option to use generally recognized diffusion models as a novel compliance and quality assurance tool with Directive 2001/62/EC as an amendment of Directive 90/128/EEC. Directive 90/128/EEC was repealed by Directive 2002/72/EC which was repealed by Regulation (EU) No 10/2011. Chapter 2.2.3. of Annex V of this Regulation states that migration modeling can be applied as screening tool for specific migration as long as the method is considered more severe than the migration testing verification method.

Migration testing

Particularly in the following cases the packaging manufacturer is advised to conduct a formal qualification via migration testing in order to safeguard the compliance of the final food packaging with the applying regulations:

- ⇒ The result of the WCC indicates a risk of exceeding the given thresholds
- ⇒ The result of the WCC with S/V ratio 6:1 exceeds the limit and Siegwerk provides information such as "Exemplary analysis indicate that printed substrates can fall below this limit"
- ⇒ For applications where Siegwerk's brochure "Know How; Customer Guidance: Printing Inks for Food Packaging" advises to consider qualification via migration testing

Wherever migration testing is explicitly advised by Siegwerk in the SoC and/or in the "Know How brochure", customers are requested to conduct such a formal qualification.

Verification data on migration should be obtained via appropriate and representative samples which cover every individual printed packaging material and article in its finished state, taking into account the normal and foreseeable conditions of use.

For detailed information on appropriate migration testing conditions, printers are advised to refer to Article 18 in conjunction with Annex III and Annex V of the Regulation (EU) No 10/2011.

For further details on risk evaluation and migration modeling or testing, customers are requested to refer to the Siegwirk brochure “Know How; Customer Guidance: Printing Inks for Food Packaging”, which is available in the Ink Safety Portal on <https://ink-safety-portal.siegwerk.com/regulatory-affairs/compliance.html>.

Non-Intentionally Added Substances (NIAS)

NIAS are all chemical substances which are not IAS and do not have an intended and specific function within the ink formulation. Such NIAS may come from impurities in used raw materials from former production steps, but can also be created due to contamination in the ink production or handling, and also during the application process of the inks (unintended side reactions during curing, drying, crosslinking or decomposition for example).

Also for NIAS, there may be an applicable migration limit in a regulation. In that case, this migration limit must not be exceeded. In the case of NIAS that have not been evaluated, and therefore no specific migration limit (SML) is available, Siegwirk performs a Risk Assessment in order to calculate a self-derived SML.

Siegwerk is performing Risk Assessments (RA) for NIAS based on the “EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Listed Substances (NLS) in printing inks for food contact materials”. For further details on risk evaluation of NIAS, customers are requested to refer to the corresponding EuPIA Guidance document on <https://www.eupia.org/key-topics/food-contact-materials/risk-assessment>.

For the result of this NIAS RA, please refer to the column “Comments”; Siegwirk may provide information such as:

- Based on a toxicological risk assessment conducted by Siegwirk a self-derived SML of x.y mg/kg can be applied for the migrant if present as NIAS. Details are available on request.