

Creating Chemistry for Compliant Paper Colorants



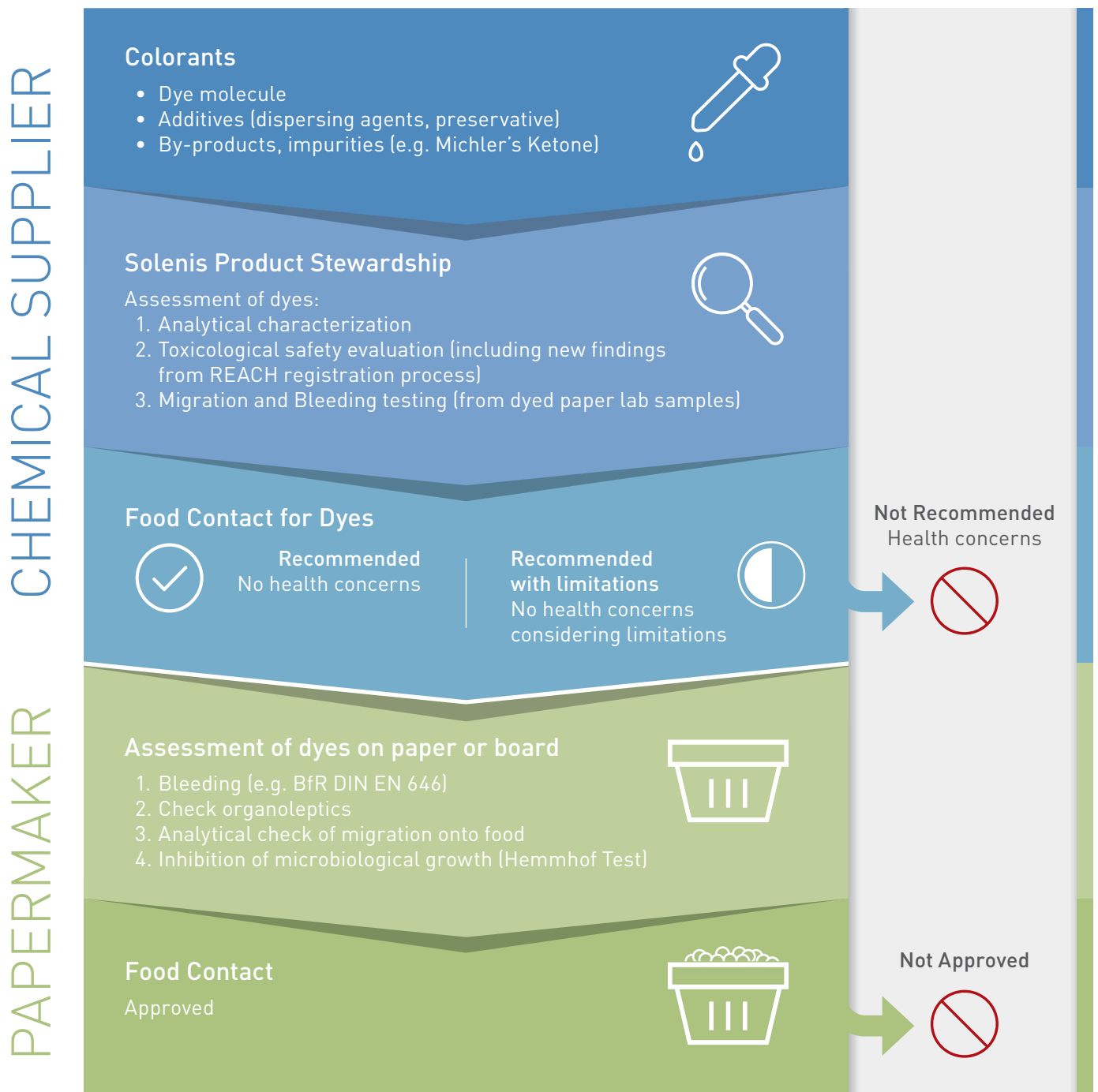
Food Contact for Paper Colorants

Whether it is in direct or indirect contact with food, packaging plays a crucial role in ensuring the quality and hygienic safety of food products. Chemical suppliers and papermakers must follow regional or national regulatory requirements.

Papermakers' regulatory focus is on five regulatory systems:

- the European framework regulation,
- Germany's recommendation from the Federal Institute for Risk Assessment (BfR),
- the complex network of specific US-FDA laws,
- a set of Chinese GB laws and
- new legislation in Latin America and more specifically in Brazil.

As a responsible partner, Solenis helps customers to understand and to decide which Solenis products are the right fit to comply within the relevant regulation. The focus of this document is on colorants only.

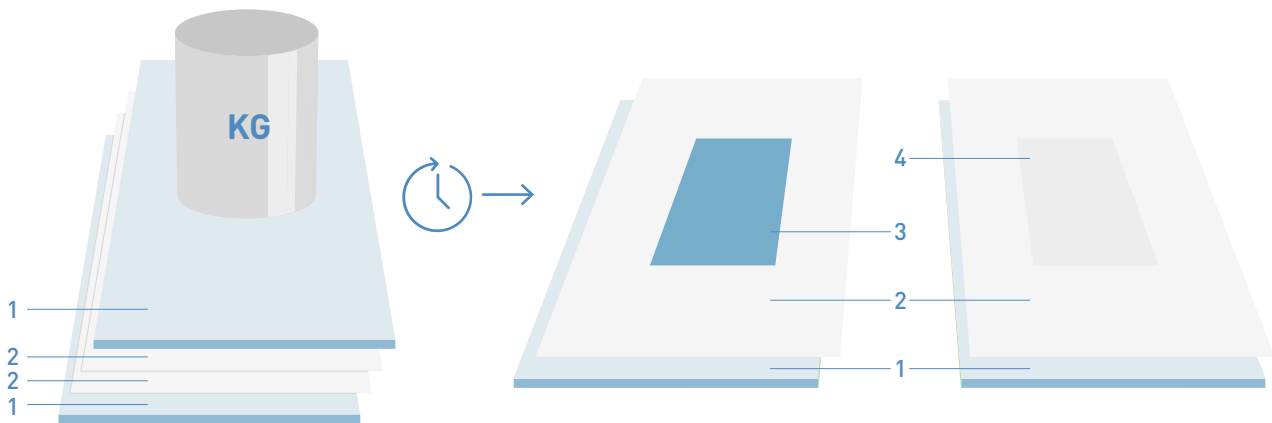


Solenis Testing

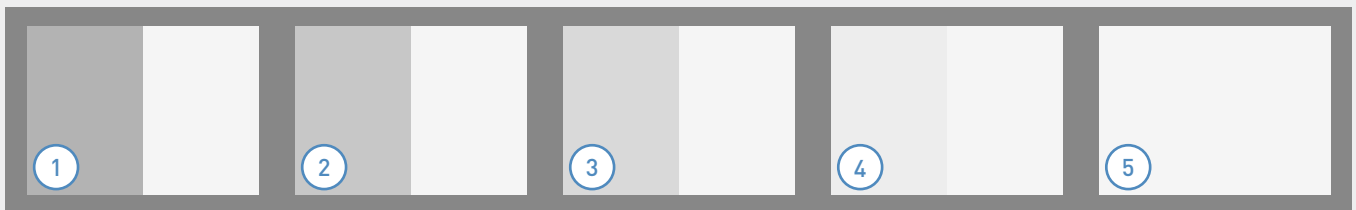
Did you know?

There must be no migration of colorants to the foodstuff. Testing is conducted according to DIN EN 646, whereby grade 5 on the so-called grey scale must be reached.

How the test is done...



The test sample of the dyed paper [3] is placed between two glass plates [1] and two sheets of white glass fiber paper [2] that are treated with the food simulant. The stack is loaded with a mass. After a defined time the glass fiber paper is dried and evaluated by comparing the contact area [4] with the available "grey scale".



A staining rated 1 means strong migration, 5 (no staining) means no migration.

A rating of 5 on the so called grey scale must be reached in order for the dyed paper to be approved for food contact.

Regional Differences and Regulations

Region	Europe	Germany	USA	China	Latin America
Regulation	EC No 1935/2004	BfR XXXVI/ 1-3	21 CFR Part 176.170	GB 4806.1-2016	RESOLUTION – RDC N° 88-89-90
			21 CFR Part 176.180	GB 4806.8-2016	
			Pre 1958 Colorants List	GB 9685-2016	
			Food Contact Notification (FCN)		

Food Contact Regulation in **Europe**

In Europe, materials and articles intended for food contact applications must comply with the framework regulation EC No 1935/2004, which ensures the safety of packaging materials in food contact applications in general.



Paper and board which is intended to come into contact with food must be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, it does not transfer its constituents to food in quantities which could:

- Endanger human health
- Bring about an unacceptable change in the composition of the food
- Bring about a deterioration in organoleptic characteristics

There is no EU regulation for packaging materials made of paper and board implemented yet. Therefore, we have to revert to applicable national regulations to assess safety of products for food contact applications, e.g. BfR recommendation XXXVI.

Food Contact Regulation in **Germany**

The German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR) Recommendations XXXVI/1-3 has gained high reputation in Europe and on international level and is based on a positive list of substances that have been evaluated to be safe.

- BfR XXXVI is valid for single and multi-layered commodities (articles, materials) made of paper or paperboard intended to come into contact with or to affect foodstuffs. It includes paper or paperboard which is intended to be used at temperatures up to 90°C (holding and reheating of food).
- BfR XXXVI/1 is specific for hot extraction (boil-in-bag packages, tea bags, hot filter papers) and for filter layers that, in their intended use, will be subject to extraction (filtration).
- BfR XXXVI/2 is specific for baking (220°C) and microwave ovens (150°C) applications.
- BfR XXXVI/3 is meant for absorber pads (e.g. in foil packed meat) based on cellulosic fibres.

Colorants are in general not listed by its chemical name in the BfR XXXVI, but are regulated via a “no migration (DIN EN 646)” clause. In contrast, both BfR XXXVI/1 and XXXVI/2, explicitly reference colorants by its chemical name. No colorants are approved under BfR XXXVI/3.

Colorants which could cleave into carcinogenic amines listed in Directive 2002/61/EC or EC/1907/2006 annex VII appendix 8 must not be used for paper and board intended to come into contact with food. Of course, Solenis does not have such dyes in our active portfolio for food contact.

Solenis recommends those colorants for the use in food contact applications in Europe where all additives in the product beyond the colorant, have been determined to be in compliance with the above recommendations.

Food Contact Regulation in China

China created a new regulation for paper for food contact applications: Guo Biao GB 9685-2016. The concept of this regulation is similar to what is established in the EU (BfR) and USA (FDA).

China has a framework regulation and a positive list of substances. Similar to the situation in the European Community, general safety of the paper product has to be confirmed by compliance with “National food safety standard – General safety requirements of food contact materials and articles” GB 4806.1-2016 and “National Food Safety Standard. Papers, Paperboard Materials and its Articles for Food Contact” GB 4806.8-2016.

Article 3 of GB 4806.1-2016

- The paper product is deemed not to endanger human health as required
- The paper product does not transfer substances which change the composition or organoleptic properties of the food
- The paper product is produced in the pre-established specifications and purity limits
- Production of the paper product is carried out in production units with the necessary quality control systems, which enables traceability through all stages of production

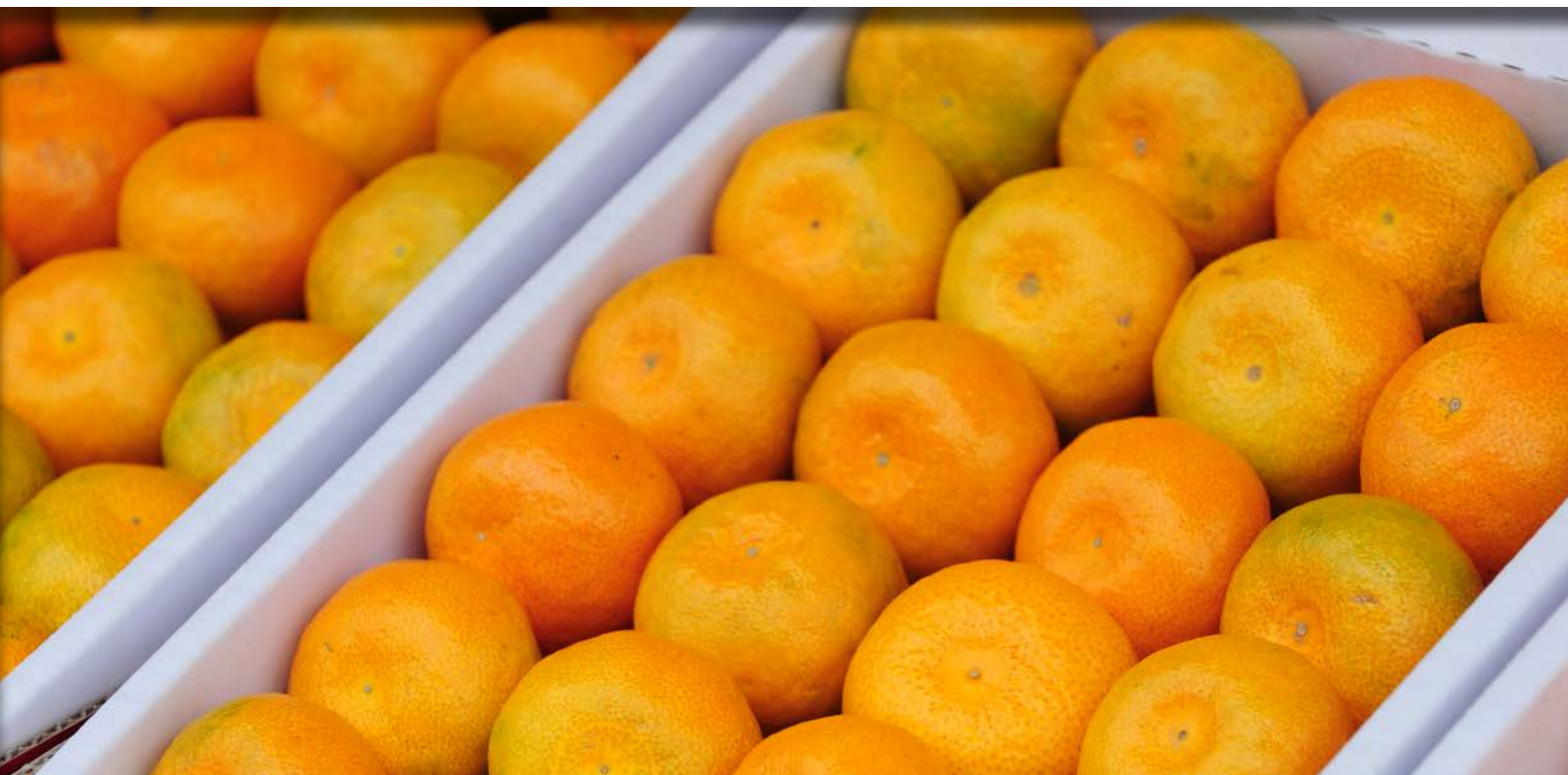
Article 4.2 of GB 4806.8-2016

- No sensory deterioration such as color or odor of the immersion solution from the migration test (The decolorization test is specified in GB 31604.7-2016)

Positive lists of substances, not products, are established specifically for each application (e.g. paper, plastic, rubber,...) and can include limitations such as SML (specific migration limits) or maximum dosage or maximum residuals in paper. There are separate lists for paper wet-end, dry-end and coating applications.

Solenis recommends those colorants for the use in food contact applications in China, where all components including the colorant are listed. Further, colorants that are not of concern and not specifically listed in the regulation can be used in compliance with GB9685-2016 if they would migrate less than 10 ppb.

Compliance with the provisions of GB 4806.1-2016 and GB 4806.8-2016, especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any given limitations, must be ensured by the person who introduces the articles into circulation.



Food Contact Regulation in the U.S.

The Food and Drug Administration (FDA) regulates the materials for food contact in the USA. Additives to paper and paperboard intended for contact with foodstuffs are subject to FDA regulation 21 CFR Part 176 .170 for moist and fatty food, and 21 CFR 176.180 for dry food.

If a paper and board manufacturer is producing a shaded or colored paper that has to be compliant with FDA food contact regulations, the following options are available regarding colorants usability:

- Is the colorant on a positive list?
- Is the colorant on the grandfathering pre-1958 list?
- Does the colorant benefit from a Food Contact Notification (FCN)?
- Is the colorant not regarded as a food additive?

Solenis recommends those colorants for the use in food contact applications in the US where all additives in the product beyond the colorant, have been determined to be in compliance with the above regulations.

Is the colorant on a positive list?

Similar to the German recommendations, the FDA regulations consist of positive lists; however, they do not contain any soluble dyes, only pigments, metals and metal oxides. Still, the listing of a substance does not automatically allow an unlimited use of it in paper and paperboard. The person introducing the finished article into circulation has to ensure that the food-contact surface of the paper or paperboard complies with the extractive limitations prescribed in FDA-regulation 21 CFR Part 176.170 (c).

Solenis example: Pergalite™ Blue R-LW
Pergalite™ Yellow Oxide M-E

Is the colorant on the grandfathering pre-58 list?

If a colorant was produced and used in the paper industry before 1958 it can be used in paper for food contact applications. A list of these dyes was compiled by the American Paper Institute (API) and is known as

the “pre-58 Colorants List”. These dyes may be safely used in manufacture of paper and paperboard for food contact, provided that the colorant is not known to cause cancer in humans or animals, or that it otherwise presents a safety issue.

Solenis constantly monitors new findings concerning the safety of the colorants on the pre-58 list. This makes sure that the highest safety standards also apply to products containing these grandfathered colorants.

Solenis example: Pergasol™ Red 2BE

Does the colorant benefit from a FCN?

New colorant applications are normally covered by the Food Contact Notification process, which means the FDA authorizes new uses of food contact substances that have been demonstrated by the submitter to be safe for the intended use. FCN complies with the highest standard on safety and are effective only for the manufacturer or supplier identified in the notification.

Solenis example: Pergalite™ Violet NZ (FCN 330)

Is it not regarded as a food additive?

Recent dyes (discovered or produced after 1958) are not included on the Pre-1958 list. However, if such dyes can be shown to not migrate from the paper or paperboard to food under expected conditions of use and there are no safety or toxicological concerns with their use, they are not considered to be food additives and they are exempted from scope of the FDA regulation CFR 21 Part 176.

Solenis recommends the following:

This no migration requirement may be considered to have been met if the dye does not bleed when tested according to DIN EN 646, Procedure A, or Bleedfastness Test - ISO PAT-W0413. The results must show no visible migration, as shown by Stage 5 on the Grey Scale, described in DIN EN 20105. The final test has to be done on the finished paper.

Solenis example: Pergasol™ Red 2B-Z



Food Contact Regulation in **Brazil**

The Brazilian Health Regulatory Agency (Anvisa) created new resolutions for Paper for Food Contact applications (national implementation of Mercusor). The concept of these resolutions is similar to what is established in the EU (BfR) and is based on a positive list of substances that have been evaluated to be safe.

RESOLUTION A - RDC N° 88, OF 29 JUNE 2016 -
Technical regulation on cellulosic materials, packaging and equipment intended to come into contact with food and other provisions that is valid for single and multi-layered commodities (articles, materials) made of paper or paperboard intended to come into contact with or to affect foodstuffs. It includes paper or paperboard which is intended to be used for holding and reheating of food.

RESOLUTION A - RDC N° 89, OF 29 JUNE 2016 -
Technical regulation on cellulosic materials for cooking and hot filtration and other provisions - is specific for hot extraction (boil-in-bag packages, tea bags, hot filter papers) and for filter layers that, in their intended use, will be subject to extraction (filtration).

RESOLUTION A - RDC N° 90, OF 29 JUNE 2016 -
Technical regulation on cellulosic materials, packaging and equipment intended to come into contact with food during cooking or heating in oven and other provisions - is specific for baking (220°C) and microwave ovens (150°C) applications.

Colorants are in general not listed by its chemical name in the RDC N°88 but are regulated via a “no migration (DIN EN 646)” clause. In contrast, both RDC N°89 and RDC N°90 explicitly reference colorants by their chemical name.

Colorants must meet the heavy metal impurity specifications.

Colorants which could cleave into restricted carcinogenic amines listed in the resolution must not be used for paper and board intended to come into contact with food. Of course, Solenis does not have such dyes in their active portfolio for food contact.

Solenis recommends those colorants for the use in food contact applications in Brazil where all additives in the product beyond the colorant, have been determined to be in compliance with the above resolution.

To learn more about how Solenis can help address your toughest challenges and more, please visit [solenis.com](https://www.solenis.com)



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