

Colorants Portfolio for Sensitive Applications in Plastics

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1 Introduction

This document gives an overview of BASF selected Colorants Portfolio for Plastics listed by national regulations and additionally provides a summary of the key regulations ruling colorants for plastics going into food contact materials and toys. It is meant as a general introduction for everyone who wants to get a baseline understanding of the regulatory framework for food contact material and toys. If further information is required, please contact ed-psr@basf.com.

Where general comments are provided, the original text of the law or standard has to be consulted to avoid misunderstandings and incorrect interpretations.

All information in this document has been compiled with great care and reflects BASF best knowledge at date of issue (July 2014). Due to continuous evolution of the subject, information may rapidly change and therefore this document can only be considered as a snapshot of current situation as date of publication (July 2014). To ensure a full updated compliance status of a given product to newest legislation requirements or technology changes, we strongly recommend our customers to systematically check this status with their BASF representative or contact BASF at ed-psr@basf.com.

2 BASF Colorants Portfolio for Sensitive Applications in Plastics

2.1 Product scoping

This document lists the BASF portfolio of colorants for plastics and fibers that will be actively supported for use in sensitive applications such as Food Packaging and Toys.

Detailed compliance status of BASF organic and inorganic pigments as well as polymer soluble colorants and Pigments Preparations is provided in Appendix table, listed for each product per national regulations.

As effect pigments are currently under review, those will be covered by a specific forthcoming update.

2.2 Definition and revisions

BASF Colorants for Plastics Portfolio screened for Sensitive Applications have been initially assessed through specific criteria such as product finger-print including purity profile as well as manufacturing set-up including consideration for cross-contamination risk.

Also, as relevant, product processing behavior in plastics was assessed and when needed, a product would have to undergo a risk assessment under standard or specific conditions of use.

For those products, Management of Change process at BASF systematically aims at retaining existing compliance status for products affected by modifications such as raw materials changes or manufacturing process modifications.

As a result of all those precautionary measures, BASF can now, for all products listed in this “Colorants Portfolio for Sensitive Applications”, deliver Food Contact Certificates (FCC) moving forward. FCC provided by BASF for Plastic Food Contact Materials is the official document which covers EU Declaration of Compliance (DoC) legal requirements as well as compliance requirements of other regional jurisdictions as applicable.

BASF Colorants Portfolio for sensitive applications is regularly reviewed in line with evolving regulatory requirements, new developments in product technology and new findings in legal environment or product toxicology.

Consequently, FCC's for products in Colorants Portfolio for Sensitive Applications will be regularly updated and whenever possible upgraded to continue meeting regulatory requirements.

Even though it is BASF intention to sustain as much as possible the compliance scope and depth of the selective Colorants Portfolio for Sensitive Applications, no guarantee can be given that all products will remain compliant under all circumstances, e.g. future evolutions of the regulatory environment. In such cases that shall remain exceptional, BASF will strive to provide updated information to customers with pre-notice time.

2.3 Purity limits for BASF products in Colorants Portfolio for Sensitive Applications

For products that have been selected in BASF Colorants Portfolio for Sensitive Applications, “spot testing” program with adapted testing scope and frequencies are defined in order to regularly check that products are manufactured in line with target purity levels. If required, spot testing can be extended for systematic batch to batch analysis by setting-up an internal specification ensuring strict monitoring of target purity profile.

Typical purity limits as defined by BASF for Colorants Portfolio for Sensitive Applications are detailed below (BASF Purity Limits 2013):

Impurity	Limit (ppm)
Aluminium (Al)	5000
Antimony (Sb)	45
Arsenic (As)	3
Barium (Ba)	100
Boron (B)	1000
Cadmium (Cd)	1
Chromium (Cr III)	25
Cobalt (Co)	10
Copper (Cu)	600
Lead (Pb)	10
Manganese (Mn)	800
Mercury (Hg)	5
Nickel (Ni)	50
Selenium (Se)	25
Strontium (Sr)	4500
Tin (Sn)	15000
Zinc (Zn)	1000
Iron (Fe)	4500
Lithium (Li)	500
Primary aromatic amines (PAA)	500
Benzidine, beta-naphthylamine, 4-aminobiphenyl	10
Polychlorinated biphenyls (PCB)	25

Those purity limits allow meeting requirements of most of targeted end use applications e.g. food contact packaging and toys applications.

2.4 BASF Colorants for Food Contact Materials (Status as of July 2014)

This portfolio is regularly reviewed according to business needs and regulatory requirements. For any updates please contact the ed-psr@basf.com mailbox.

The overview of products' compliance status in the table below should be used as an internal guide only. In any case, it does not replace the product detailed information in the Food Contact Certificates.

For more detailed information on specific country requirements and conditions of use, please refer to the relevant Food Contact Certificates which are available at ed-psr@basf.com upon request.

BASF Colorants for food contact applications

Status: July 2014

			Food Contact Regulations										
Product	Old product name	C.I. Name	European Union						USA	Japan		Aus.	China
			1935/2004/EC – Art. 3	EC Regulation 10/2011	AP(89)1	Germany BfR IX	France Brochure 1227	Italy Decreto 21/3/73	FDA, 21CFR	JHOSPA	JHPA	AS 2070-1999	GB9685-2008
Cinquasia® Magenta K 4535	Cinquasia® Magenta RT-235-D	PR 202	●	●	●	●	❖	●	❖	❖	○	●	❖
Cinquasia® Magenta K 4535 FP	Cromophtal® Magenta P	PR 202	●	●	●	●	❖	●	❖	❖	○	●	❖
Cinquasia® Pink K 4410	Cromophtal® Pink 2000	PR 122	●	●	●	●	●	●	❖	❖	●	●	❖
Cinquasia® Pink K 4430 FP	Cromophtal® Pink PT	PR 122	●	●	●	●	●	●	❖	❖	●	●	❖
Cinquasia® Red K 4104	Cromophtal® Red 2020	PV 19	●	●	●	●	●	●	❖	❖	●	●	❖
Cinquasia® Red K 4111	Cromophtal® Red TBR	PV 19	●	○	●	●	○	○	❖	○	❖	●	○
Cinquasia® Red K 4330	Cinquasia® Red B RT-195-D	-	●	●	●	●	○	●	❖	❖	○	●	○
Cinquasia® Violet K 5350	Cinquasia® Violet R RT-891-D	PV 19	●	❖	●	●	○	❖	❖	❖	○	●	❖
Cinquasia® Violet K 5350 FP	Cromophtal® Violet RP	PV 19	●	❖	●	●	○	❖	❖	❖	○	●	❖
Cromophtal® Orange K 2960	Cromophtal® Orange GP	PO 64	●	●	●	●	●	●	❖	❖	○	●	❖
Cromophtal® Red K 3830	Cromophtal® Red G	PR 220	●	●	●	●	❖	●	❖	❖	❖	●	❖
Cromophtal® Red K 3890	Cromophtal® Red BRN	PR 144	●	●	●	●	❖	●	○	❖	❖	●	❖
Cromophtal® Red K 3890 FP	Cromophtal® Red BRNP	PR 144	●	●	●	●	❖	●	○	❖	❖	●	❖
Cromophtal® Red K 3900	Cromophtal® Red BN	PR 214	●	●	●	●	❖	●	○	❖	❖	●	❖
Cromophtal® Red K 3900 FP	Cromophtal® Red BNFP	PR 214	●	●	●	●	❖	●	○	❖	❖	●	❖
Cromophtal® Scarlet K 3540	Cromophtal® Scarlet RN	PR 166	●	●	●	●	❖	●	○	❖	❖	●	❖
Cromophtal® Yellow K 1210	Cromophtal® Yellow 3G	PY 93	●	●	●	●	❖	●	❖	❖	❖	●	❖
Cromophtal® Yellow K 1210 FP	Cromophtal® Yellow 3GNP	PY 93	●	●	●	●	❖	●	❖	❖	❖	●	❖
Cromophtal® Yellow K 1310	Cromophtal® Yellow 4GV	PY 215	●	❖	●	●	○	❖	❖	❖	○	●	○
Cromophtal® Yellow K 1410	Cromophtal® Yellow 2GO	PY 180	●	●	●	●	●	●	❖	❖	○	●	❖
Cromophtal® Yellow K 1500	Cromophtal® Yellow GR	PY 95	●	●	●	●	●	●	❖	❖	❖	●	❖
Cromophtal® Yellow K 1500 FP	Cromophtal® Yellow GRP	PY 95	●	●	●	●	●	●	❖	❖	❖	●	❖
Eupolen® PE Blue 69-1501		PB 15:1	❖	❖	●	❖	○	❖	❖	○	○	❖	○
Eupolen® PE Blue 69-2001		PB 15:1	●	●	●	●	●	●	❖	○	○	●	❖
Eupolen® PE Blue 70-9001		PB 15:3	●	❖	●	●	●	●	❖	○	●	●	❖
Eupolen® PE Blue 70-9005		PB 15:3	●	❖	●	●	●	●	❖	○	●	●	❖
Eupolen® PE Blue 71-0401		PB 15:4	●	❖	●	●	○	●	❖	○	○	●	○
Eupolen® PE Brown 29-1505		PR 101	●	●	●	●	●	●	❖	○	●	●	❖
Eupolen® PE Green 87-3001		PG 7	❖	❖	●	❖	❖	❖	❖	○	❖	❖	❖
Eupolen® PE Green 87-3005		PG 7	❖	❖	●	❖	❖	❖	❖	○	❖	❖	❖
Eupolen® PE Green 87-3501		PG 7	❖	❖	●	❖	❖	❖	❖	○	○	❖	❖
Eupolen® PE Green 93-6001		PG 36	❖	❖	●	❖	❖	❖	❖	○	○	❖	❖

BASF Colorants for food contact applications

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			Food Contact Regulations										
Product	Old product name	C.I. Name	European Union						USA	Japan	Aus.	China	
			1935/2004/EC - Art. 3	EC Regulation 10/2011	AP(89)1	Germany BfR IX	France Brochure 1227	Italy Decreto 21/3/73	FDA, 21CFR	JHOSPA	JHPA	AS 2070-1999	GB9685-2008
Eupolen® PE Red 39-1101		PR 178	●	●	●	●	●	●	❖	○	○	●	❖
Eupolen® PE Red 47-9001		PR 122	●	●	●	●	●	●	❖	○	○	●	❖
Eupolen® PE Yellow 09-6101		PY 138	❖	●	●	❖	❖	❖	❖	○	❖	❖	❖
Eupolen® PE Yellow 13-1501		PY 215	●	❖	●	●	○	❖	❖	○	○	●	○
Eupolen® PE Yellow 17-6001		PY 191:1	●	❖	●	●	❖	❖	❖	○	○	●	❖
Eupolen® PE Yellow 18-0001	Eupolen® PE Yellow 22-7001	PY 183	●	●	●	●	●	●	❖	○	○	●	❖
Eupolen® PE Yellow 18-0004	Eupolen® PE Yellow 22-7004	PY 183	●	●	●	●	●	●	❖	○	○	●	❖
Eupolen® PE Yellow 18-4101		PY 139	❖	○	●	●	○	○	○	○	○	●	○
Eupolen® PE Yellow 18-4105		PY 139	❖	○	●	●	○	○	○	○	○	●	○
Eupolen® PE Yellow 20-8501		PY 110	●	❖	●	●	❖	❖	❖	○	○	●	❖
Heliogen® Blue K 6850		PB 15	●	●	●	●	●	●	❖	❖	●	●	❖
Heliogen® Blue K 6860		PB 15	●	❖	●	●	○	●	○	○	○	●	○
Heliogen® Blue K 6902		PB 15:1	●	❖	●	●	●	●	❖	❖	●	●	❖
Heliogen® Blue K 6907		PB 15:1	●	❖	●	●	●	●	❖	❖	●	●	○
Heliogen® Blue K 6911	Heliogen® Blue K 6911 D	PB 15:1	●	❖	●	●	●	●	❖	❖	●	●	○
Heliogen® Blue K 6912 FP	Heliogen® Blue K 6911 FP	PB 15:1	●	❖	●	●	●	●	❖	○	●	●	○
Heliogen® Blue K 6916		PB 15:1	●	❖	●	●	○	●	○	❖	○	●	○
Heliogen® Blue K 7090		PB 15:3	●	❖	●	●	●	●	❖	❖	●	●	❖
Heliogen® Blue K 7090 FP		PB 15:3	●	❖	●	●	●	●	❖	○	●	●	❖
Heliogen® Blue K 7097	Cromophtal® Blue 4GNP.	PB 15:3	●	❖	●	●	●	●	❖	❖	●	●	❖
Heliogen® Blue K 7104 LW		PB 15:4	●	❖	●	●	○	●	❖	❖	○	●	○
Heliogen® Green K 8683		PG 7	❖	●	●	❖	❖	❖	❖	○	❖	❖	❖
Heliogen® Green K 8730		PG 7	❖	❖	●	❖	❖	❖	❖	❖	❖	❖	❖
Heliogen® Green K 8730 FP		PG 7	❖	❖	●	❖	❖	❖	❖	○	❖	❖	❖
Heliogen® Green K 8730 Z		PG 7	❖	❖	●	❖	❖	❖	❖	○	❖	❖	❖
Heliogen® Green K 8740	Heliogen® Green K 8740 LW	PG 7	❖	❖	●	❖	❖	❖	❖	○	❖	❖	❖
Heliogen® Green K 9360 FK		PG 36	❖	❖	●	●	○	❖	○	○	○	❖	❖
Irgalite® Red K 4060 FP	Irgalite® Red 2BSP	PR 48:3	❖	○	●	●	○	○	○	○	○	●	○
Irgalite® Red K 4170 FP	Irgalite® Red 2BP	PR 48:2	●	❖	●	●	❖	❖	○	○	●	●	○
Irgalite® Rubine K 4270 FP	Irgalite® Rubine 4BP	PR 57:1	●	❖	●	●	❖	❖	○	❖	●	●	○
Irgalite® Scarlet K 4165		PR 48:3	❖	○	●	●	○	○	○	○	○	●	○
Irgazin® Flame Red K 3800	Cromophtal® DPP Flame Red FP	PR 272	●	●	●	●	❖	●	○	❖	○	●	❖
Irgazin® Orange K 2890	Cromophtal® Orange 2G	PO 61	●	●	●	●	●	●	○	❖	❖	●	○
Irgazin® Orange K 2910	Cromophtal® DPP Orange TRP	PO 71	●	●	●	●	❖	●	○	❖	○	●	○
Irgazin® Red K 3810	Irgazin® DPP Red BTR	PR 254	●	●	●	●	●	●	❖	○	❖	●	❖
Irgazin® Red K 3840	Cromophtal® Red 2030	PR 254	●	●	●	●	●	●	❖	❖	❖	●	❖
Irgazin® Red K 3840 LW	Cromophtal® Red 2028	PR 254	●	●	●	●	❖	●	❖	❖	○	●	❖
Irgazin® Red K 3840 SQ	Cromophtal® Red 1030-P	PR 254	●	●	●	●	●	●	❖	❖	❖	●	❖
Irgazin® Red K 3842	Cromophtal® DPP Red BP	PR 254	●	●	●	●	●	●	❖	❖	❖	●	❖
Irgazin® Red K 3845 LW	Cromophtal® DPP Red BOC	PR 254	●	❖	●	●	❖	❖	○	❖	❖	●	❖
Irgazin® Rubine K 4080	Cromophtal® Rubine TR	-	●	●	●	●	○	●	❖	❖	○	●	○
Irgazin® Rubine K 4085	Irgazin® DPP Rubine TR	PR 264	●	●	●	●	❖	●	○	○	○	●	❖

BASF Colorants for food contact applications

Status: July 2014

			Food Contact Regulations										
Product	Old product name	C.I. Name	European Union					USA	Japan	Aus.	China		
			1935/2004/EC - Art. 3	EC Regulation 10/2011	AP(89)1	Germany BfR IX	France Brochure 1227	Italy Decreto 21/3/73	FDA, 21CFR	JHOSPA	JHPA	AS 2070-1999	GB9685-2008
Irgazin® Yellow K 2060	Irgazin® Yellow 3RLTN	PY 110	●	●	●	●	❖	●	❖	○	❖	●	❖
Irgazin® Yellow K 2060 FP	Cromophtal® Yellow 3RLP	PY 110	●	●	●	●	❖	●	❖	❖	❖	●	❖
Irgazin® Yellow K 2060 SQ		PY 110	●	●	●	●	❖	●	❖	○	❖	●	❖
Irgazin® Yellow K 2080	Cromophtal® Yellow 2RLP	PY 110	●	●	●	●	❖	●	❖	❖	❖	●	❖
Microlen® Black 0068 MC	Microlen Black 782-MC	PBk 7	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Blue 6907 MC	Microlen® Blue 6907-MC	PB 15:1	●	❖	●	●	❖	❖	❖	○	○	●	○
Microlen® Blue 6911 MC	Microlen® Blue BCS-MC	PB 15:1	●	❖	●	●	❖	❖	❖	○	○	●	○
Microlen® Blue 6916 MC		PB 15:1	●	❖	●	●	○	❖	○	○	○	●	○
Microlen® Blue 7079 MC	Microlen® Blue 4GNP-MC	PB 15:1	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Blue 7098 MC	Microlen® Blue PD4167-MC	PB 15:3	●	○	●	●	○	○	○	○	○	●	○
Microlen® Flame Red 3800 MC	Microlen® DPP Flame Red FP-MC	PR 272	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Green 8730 MC	Microlen® Green 8730-MC	PG 7	❖	❖	●	❖	❖	❖	❖	○	○	❖	❖
Microlen® Magenta 4535 MC	Microlen® Magenta RT-235-MC	PR 202	●	❖	●	●	❖	●	❖	○	○	●	❖
Microlen® Orange 2910 MC	Microlen® DPP Orange TR-MC	PO 71	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Orange 2960 MP	Microlen® Orange GP-MP	PO 64	●	●	●	●	●	●	❖	○	○	●	❖
Microlen® Pink 4430 MC	Microlen® Pink PT-MC	PR 122	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Red 3840 LW MC	Microlen® Red 2028-MC	PR 254	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Red 3840 MC	Microlen® Red 2030-MC	PR 254	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Red 3890 MC	Microlen® Red BRN-MC	PR 144	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Red 3890 MCQ	Microlen® Red BRN-MCQ	PR 144	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Red 4060 MC	Microlen® Red 2BSH-MC	PR 48:3	❖	○	●	●	○	○	○	○	○	●	○
Microlen® Red 4104 MC	Microlen® Red 2020-MC	PV 19	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Red 4170 MC	Microlen® Red 2BPH-MC	PR 48:2	●	❖	●	●	❖	❖	○	○	○	●	○
Microlen® Red 4330 MC	Microlen® Red RT-195-MC	-	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Rubine 4085 MC	Microlen® DPP Rubine TR-MC	PR 264	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Rubine 4270 MC	Microlen® Rubine 4BP-MC	PR 57:1	●	❖	●	●	❖	❖	○	○	○	●	○
Microlen® Yellow 1070 MC	Microlen® Yellow WGP-MC	PY 168	●	❖	●	●	❖	❖	○	○	○	●	❖
Microlen® Yellow 1210 MC	Microlen® Yellow 3G-MC	PY 93	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Yellow 1210 MCQ	Microlen® Yellow 3G-MCQ	PY 93	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Yellow 1410 MC		PY 180	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Yellow 1500 MC	Microlen® Yellow GR-MC	PY 95	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Yellow 2070 MC	Microlen® Yellow 2RLTS-MC	PY 110	●	❖	●	●	❖	❖	❖	○	○	●	❖
Microlen® Yellow 2070 MCQ	Microlen® Yellow 2RLTS-MCQ	PY 110	●	❖	●	●	❖	❖	❖	○	○	●	❖
Oracet® Blue 690	Oracet® Blue PD2104	SB 104	●	●	●	●	●	●	❖	○	○	●	❖
Oracet® Orange 220	Oracet® Orange ES	SO 116	●	●	●	●	○	●	○	○	○		○
Oracet® Red 344	Oracet® Red GN	SR 135	●	●	●	●	❖	●	❖	❖	○	●	❖
Oracet® Yellow 125	Oracet® Yellow PD 2114	SY 114	●	●	●	●	●	●	○	○	○	●	❖
Oracet® Yellow 140	Oracet® Yellow RB	PY 147	●	●	●	●	❖	●	❖	❖	❖	●	❖
Oracet® Yellow 144 FE	Filester® Yellow RNB	PY 147	●	●	●	●	❖	●	❖	❖	❖	●	❖
Oracet® Yellow 180	Oracet® Yellow GHS	SY 163	●	●	●	●	❖	●	○	❖	○	●	❖
Paliogen® Red K 3911	Paliogen® Red K 3911 HD	PR 178	●	●	●	●	●	●	❖	●	○	●	❖
Paliogen® Red K 4180		PR 179	●	●	●	●	○	●	❖	❖	○	●	❖

BASF Colorants for food contact applications

Status: July 2014

			Food Contact Regulations										
			European Union					USA	Japan	Aus.	China		
Product	Old product name	C.I. Name	1935/2004/EC – Art. 3	EC Regulation 10/2011	AP(89)1	Germany BfR IX	France Brochure 1227	Italy Decreto 21/3/73	FDA, 21CFR	JHOSPA	JHPA	AS 2070-1999	GB9685-2008
Paliotol® Orange K 2920		PO 79	●	●	●	●	○	●	❖	○	○		○
Paliotol® Yellow K 0961	Paliotol® Yellow K 0961 HD	PY 138	❖	●	●	❖	❖	❖	❖	❖	❖	❖	❖
Paliotol® Yellow K 1070	Irgalite® Yellow WGP	PY 168	●	●	●	●	❖	●	○	❖	○	●	❖
Paliotol® Yellow K 1760 FP	Cromophtal® Yellow HRPN	PY 191:1	●	❖	●	●	❖	❖	❖	○	○	●	❖
Paliotol® Yellow K 1800	Paliotol® Yellow K 2270	PY 183	●	●	●	●	●	●	❖	❖	○	●	❖
Paliotol® Yellow K 1841		PY 139	❖	○	●	●	○	○	○	❖	○	●	○
Paliotol® Yellow K 1841 FP		PY 139	❖	○	●	●	○	○	○	❖	○	●	○
Rightfit® Red K 3790		PR 276	●	●	●	●	○	●	❖	○	○		○
Rightfit® Red K 4350		PR 277	●	❖	●	●	○	❖	❖	○	○		○
Sicopal® Black K 0095		PBr 29	●	❖	●	●	○	❖	○	○	○	●	○
Sicopal® Blue K 6310		PB 28	●	●	●	●	●	●	❖	❖	●	●	❖
Sicopal® Blue K 7210		PB 36	●	●	●	●	●	●	○	❖	○	●	❖
Sicopal® Yellow K 1120 FG		PY 184	●	❖	●	●	○	❖	○	○	○	●	○
Sicotan® Brown K 2611		PY 164	●	●	●	●	○	●	○	○	○	●	○
Sicotan® Brown K 2711		PY 164	●	●	●	●	○	●	○	○	○	●	○
Sicotan® Yellow K 1010		PY 53	●	●	●	●	●	●	❖	❖	●	●	❖
Sicotan® Yellow K 1011		PY 53	●	●	●	●	●	●	❖	❖	●	●	❖
Sicotan® Yellow K 1011 FG		PY 53	●	●	●	●	●	●	❖	○	●	●	❖
Sicotan® Yellow K 2001		PBr 24	●	●	●	●	●	●	❖	❖	○	●	❖
Sicotan® Yellow K 2001 FG		PBr 24	●	●	●	●	●	●	❖	❖	○	●	❖
Sicotan® Yellow K 2011		PBr 24	●	●	●	●	●	●	❖	❖	○	●	❖
Sicotan® Yellow K 2011 FG		PBr 24	●	●	●	●	●	●	❖	○	○	●	❖
Sicotan® Yellow K 2107		PBr 24	●	●	●	●	●	●	❖	❖	○	●	❖
Sicotan® Yellow K 2111		PBr 24	●	❖	●	●	❖	❖	❖	○	○	●	❖
Sicotan® Yellow K 2111 FG		PBr 24	●	❖	●	●	❖	❖	❖	○	○	●	❖
Sicotan® Yellow K 2112		PBr 24	●	❖	●	●	❖	❖	❖	❖	○	●	❖
Sicotan® Yellow K 2112 FG		PBr 24	●	❖	●	●	❖	❖	❖	○	○	●	❖
Sicotrans® Red K 2819		PR 101	●	❖	●	●	●	●	❖	❖	●	●	❖
Sicotrans® Red K 2915		PR 101	●	❖	●	●	●	●	❖	❖	●	●	❖

- Compliant
- Not Compliant
- ❖ Compliant with use restrictions, for more information please contact ed-psr@basf.com.

2.5 BASF Colorants for Toys (Status as of July 2014)

This portfolio is regularly reviewed according to business needs and regulatory requirements. For any updates please contact the ed-psr@basf.com mailbox.

The overview of products status in the table below should be used as an internal guide only. In any case, it does not replace the product detailed information contained in specific statements about toys applications.

For more detailed information on specific country or application requirements, please contact us at ed-psr@basf.com.

Please note that in EU, toys for children under 3 years and toys for mouth contact have to fulfil Article 3 of the Framework Regulation (EC) No 1935/2004.

BASF Colorants for toys

Status: July 2014			Toys for children under 3 years and toys for mouth contact		Toys for children above 3 years and no mouth contact		
			European Union	Europe	USA	Australia	
Product	Old product name	C.I. Name	1935/2004/EC - Art. 3	Norm 71-3, 2002	Norm 71-3, 2013	ASTM 963-07	AS/NZS ISO8124.3:2003
Cinquasia® Magenta K 4535	Cinquasia® Magenta RT-235-D	PR 202	•	•	•	•	•
Cinquasia® Magenta K 4535 FP	Cromophta® Magenta P	PR 202	•	•	•	•	•
Cinquasia® Pink K 4410	Cromophta® Pink 2000	PR 122	•	•	•	•	•
Cinquasia® Pink K 4430 FP	Cromophta® Pink PT	PR 122	•	•	•	•	•
Cinquasia® Red K 4104	Cromophta® Red 2020	PV 19	•	•	•	•	•
Cinquasia® Red K 4111	Cromophta® Red TBR	PV 19	•	•	•	•	•
Cinquasia® Red K 4330	Cinquasia® Red B RT-195-D	-	•	•	•	•	•
Cinquasia® Violet K 5350	Cinquasia® Violet R RT-891-D	PV 19	•	•	•	•	•
Cinquasia® Violet K 5350 FP	Cromophta® Violet RP	PV 19	•	•	•	•	•
Cromophta® Brown K 3001	Cromophta® Brown 5R	PBr 23	•	•	•	•	•
Cromophta® Orange K 2960	Cromophta® Orange GP	PO 64	•	•	•	•	•
Cromophta® Red K 3830	Cromophta® Red G	PR 220	•	•	•	•	•
Cromophta® Red K 3890	Cromophta® Red BRN	PR 144	•	•	•	•	•
Cromophta® Red K 3890 FP	Cromophta® Red BRNP	PR 144	•	•	•	•	•
Cromophta® Red K 3900	Cromophta® Red BN	PR 214	•	•	•	•	•
Cromophta® Red K 3900 FP	Cromophta® Red BNFP	PR 214	•	•	•	•	•
Cromophta® Red K 4035	Cromophta® Red 2B	PR 221	•	•	•	•	•
Cromophta® Scarlet K 3540	Cromophta® Scarlet RN	PR 166	•	•	•	•	•
Cromophta® Violet K 5700	Cromophta® Violet B	PV 37	•	•	•	•	•
Cromophta® Yellow K 0990	Cromophta® Yellow 8GN	PY 128	•	•	•	•	•
Cromophta® Yellow K 0990 FP	Cromophta® Yellow 8GNP	PY 128	•	•	•	•	•
Cromophta® Yellow K 1210	Cromophta® Yellow 3G	PY 93	•	•	•	•	•
Cromophta® Yellow K 1210 FP	Cromophta® Yellow 3GNP	PY 93	•	•	•	•	•
Cromophta® Yellow K 1310	Cromophta® Yellow 4GV	PY 215	•	•	•	•	•
Cromophta® Yellow K 1410	Cromophta® Yellow 2GO	PY 180	•	•	•	•	•
Cromophta® Yellow K 1500	Cromophta® Yellow GR	PY 95	•	•	•	•	•
Cromophta® Yellow K 1500 FP	Cromophta® Yellow GRP	PY 95	•	•	•	•	•
Eupolen® PE Blue 69-1501		PB 15:1	❖	•	•	•	•
Eupolen® PE Blue 69-2001		PB 15:1	•	•	•	•	•
Eupolen® PE Blue 70-9001		PB 15:3	•	•	•	•	•

BASF Colorants for toys

Status: July 2014

Product	Old product name	C.I. Name	Toys for children under 3 years and toys for mouth contact		Toys for children above 3 years and no mouth contact		
			European Union	Europe	USA	Australia	
			1935/2004/EC - Art. 3	Norm 71-3, 2002	Norm 71-3, 2013	ASTM 963-07	AS/NZS ISO8124.3:2003
Eupolen® PE Blue 70-9005		PB 15:3	•	•	•	•	•
Eupolen® PE Blue 71-0401		PB 15:4	•	•	•	•	•
Eupolen® PE Brown 29-1505		PR 101	•	•	•	•	•
Eupolen® PE Green 87-3001		PG 7	❖	•	•	•	•
Eupolen® PE Green 87-3005		PG 7	❖	•	•	•	•
Eupolen® PE Green 87-3501		PG 7	❖	•	•	•	•
Eupolen® PE Green 93-6001		PG 36	❖	•	•	•	•
Eupolen® PE Red 39-1101		PR 178	•	•	•	•	•
Eupolen® PE Red 47-9001		PR 122	•	•	•	•	•
Eupolen® PE Yellow 09-6101		PY 138	❖	•	•	•	•
Eupolen® PE Yellow 13-1501		PY 215	•	•	•	•	•
Eupolen® PE Yellow 17-6001		PY 191:1	•	•	•	•	•
Eupolen® PE Yellow 18-0001	Eupolen® PE Yellow 22-7001	PY 183	•	•	•	•	•
Eupolen® PE Yellow 18-0004	Eupolen® PE Yellow 22-7004	PY 183	•	•	•	•	•
Eupolen® PE Yellow 18-4101		PY 139	❖	•	•	•	•
Eupolen® PE Yellow 18-4105		PY 139	❖	•	•	•	•
Eupolen® PE Yellow 20-8501		PY 110	•	•	•	•	•
Heliogen® Blue K 6850		PB 15	•	•	•	•	•
Heliogen® Blue K 6860		PB 15	•	•	•	•	•
Heliogen® Blue K 6902		PB 15:1	•	•	•	•	•
Heliogen® Blue K 6907		PB 15:1	•	•	•	•	•
Heliogen® Blue K 6911	Heliogen® Blue K 6911 D	PB 15:1	•	•	•	•	•
Heliogen® Blue K 6912 FP	Heliogen® Blue K 6911 FP	PB 15:1	•	•	•	•	•
Heliogen® Blue K 6916		PB 15:1	•	•	•	•	•
Heliogen® Blue K 7090		PB 15:3	•	•	•	•	•
Heliogen® Blue K 7090 FP		PB 15:3	•	•	•	•	•
Heliogen® Blue K 7097	Cromophta® Blue 4GNP.	PB 15:3	•	•	•	•	•
Heliogen® Blue K 7104 LW		PB 15:4	•	•	•	•	•
Heliogen® Green K 8683		PG 7	❖	•	•	•	•
Heliogen® Green K 8730		PG 7	❖	•	•	•	•
Heliogen® Green K 8730 FP		PG 7	❖	•	•	•	•
Heliogen® Green K 8730 Z		PG 7	❖	•	•	•	•
Heliogen® Green K 8740	Heliogen® Green K 8740 LW	PG 7	❖	•	•	•	•
Heliogen® Green K 9360 FK		PG 36	❖	•	•	•	•
Irgalite® Red K 4060 FP	Irgalite® Red 2BSP	PR 48:3	❖	•	SST	•	•
Irgalite® Red K 4170 FP	Irgalite® Red 2BP	PR 48:2	•	•	•	•	•
Irgalite® Rubine K 4270 FP	Irgalite® Rubine 4BP	PR 57:1	•	•	•	•	•
Irgalite® Scarlet K 4165		PR 48:3	❖	•	SST	•	•
Irgazin® Flame Red K 3800	Cromophta® DPP Flame Red FP	PR 272	•	•	•	•	•
Irgazin® Orange K 2890	Cromophta® Orange 2G	PO 61	•	•	•	•	•
Irgazin® Orange K 2910	Cromophta® DPP Orange TRP	PO 71	•	•	•	•	•
Irgazin® Red K 3810	Irgazin® DPP Red BTR	PR 254	•	•	•	•	•

BASF Colorants for toys

Status: July 2014

Product	Old product name	C.I. Name	Toys for children under 3 years and toys for mouth contact		Toys for children above 3 years and no mouth contact		
			European Union	Europe	USA	Australia	
			1935/2004/EC - Art. 3	Norm 71-3, 2002	Norm 71-3, 2013	ASTM 963-07	AS/NZS ISO8124.3:2003
Irgazin® Red K 3840	Cromophta® Red 2030	PR 254	•	•	•	•	•
Irgazin® Red K 3840 LW	Cromophta® Red 2028	PR 254	•	•	•	•	•
Irgazin® Red K 3840 SQ	Cromophta® Red 1030-P	PR 254	•	•	•	•	•
Irgazin® Red K 3842	Cromophta® DPP Red BP	PR 254	•	•	•	•	•
Irgazin® Red K 3845	Irgazin® DPP Red BO	PR 254	•	•	•	•	•
Irgazin® Red K 3845 LW	Cromophta® DPP Red BOC	PR 254	•	•	•	•	•
Irgazin® Rubine K 4080	Cromophta® Rubine TR	-	•	•	•	•	•
Irgazin® Rubine K 4085	Irgazin® DPP Rubine TR	PR 264	•	•	•	•	•
Irgazin® Yellow K 2060	Irgazin® Yellow 3RLTN	PY 110	•	•	•	•	•
Irgazin® Yellow K 2060 FP	Cromophta® Yellow 3RLP	PY 110	•	•	•	•	•
Irgazin® Yellow K 2060 SQ		PY 110	•	•	•	•	•
Irgazin® Yellow K 2070	Cromophta® Yellow 2RLTS	PY 110	•	•	•	•	•
Irgazin® Yellow K 2080	Cromophta® Yellow 2RLP	PY 110	•	•	•	•	•
Microlen® Black 0068 MC	Microlen Black 782-MC	PBk 7	•	•	•	•	•
Microlen® Blue 6907 MC	Microlen® Blue 6907-MC	PB 15:1	•	•	•	•	•
Microlen® Blue 6911 MC	Microlen® Blue BCS-MC	PB 15:1	•	•	•	•	•
Microlen® Blue 6916 MC		PB 15:1	•	•	•	•	•
Microlen® Blue 7079 MC	Microlen® Blue 4GNP-MC	PB 15:1	•	•	•	•	•
Microlen® Blue 7098 MC	Microlen® Blue PD4167-MC	PB 15:3	•	•	•	•	•
Microlen® Flame Red 3800 MC	Microlen® DPP Flame Red FP-MC	PR 272	•	•	•	•	•
Microlen® Green 8730 MC	Microlen® Green 8730-MC	PG 7	❖	•	•	•	•
Microlen® Magenta 4535 MC	Microlen® Magenta RT-235-MC	PR 202	•	•	•	•	•
Microlen® Orange 2910 MC	Microlen® DPP Orange TR-MC	PO 71	•	•	•	•	•
Microlen® Orange 2960 MP	Microlen® Orange GP-MP	PO 64	•	•	•	•	•
Microlen® Pink 4430 MC	Microlen® Pink PT-MC	PR 122	•	•	•	•	•
Microlen® Red 3840 LW MC	Microlen® Red 2028-MC	PR 254	•	•	•	•	•
Microlen® Red 3840 MC	Microlen® Red 2030-MC	PR 254	•	•	•	•	•
Microlen® Red 3845 LW MC	Microlen® DPP Red BOC-MC	PR 254	•	•	•	•	•
Microlen® Red 3890 MC	Microlen® Red BRN-MC	PR 144	•	•	•	•	•
Microlen® Red 3890 MCQ	Microlen® Red BRN-MCQ	PR 144	•	•	•	•	•
Microlen® Red 4060 MC	Microlen® Red 2BSH-MC	PR 48:3	❖	•	SST	•	•
Microlen® Red 4104 MC	Microlen® Red 2020-MC	PV 19	•	•	•	•	•
Microlen® Red 4170 MC	Microlen® Red 2BPH-MC	PR 48:2	•	•	•	•	•
Microlen® Red 4330 MC	Microlen® Red RT-195-MC	-	•	•	•	•	•
Microlen® Rubine 4085 MC	Microlen® DPP Rubine TR-MC	PR 264	•	•	•	•	•
Microlen® Rubine 4270 MC	Microlen® Rubine 4BP-MC	PR 57:1	•	•	•	•	•
Microlen® Yellow 1070 MC	Microlen® Yellow WGP-MC	PY 168	•	•	•	•	•
Microlen® Yellow 1210 MC	Microlen® Yellow 3G-MC	PY 93	•	•	•	•	•
Microlen® Yellow 1210 MCQ	Microlen® Yellow 3G-MCQ	PY 93	•	•	•	•	•
Microlen® Yellow 1410 MC		PY 180	•	•	•	•	•
Microlen® Yellow 1500 MC	Microlen® Yellow GR-MC	PY 95	•	•	•	•	•
Microlen® Yellow 2070 MC	Microlen® Yellow 2RLTS-MC	PY 110	•	•	•	•	•

BASF Colorants for toys

Status: July 2014

Product	Old product name	C.I. Name	Toys for children under 3 years and toys for mouth contact	Toys for children above 3 years and no mouth contact			
			European Union	Europe		USA	Australia
			1935/2004/EC - Art. 3	Norm 71-3, 2002	Norm 71-3, 2013	ASTM 963-07	AS/NZS ISO8124.3:2003
Microlen® Yellow 2070 MCQ	Microlen® Yellow 2RLTS-MCQ	PY 110	•	•	•	•	•
Microlith® Blue 7080 KP	Microlith® Blue 4G-KP	PB 15:3		•	•	•	•
Microlith® Brown 3001 KP	Microlith® Brown 5R-KP	PBr 23		•	•	•	•
Microlith® Green 8750 KP	Microlith® Green G-KP	PG 7		•	•	•	•
Microlith® Red 3840 KP	Microlith® DPP Red B-KP	PR 254		•	•	•	•
Microlith® Red 3890 KP	Microlith® Red BR-KP	PR 144		•	•	•	•
Microlith® Scarlet 3540 KP	Microlith® Scarlet R-KP	PR 166		•	•	•	•
Microlith® Yellow 2060 KP	Microlith® Yellow 3R-KP	PY 110		•	•	•	•
Microlith® Yellow 1210 KP	Microlith® Yellow 3G-KP	PY 93		•	•	•	•
Oracet® Blue 640	Thermoplast Blue 684	SV 13	•	•		•	•
Oracet® Blue 690	Oracet® Blue PD2104	SB 104	•	•	•	•	•
Oracet® Orange 220	Oracet® Orange ES	SO 116	•	•	•	•	
Oracet® Orange 230	Oracet® Orange G	SO 60	•	•	•	•	•
Oracet® Red 344	Oracet® Red GN	SR 135	•	•	•	•	•
Oracet® Red 454	Thermoplast Red 454	SR 195	•	•	•	•	•
Oracet® Violet 580	Oracet® Violet TR	SV 13	•	•	•	•	•
Oracet® Yellow 125	Oracet® Yellow PD 2114	SY 114	•	•	•	•	•
Oracet® Yellow 140	Oracet® Yellow RB	PY 147	•	•	•	•	•
Oracet® Yellow 144 FE	Filester® Yellow RNB	PY 147	•	•	•	•	•
Oracet® Yellow 180	Oracet® Yellow GHS	SY 163	•	•	•	•	•
Paliogen® Red K 3911	Paliogen® Red K 3911 HD	PR 178	•	•	•	•	•
Paliogen® Red K 4180		PR 179	•	•	•	•	•
Paliotol® Orange K 2920		PO 79	•	•	•	•	
Paliotol® Yellow K 0961	Paliotol® Yellow K 0961 HD	PY 138	❖	•	•	•	•
Paliotol® Yellow K 1070	Irgalite® Yellow WGP	PY 168	•	•	•	•	•
Paliotol® Yellow K 1760 FP	Cromophta® Yellow HRPN	PY 191:1	•	•	•	•	•
Paliotol® Yellow K 1800	Paliotol® Yellow K 2270	PY 183	•	•	•	•	•
Paliotol® Yellow K 1841		PY 139	❖	•	•	•	•
Paliotol® Yellow K 1841 FP		PY 139	❖	•	•	•	•
Rightfit® Red K 3790		PR 276	•	•	•	•	
Rightfit® Red K 4350		PR 277	•	•	•	•	
Sicopal® Black K 0095		PBr 29	•	•	SST	•	•
Sicopal® Blue K 6210		PB 28	•	•	SST	•	•
Sicopal® Blue K 6310		PB 28	•	•	SST	•	•
Sicopal® Blue K 7210		PB 36	•	•	SST	•	•
Sicopal® Brown K 2595		PY 119	•	•	SST	•	•
Sicopal® Brown K 2795		PBr 29	•	•	SST	•	•
Sicopal® Brown K 2795 FG		PBr 29	•	•	SST	•	•
Sicopal® Orange K 2430		PO 82	•	•	SST	•	
Sicopal® Yellow 1120 FG		PY 184	•	•	SST	•	•
Sicotan® Brown K 2611		PY 164	•	•	SST	•	•
Sicotan® Brown K 2711		PY 164	•	•	SST	•	•

BASF Colorants for toys

Status: July 2014

Product	Old product name	C.I. Name	Toys for children under 3 years and toys for mouth contact		Toys for children above 3 years and no mouth contact		
			European Union	Europe	USA	Australia	
			1935/2004/EC - Art. 3	Norm 71-3, 2002	Norm 71-3, 2013	ASTM 963-07	AS/NZS ISO8124.3:2003
Sicotan® Brown K 2755		PY 53	●	●	SST	●	●
Sicotan® Yellow K 1010		PY 53	●	●	SST	●	●
Sicotan® Yellow K 1011		PY 53	●	●	SST	●	●
Sicotan® Yellow K 1011 FG		PY 53	●	●	SST	●	●
Sicotan® Yellow K 2001		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2001 FG		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2011		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2011 FG		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2107		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2111		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2111 FG		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2112		PBr 24	●	●	SST	●	●
Sicotan® Yellow K 2112 FG		PBr 24	●	●	SST	●	●
Sicotrans® Red K 2819		PR 101	●	●	●	●	●
Sicotrans® Red K 2915		PR 101	●	●	●	●	●

- Compliant
 - Not Compliant
 - ❖ Compliant with use restrictions, for more information please contact ed-psr@basf.com.
- SST Status Statement Toys (EN 71-3:2013 Heavy Metal Status Statement)

3 Legislations for Food Contact Materials

3.1 EU legislations

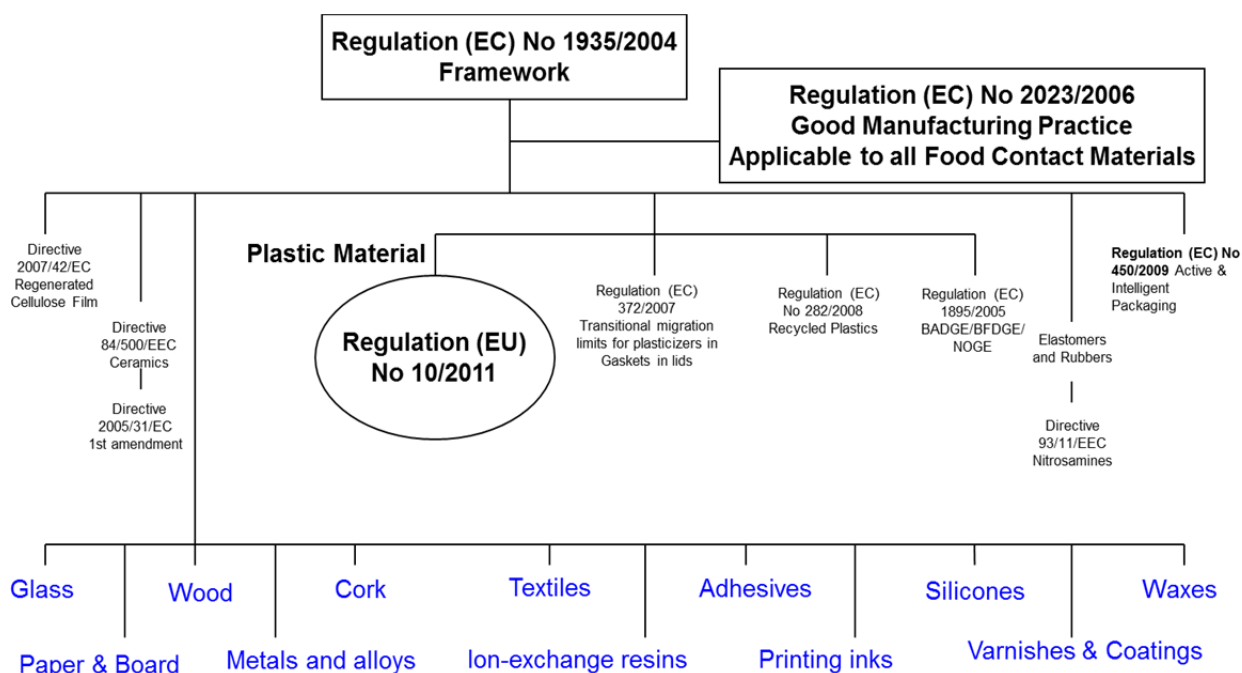


Figure 1: Overview of the EU legislation for Food Contact Materials

European Regulations are directly binding to all 27 Member States. In addition to the direct members of the European Union, some countries within Europe are transforming these regulations into their national law, e.g. Switzerland.

3.1.1 All Food Contact Materials and Articles

Regulation (EC) No 1935/2004, the framework regulation on materials and articles intended to come into contact with food, sets general requirements for all food contact materials.

Framework Regulation sets following rules:

- General safety principles
- Groups of food contact materials and articles
- Procedure for authorization
- Establishment of an European Reference Laboratory for food contact materials
- Mandates the development of implementing measures for specific requirements

General safety principles of the Framework Regulation

The Framework Regulation - in force since 3 December 2004 - requires that food contact materials:

- Meet Article 3 of the regulation: Must not transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its taste and odor.
- Are manufactured according to good manufacturing practice as detailed in The Good Manufacturing Practice Regulation (EC) No 2023/2006 that sets down the requirements/principles of good manufacturing practices for all food contact materials and articles.
- An article intended for food contact must be labelled or bear the glass-and-fork symbol. This labelling is not obligatory if food contact is obvious by the article's nature e.g. knife, fork, wine glass.
- Labelling, advertising and presentation of food contact materials must not mislead consumers.

- Accompanied by a “Declaration of Compliance” containing information on the appropriate use of food contact materials or articles, if necessary. (Article 16)
- Are traceable throughout the production chain.

3.1.2 Plastic Food Contact Materials and Articles

Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and amendments sets the rules for plastic food contact materials. This regulation is commonly known as the “PIM” or Plastics Implementation Measure. It is one of the implementing measures mandated by the Framework Regulation and addresses plastics specifically.

The Regulation entered in force on May 11, 2011 and foresees transitional provisions up to January 1, 2016. By then all Food Contact Materials and Articles on the market will have to fulfill the requirements of the Regulation (EU) No 10/2011.

What the Regulation covers:

- Plastic materials and articles, whether or not printed and coated
- Plastic multi-layer materials and articles held together by adhesives or by other means, whether or not printed and coated
- Plastic layers or plastic coatings, forming gaskets in caps and closures, that make a set of two or more layers of different types of materials
- Plastic layers in multi-material multi-layer materials and articles

Rules set by the Regulation:

- Union list of authorized monomers and additives for use in plastics manufacture
- Restrictions and specification for authorized substances including specific migration limits
- Rules on non-intentionally added substances i.e. impurities and reaction products
- Overall migration limit
- Rules on compliance especially migration testing, listing simulants, testing conditions
- The concept of functional barrier
- Authorization for nano-materials before use
- Declaration of compliance and supporting documentation

As mentioned in the Union Guideline to Regulation (EU) No 10/2011 published in February 2014 “Even though colorants fall under the definition of additives, they are not covered by the Union list of substances. Colorants used in plastics are covered by national measures. However, they have to comply with the general safety requirements of Article 3 of the Framework Regulation (EC) No 1935/2004 and are subject to risk assessment in accordance with Article 19 of the Plastics Regulation (EU) No 10/2011.

“Article 19”

Assessment of substances not included in the Union list

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognized scientific principles on risk assessment.”

3.1.3 Council of Europe Resolutions

The Council of Europe has established general recommendations for various types of materials which are frequently used in production, distribution, processing and consumption of foodstuffs. The following (non-plastic) materials have been addressed: coatings, cork, glass, inks, metals and alloys, paper and board, resins for ion exchange and adsorption, rubber, silicones.

For all materials, the requirement is present that they should not transfer their constituents to foodstuffs in quantities which could endanger human health, bring about unacceptable change in composition or deterioration of organoleptic characteristics. Specific requirements are set in the supplementary Technical Documents and substance inventories can be found in the Appendixes of the resolutions. The substance inventories are based on notifications by industry or national authorities. Listed substances have not necessarily been risk assessed.

All resolutions are not legally binding. They have the character of a guideline, as long as they are not transferred into national law.

Resolution AP(89)1

Resolution AP(89)1 applies to the use of colorants in plastic materials and articles coming into contact with food.

The Resolution defines purity requirements for pigments including concentration limits for extractable heavy metals, primary aromatic amines (PAA) and Polychlorinated Biphenyls (PCB).

Impurity	Limit (ppm)
Antimony (Sb)	500
Arsenic (As)	100
Barium (Ba)	100
Cadmium (Cd)	100
Chromium (Cr III)	1000
Lead (Pb)	100
Mercury (Hg)	50
Selenium (Se)	100
Primary aromatic amines (PAA)	500
Polychlorinated biphenyls (PCB)	25

3.2 France

The French Authority issued a document titled “Matériaux au contact des denrées alimentaires, produits de nettoyage de ces matériaux” – Edition (July 2002) No. 1227.

French Positive List for Plastic Materials

In Circular No. 176 of December 2, 1959 the French Ministry of Agriculture published a list of colorants which can be used for the coloration of food packaging in France. Since then, this list has frequently been revised.

For the complete list of pigments with their use limitations (e.g. concentration, type of polymers, etc.) it is necessary in each case to consult the document No. 1227.

It should be noted that the colorants in the French Positive List generally are listed according to their Color Index classification (generic names and constitution numbers). If not, it is under their CAS number (Chemical Abstract Service) and/or French chemical name. French authorities have not yet established their country-specific rules into the European Union, where colorants themselves are not yet regulated. Establishment of these rules would require an official notification agreed by all member states in order to avoid the creation of potential trade barriers.

The current French positive list split in A and B (Projet d'Arrêté) can be considered as a draft, and should be taken in the scope of a recommendation (non-complete list). Nevertheless, the colorants have to fulfil the requirements of Article 3 of the Regulation (EC) No 1935/2004.

3.3 Germany

In BfR Recommendation IX, colorants for plastic food contact materials are defined as all substances that have coloring properties, including those possibly used as vehicle or production & processing aids, as well as any technically unavoidable contaminants.

Therefore, a list of productions and processing aids is included with maximum use levels. For the colorants themselves, purity requirements on metal release and primary aromatic amines are established. In addition, any release of colored substances is not allowed.

3.4 Italy

In Italy the national regulation Decreto Ministeriale 21/3/73 as latest amended (Decree 23/04/09) has to be met for various food contact materials like plastic, paper, rubber etc. For colorants in plastic food contact materials purity limits are required in the same way as in the Council of Europe Resolution AP(89)1 i.e. heavy metals, primary aromatic amines (PAA) and Polychlorinated Biphenyls (PCB).

3.5 Australia

AS 2070-1999: Plastic materials for food contact uses.

This standard specifies materials and the procedures for use during the various stages of production of plastic materials, coating and printing of plastic items for food contact and subsequent use. Part 9.2 deals with colorants and states that colorants shall comply with the Council of Europe Resolution AP(89)1.

3.6 Canada

In Canada, colorants are not subject to specific regulations; hence there is no "positive list". However, a regulation does exist which constitutes a guideline for packaging materials. It can be found under Division 23 of the Food and Drug Regulations, Section B23.001.

In case more information is required, please contact ed-psr@basf.com.

3.7 China

Regulatory Framework in China

In China, food contact materials (FCMs) are regulated under the Chinese Food Safety Law issued in 2009. Article 32, together with article 62, of the Food Safety Law prohibits the importation, use, or purchase of food-related products (e.g., food additive, food packaging materials) not complying with applicable Chinese Food Safety Standards.

Finished articles usually need to be tested with appropriate food stimulants related to real use conditions (type of food, temperature) to demonstrate compliance.

Positive List of Food Contact Additives and Colorants

The most important food safety standard for food contact additives in China is GB 9685-2008 "Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials".

China GB 9685-2008 provides a positive list of food contact additives and additional limits such as SML (Specific Migration Limit) and QM (Maximum Quantity allowed). where colorants are considered as "Food contact additives" and therefore must be listed. Since GB 9685 does not differentiate between direct or indirect contact. Many inks or adhesives to be used in food packaging materials and not intended to be in direct contact with food are also affected by this standard.

3.8 India

In India the new Food Safety and Standards (packaging and labelling) regulations became effective in 2011 bringing the food safety regulation to a federal level with the new authority FSSAI. The major restrictions/limitations of a substance to be used for food contact materials are still captured in the Indian Standards issued by the BIS Bureau of Indian Standards. As an example the standard for pigments and colorants is listed here: IS 9833:1981 – List of Pigments & Colorants for Use in Plastics in Contact with Foodstuffs, Pharmaceuticals & Drinking Water (Draft) – 01/Apr/2012. Via the link to the regulation the former voluntary standards are now regarded as mandatory.

In case more information is required, please contact ed-psr@basf.com.

3.9 Japan

In Japan there are government regulations (e.g. Food Sanitation Law) for food packaging and toys. The industry has published recommendations which are accepted by all involved parties and conform to the regulations.

The Japan Hygienic PVC Association (JHPA) mentions in its Positive List for PVC the chemical constitutions as well as the Color Index denomination.

Contrary to this, the Japan Hygienic Olefin Styrene Plastics Association (JHOSPA) registers products with their trade names only. Chemically identical products with different names are thus not accepted.

3.10 Mercosul/Mercosur

In the South-American region colorants for plastic food contact materials have to meet the requirements of the Mercosul/Mercosur GMC Resolución N° 15/2010, implemented e.g. in Brazil (Resolução RDC N° 52/2010). These are purity limits similar to the Council of Europe Resolution AP(89)1. However, more elements and partly different analytical methods have to be considered.

In case more information is required, please contact ed-psr@basf.com.

3.11 USA

Food contact substances (FCS) are regulated by the Food and Drug Administration (FDA) for use in food contact applications (the colored polymer is in direct contact with the food). These substances were either regulated in the Code of Federal Regulations (CFR), Title 21, Parts 170–199 or as amended, or are listed on the FDA's Inventory of Effective Premarket Notifications website listing the Food Contact Notifications (FCN) <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/default.htm>.

They have to meet the general provisions of § 174.5 and section 402 applicable to indirect food additives which are comparable to the requirements of Article 3 of the Regulation (EC) No 1935/2004.

The substances listed in paragraph (e) of 21 CFR 178.3297 may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the following provisions:

- (a) The term colorant means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. The term "colorant" includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food contact material.
- (b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.
- (c) Colorants listed in 21 CFR 178.3297 must conform to the description and specifications as indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation.

- d) Color additives and their lakes listed for direct use in foods, under the provisions of the color additive regulations in parts 73, 74, 81, and 82 of this chapter, may also be used as colorants for food contact polymers.

For more detailed explanation please refer to 7 Appendix: Definitions and Abbreviations.

4 Legislation on Toys

4.1 Europe

The Toy Safety Directive 2009/48/EC (TSD) provides harmonized EU-wide standards on physical and mechanical properties, flammability, chemical and electrical properties, etc. of toys.

The new TSD 2009/48/EC requires a series of safety assessments, including the Chemical Safety Assessment (CSA). It broadens the requirements of chemical properties, e.g. migration limits, to 19 chemical elements. The migration limits for these chemical elements are considerably lower than under the old TSD. In addition, certain fragrances, CMR substances and nitrosamines are restricted. Toys for children under 3 years and toys for mouth contact have to fulfil Article 3 of the Framework Regulation (EC) No 1935/2004.

Annex II, Part III of the New TSD and its amendment (Commission Directive 2012/7/EU) for Category I

Migration limits for toys or components of toys (dry, brittle, powder-like or pliable toy materials)

Element	Limit (ppm)
Aluminium (Al)	5625
Antimony (Sb)	45
Arsenic (As)	3.8
Barium (Ba)	4500
Boron (B)	1200
Cadmium (Cd)	1.3
Chromium (III) (Cr III)	37.5
Chromium (VI) (Cr IV)	0.02
Cobalt (Co)	10.5
Copper (Cu)	622.5
Lead (Pb)	13.5
Manganese (Mn)	1200
Mercury (Hg)	7.5
Nickel (Ni)	75
Org. Tin (org. Sn)	0.9
Selenium (Se)	37.5
Strontium (Sr)	4500
Tin (Sn)	15000
Zinc (Zn)	3750

4.2 Australia, AS/NZS ISO 8124-3:2010

ISO 8124-3:2010 specifies some maximum acceptable levels, methods of sampling and extraction prior to analysis for the migration of the elements antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium from toy materials and parts of toys.

The maximum acceptable element migration from toy materials is equivalent to the old EN 71-3:2002 requirements as listed in 7 Appendix: Definitions and Abbreviations.

4.3 USA, ASTM 963-07

All toys in the United States must meet the ASTM F963 safety requirements, Standard Consumer Safety Specification for Toy Safety. The limits and test method of soluble elements are equivalent to the old EN 71-3:2002 as listed in 7 Appendix: Definitions and Abbreviations.

5 Other Sensitive Applications

Apart from Food contact Packaging and Toys applications, additional applications can be considered based on the risk dimensions of their intended use.

The following briefly covers the requirements for some of those applications, detailed by national regulations when applicable.

5.1 Medical Devices

A medical device is an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions. Medical devices act by mainly physical, mechanical, or thermal means.

The medical device application is a highly regulated end application. The requirements depend on the risk class of the end application. The approval of end application requires a considerable amount of data on plastic raw materials, plastic converting steps and safety assessment of the end article. There is no specific regulation for all plastic raw materials. Food contact compliance is obligatory for plastic colorants used in medical devices.

In the EU, all medical devices must be identified with the CE mark.

5.2 Pharmaceutical Packaging

Pharmaceutical packaging is a part of the pharmaceutical drug registration. The regulation of pharmaceutical drugs varies from jurisdiction to jurisdiction. The requirements depend on the risk class of the end application. Food contact compliance is obligatory for plastic colorants used in pharmaceutical packaging.

5.3 Cosmetic Packaging Applications

The EU Cosmetic Regulation (EC) No 1223/2009 (Annex I, Part A) introduced the requirement to report on packaging materials, impurities and traces within the product safety information. The product safety information includes the relevant characteristics of the packaging material, in particular the purity and stability of the final packaging and its components. Statements are required if prohibited substances are present in trace amounts and evidence that it is technically unavoidable.

5.4 Drinking Water Applications

Drinking water approvals are applicable to materials and end-articles in contact with drinking water. The regulatory requirements are country specific. The responsibility rests with the end-article producer. In Europe, the approval procedures for use with drinking water are regulated by the individual countries. The approvals are granted by institutes that are authorized to carry out tests and issue certificates on the basis of the corresponding requirements. The relevant approval regulations include the Recommendations Pertaining to Plastics and Drinking Water (KTR) as well as the standards of the German Technical and Scientific Association for Gas and Water (DVGW), the Water Regulations Advisory Scheme (WRAS) in Great Britain, the Certificate of Sanitation Conformity (ACS) in France and for China, approvals are obtained from the Chinese MOH (Ministry of Health).

In USA, NSF International (National Science Foundation), an independent US Government agency, carries out drinking water approvals in accordance with Standard 61 (NSF61) The NSF tests and certifies all products within the entire drinking water system.

6 Disclaimer

For notice:

Appropriate processing conditions for the articles have to be applied. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be tested and ensured in each case by the person who introduces the articles into circulation. Since our products are manufactured on an industrial scale, the presence of traces of impurities cannot be ruled out. Kindly also take note of the fact that analysis of our product for compliance with the above mentioned legislation is not routinely carried out for each lot. It is performed randomly and on the basis of standardized tests. Therefore, regulatory compliance is not part of our quality control nor part of the product Specification or the Certificate of Analysis.

7 Appendix: Definitions and Abbreviations

Pigments

According to DIN 55943: 2001-10 is a pigment “particulate substance which is practically insoluble in the medium in which it is incorporated, used as a colorant or due to its anti-corrosion and magnetic properties.”

Dyes

“Dyes” is a collective term for colorants soluble in solvents and/or binders.

Colorants (ETAD Definition)

A colorant is a product intended to impart or modify the color of a substrate. In order to do it, the colorant will possess the ability to change the color of reflected or transmitted light as the result of wavelength-selective absorption.

In addition, a colorant may also contain deliberately added components, which

- Maintain the properties of the colorant during production and use;
- Influence specific properties of the colorant as fitting to its application.

These added components should be termed as **colorant additives**.

Furthermore, depending on the production process, a colorant may also contain certain **non-intentionally added substances** (NIAS) e.g. residues of starting materials, byproducts ... These NIAS are not intended to have a technical effect in the substrate to which the colorant is applied.

EU Food Contact Materials

As defined in the EU Framework Regulation (EC) No 1935/2004.

Materials and articles which in their finished state

- Are intended to be brought into contact with food
- Are already in contact with food and were intended for that purpose
- Can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use

Examples

- Food packaging and containers, kitchen equipment, cutlery and dishes
- Processing equipment, such as coffee makers or production machinery
- Containers used in transport of food

EU legislation for food contact materials covers materials in contact with water intended for human consumption, e.g. bottles, with the exception of fixed public or private water supply equipment.

NIAS (Non Intentionally Added Substances)

As defined in the Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

“NIAS” stands for **Not-Intentionally Added Substance** and is an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product.

Examples of NIAS in products are:

- Impurities
Present in the raw materials or solvents
- Reaction products
Formed during the **synthesis** of the additive or pigment
Formed during the **manufacturing and use** of plastic materials and articles
Formed during the **storage and manufacturing** of polymers
- Degradation products

FCS (Food Contact Substances)

As defined by the U.S. Food and Drug Administration (FDA) in section 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food (formerly known as indirect food additives). Common types of food contact substances include coatings, plastics, paper, adhesives, as well as colorants, antimicrobials, and antioxidants found in packaging.

Hierarchy from Food Contact Substance (FCS) through Food Contact Material (FCM) to Food Contact Article (FCA):

The Food Contact Substance (FCS) is a single substance, such as a polymer, an antioxidant or colorant in a polymer. As a substance, it is reasonably pure (the Chemist's definition of substance). Even though a polymer may be composed of several monomers, it still has a well-defined composition.

Food contact notifications (FCN) are required only for new uses of FCSs that are food additives. Although a notification is not required for a food contact substance that is GRAS or prior sanctioned for its intended use in contact with food, some companies do choose to notify the Agency in order to clarify the regulatory status of such substances.

Unlike food additive regulations and threshold of regulation exemptions (TOR), approvals under the FCN process are proprietary. This is because Section 409(h)(1)(C) of the FD&C Act states that an FCN is effective only for the manufacturer and substance identified in the notification. Thus, any person wishing to rely on an FCN needs to demonstrate that the FCS being marketed has been manufactured or supplied by the manufacturer identified in the FCN and is being used under the conditions that are the subject of the FCN

Food Contact Material (FCM) is made with the FCS and (usually) other substances. It is often (but not necessarily) a mixture, such as an antioxidant in a polymer. The composition may be variable.

The Food Contact Article is the finished film, bottle, tray, or whatever that is formed out of the FCM.

GRAS (Generally Recognized As Safe)

“GRAS” is an acronym for the phrase **Generally Recognized As Safe**.

As defined by the U.S. Food and Drug Administration (FDA) in sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Any substance that is intentionally added to food is a food additive and subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive.

For example, substances whose use meets the definition of a pesticide, a dietary ingredient of a dietary supplement, a color additive, a new animal drug, or a substance approved for such use prior to September 6, 1958, are excluded from the definition of food additive.

Sections 201(s) and 409 were enacted in 1958 as part of the Food Additives Amendment to the FD&C Act. While it is impracticable to list all ingredients whose use is generally recognized as safe, FDA published a partial list of food ingredients whose use is generally recognized as safe to aid the industry's understanding of what did not require approval.

Section 174.5(d)(1) of the Food Additive Regulations states that substances generally recognized as safe "among experts qualified by scientific training and experience to evaluate their safety", under conditions of good manufacturing practices, are permitted to be used as components of articles that contact food.

Parts 182, 184, and 186 of the Food Additive Regulations list many substances that are recognized or affirmed as GRAS by FDA. Section 182.1 of the Food Additive Regulations makes it clear that those listed are by way of illustration and do not represent an all-inclusive list. The absence of a substance from the list does not preclude an independent determination that the substance is GRAS when used in a particular application. For example, any substance generally recognized as safe in or on food is also permitted to be used under conditions of good manufacturing practice as a component of articles that contact food. 21 CFR §174.5(d)(1).

FDA has codified requirements for the classification of substances as GRAS under 21 C.F.R. § 170.30(a). As stated therein, general recognition of safety must be based on:

- (1) Scientific procedures, or
- (2) In the case of a substance used in food prior to January 1, 1958, through experience based on common use in food.

General recognition of safety requires a "common knowledge" about the substance throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food. For substances not widely used in food prior to 1958, general recognition of safety based on "scientific procedures" requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. Unlike a food additive petition, however, general recognition of safety is ordinarily based on published studies which may be corroborated by unpublished studies and other data and information.

The exclusion of substances which are GRAS from the definition of the term "food additive" means that such substances do not require pre-clearance by FDA under Section 409 of the Act. If a manufacturer determines that a particular substance is GRAS, he is free to market the substance without notification to, or approval by, FDA. Obviously, if FDA should consider the manufacturer's determination of GRAS status to be erroneous, the Agency can take appropriate regulatory action; in this case the burden of proof would fall upon FDA to demonstrate that the substance is not GRAS. This is an unlikely consequence unless a real public health problem presents itself.

TOR (Threshold of Regulation)

The Threshold of Regulation (TOR) lists exemptions that have been issued under 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles. A substance used in a food contact article may be exempted by FDA from the need of an FCN or a petition (regulation) as a food additive if the use in question has been shown to result in a very low concentration (0.5 ppb). Threshold of Regulation Exemptions are generally applicable and are effective for the food contact substance (FCS) for the listed intended use regardless of manufacturer or supplier.

Prior Sanctioned Substances

Prior Sanctioned substances under 21 CFR 181 are those substances whose use in contact with food is the subject of a letter issued by FDA or USDA before 1958 offering no objection to a specific use of a specific substance.

FCN (Food Contact Notification)

The FCN process has been introduced with the Food and Drug Administration Modernization Act of 1997 (FDAMA). The FCNs are proprietary to the manufacturer for which the notification is effective.

EU Toy Norm EN 71-3:2002

European standard EN 71, Part 3 (migration of substances from toy materials), lays down limits for heavy metals that are soluble in 0.07 N hydrochloric acid. The EN 71-3:2002 has been revised in 2013 but is still used as reference for other Toy regulations in other countries.

Element	Limit (ppm)
Antimony (Sb)	60
Arsenic (As)	25
Barium (Ba)	1000
Cadmium (Cd)	75
Chromium (Cr III)	60
Lead (Pb)	90
Mercury (Hg)	60
Selenium (Se)	500

Note

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Asia

BASF East Asia Regional Headquarters Limited
Dispersions and Pigments
45/F Jardine House
No. 1 Connaught Place
Hong Kong
Phone: +852 2731 0111

Europe, Africa and West Asia

BASF SE
Pigments
E-EDC/FK – J550
67056 Ludwigshafen
Deutschland
Phone: +49 621 60 58262

North America

BASF Corporation
24710 West Eleven Mile Road
Southfield, MI 48033
USA
Phone: 800-961-7829

South America

BASF S.A.
Av. das Nacoes Unidas, 14.171, 17o. andar, Morumbi
04794-000 Sao Paulo
Brazil
Phone: +55 11 2039-3166