

Chromazone Regulatory Information

REACH REGULATIONS

All Chromazone components have been either registered or pre-registered under REACH.

Chromazone products, apart from those that specifically contain Bisphenol A, manufactured by LCR do not contain any chemicals listed in SVHC as per 7th July 2017 update.

BISPHENOL A

Bisphenol A is now on the SVHC list and is declared on the SDS for those products that contain it.

Chromazone is manufactured in formulations containing Bis A and not containing Bis A. The presence or absence of Bis A is clearly indicated in the product names with Bis A Free being used in the name of all formulations not containing Bis A.

CHEMICAL REGISTRATION INVENTORIES.

We can confirm all components in standard formulation Chromazone comply with EINECS, TSCA, DSL/NDL.

Please contact us if you require compliance with Korean KECL or Australia AICS, since some formulations do not comply fully.

RoHS , WEE

Chromazone products comply with RoHS and WEE. Test certificates for evaluated ChromaZone formulations can be consulted on request.

EN 71-3:1994/AC:2002 is a regulation defining migration limits of heavy metals in toys. Chromazone products have been independently tested and they do not



contain the listed metals in excess of EN71 set limits. Typical analysis attached below.



40103003T3
Turquoise 31 powder

The actual regulation refers to the extraction of metals from the toy or from the final end product. As such, the end product may require testing for full compliance validation.

Chromazone is made under good manufacturing practices that comply with those stipulated by Eupia / CEPE for the production of pigments to be used in indirect food contact packaging.

THE COUNCIL OF EUROPE RESOLUTION AP (89)-1.

Scope and Description of the regulation

Ap (89)-1 regulation is ruling the use of Colorants coming into contact with food.

AP (89) stipulates purity criteria for colorants used in plastics that may come into food contact. By inference the ink industry uses this as a guideline for colorants suitable for printing on food packaging.

AP (89)-1 tests are conducted on the colorant as opposed to EN71 where the end product is tested.

The colorant is tested for migration into food as actual colour. The test method involves spreading the colorant onto filter paper and testing migration with various solutions. The extraction levels of various chemicals - Please refer to table 1 here below for exhaustive list of chemicals tested- is part of the AP (89)-1 testing procedure.

The AP (89)-1 set limits are lower than Those of RoHS for heavy metals (see here below):

Note

Chromazone is manufactured either containing Bisphenol A (4,4'-isopropylidenediphenol , CAS 80-05-7) or as Bisphenol A free formulation.

Products sold as Bisphenol A free do not have any Bisphenol A intentionally added.

Test Results

Chromazone powder has been independently tested by a laboratory accredited to ISO 17025. All tests were run using analytical methods stipulated in AP (89) (see table 2). Tests were run on two different batches representing a typical production ChromaZone batch.

- None of the elements or chemicals stipulated in AP (89) is intentionally added to our ChromaZone products.
- Test results showed no substance above the failure levels laid out in AP (89)-1 (See table 1)
- Tests carried out to date on specific batches have never shown any failure to comply.
- For specific formulations AP (89) test can be carried out, at the customer's expense in an independent analytical laboratory. Figures obtained would only be expressly guaranteed for the batch tested. We expect all batches to show the same test results.

Chromazone products manufactured as Bisphenol A free and Bisphenol A have passed the AP (89)-1 tests.

Table (1): AP (89)-1 Test Result for Chromazone Powder.

	Method	Test Sample	LOD	Units	Results
Antimony	T357	AR	10 mg/kg		<10
Arsenic	T357	AR	10 mg/kg		<10
Barium	T357	AR	10 mg/kg		<10
Cadmium	T357	AR	10 mg/kg		<10
Chromium	T357	AR	10 mg/kg		<10
Lead	T357	AR	10 mg/kg		<10
Mercury	T357	AR	1 mg/kg		<1
Selenium	T357	AR	10 mg/kg		<10
Zinc	T357	AR	10 mg/kg		<10
2-Naphthylamine	T362	AR	0.1 mg/kg		<0.1
4-Aminobiphenyl	T362	AR	0.1 mg/kg		<0.1
Amines (Aromatic) as Aniline	T362	AR	1 mg/kg		<1.0
Benzidine	T362	AR	0.1 mg/kg		<0.1
PCB (Total Mono-Deca) expressed as Decachlorobiphenyl	T353	AR	1 mg/kg		<1.0
Sulfonated aromatic amines (as aniline sulfonic acid)	T362	AR	1 mg/kg		<1.0

Table 2: tests method

Method Index

Value	Description
T353	GC/MS (ETAD 227)
T357	ICP/OES (15min 0.1M HCl dige
T362	GC/MS (ETAD 212)

COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

Chromazone powder contains low levels of formaldehyde and there is a SML of 15mg/kg. The production of plastic master batch and further production of plastics will change the levels of formaldehyde. The SML levels should not be exceeded and the finished product should be tested to ensure compliance. Experience has shown formaldehyde not to be an issue with plastics incorporating master batch but responsibility lies with the article manufacturer to confirm this.

DIRECT AND INDIRECT FOOD CONTACT INKS

Direct food Contact:

Chromazone products are not suitable for use in direct food contact inks unless the formulation has been validated through a certification body accredited for giving food contact approval. Please contact us for more information on how to proceed.

Indirect food Contact:

Chromazone products are manufactured under BS EN ISO 9001:2008 and as such meets the Good Manufacturing Practices for The Production of Packaging Inks manufactured for the non food contact surfaces (indirect food contact) of food packaging and articles intended to come into contact with food.

Chromazone slurries and inks contain some formaldehyde and the printed ink would need to have formaldehyde below the SML of 15mg/kg. The printed article should be tested to ensure this is the case.

Chromazone inks and raw materials manufactured by LCR do not contain any chemicals on the CEPE forbidden chemicals list. While ChromaZone powder specifically containing Bisphenol A passes the AP (89) test, the CEPE / EUPIA guideline on selecting materials for manufacturing indirect food contact inks excludes substances which are classified as toxic to reproduction class 3, which Bisphenol A belongs to.

- Bisphenol A free Chromazone raw material and inks are suitable for manufacturing indirect food contact printed food packaging.
- Bisphenol A Chromazone raw material and inks are not suitable for manufacturing indirect food contact printed food packaging unless approved by a certification body.

PHTHALATES

None of the phthalates listed below are added intentionally to Chromazone.

Phthalates	Di(2-ethylhexyl)phthalate	<300ppm	117-81-7
	Butylbenzyl phthalate		85-68-7
	Dibutyl phthalate		84-74-2
	Diisobutyl phthalate		84-69-5
	Di-iso-nonyl phthalate	<300ppm	28553-12-0 & 68515-48-
	Di-n-octyl phthalate		117-84-0
	Dicyclohexyl phthalate		84-61-7
	Di-n-pentyl phthalate-D4	<300ppm	131-18-0
	Di-iso-decyl phthalate	<300ppm	26761-40-0 & 68515-49-1
	Diisooctyl phthalate	<300ppm	27554-26-3
	Di-n-hexyl phthalate	<300ppm	84-75-3

TIN COMPOUNDS

None of these compounds are used in Chromazone

Organotin	Tributyl tin compound (TBT)	No use	/
	Triphenyl tin compound (TPT)	No use	/
	dibutyltin compounds (DBT)	No use	/
	dioctyltin compounds (DOT)	No use	/

Chromazone powder does not contain any of the following: Radio active material, ozone depleting chemicals, benzene, azo colourants, perfluorooctane sulphonate, dimethyl fumarate.

No PAHS listed below are intentionally added to Chromazone.

Benzo(a) Pyrene	<0.2ppm	50-32-8
Naphthalene	<1ppm	91-20-3
Acenaphthylene	Total < 1ppm	208-96-8
Acenaphthene		83-32-9
Fluorene		86-73-7
Phenanthrene		85-01-8
Anthracene		120-12-7
Fluoranthene		206-44-0
Pyrene		129-00-0
Benzo(a)anthracene		<0.2ppm
Chrysene	<0.2ppm	218-01-9
Benzo(b)fluoranthene	<0.2ppm	205-99-2
Benzo(k)fluoranthene	<0.2ppm	207-08-9
Indeno(1,2,3-cd)pyrene	<0.2ppm	193-39-5
Dibenzo(a,h)anthracene	<0.2ppm	53-70-3
Benzo(g,h,i)perylene	<0.2ppm	191-24-2
Benzo(j)fluoranthene	<0.2ppm	205-82-3
Ben-zo(e)pyren	<0.2ppm	192-97-2

None of the following chemicals are intentionally added.

Halogen	bromine	<900ppm	/
	chlorine	<900ppm	/
	bromine +chlorine	<1500ppm	/
2-(2'-hydroxy-3',5'-di-tert-butylphenyl)benzotriazole		No use	/
Nonylphenol		<100ppm	25154-52-3
Nonylphenol ethoxylate		<100ppm	/
Formamide		<200ppm	75-12-7
Triclosan		No content	3380-34-5
Toluene		<2mg/l	108-88-3
Xylene(all isomers)		<2mg/l	1330-20-7
Ethylbenzene		<1mg/l	100-41-4

1,3,5-Trimethylbenzene	<3mg/l	108-67-8
Nitrobenzene	No use	98-95-3
Methanol	5mg/l	67-56-1

Phenol	<15mg/l	108-95-2
Styrene	<0.75mg/l	100-42-5
2-Methoxypropyl Acetate	<0.5mg/l	70657-70-4
2-Ethoxyethanol		110-80-5
2-Ethoxyethyl acetate		111-15-9
Cyclohexanone	46mg/l	108-94-1

Formaldehyde will be present below 0.1% in Chromazone powder.