

## **LCR Hallcrest Thermochromics (Chromazone) Regulatory Information**

### **REACH REGULATIONS**

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

Chromazone products manufactured by TMC do not contain any chemicals listed in SVHC as per 19<sup>th</sup> December 2015 update.

### **CHEMICAL REGISTRATION INVENTORIES.**

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

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.

### **DIN EN 71-3:2014-12 Safety of Toys - Migration of certain 19 elements**

is a regulation defining migration limits of heavy metals in toys. Chromazone pigments have been independently tested and they do not contain the listed metals in excess of EN71 set limits.

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 Deca-chlorobiphenyl	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	Description
Value	
T353	GC/MS (ETAD 227)
T357	ICP/OES (15min 0.1M HCl digest)
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 TMC 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.