

April 18, 2024

**Atrium**

**RE: Regulatory review**

The following is in response to your request for a product review related to the above referenced topic. This product review applies to the products listed in Appendix A.

**EuPIA Exclusion Policy For Printing Inks and Related Products, 6th Edition**

INX International Ink Co. has thoroughly reviewed the EuPIA Exclusion Policy, 6<sup>th</sup> Edition of March 2024. INX has researched the chemical components used in the below referenced formulations as managed within its EMS systems or the materials used in the manufacture of these products and has determined that all products in Appendix A meet or are exempted from the Selection Criteria lists A and B in the EuPIA Exclusion Policy. Further, no components are present from the Substances List C, D, E, F, or G.

This review is based on standard hazard assessment procedures from known information conveyed through MSDS and other technical documents as well as information obtained from exhaustive surveys to our suppliers.

**Swiss Ordinance 817.023.21 for Packaging Inks (Swiss Ordinance):**

The Swiss Federal Department of Home Affairs (DFI) adopted in March 2008 an amendment to the Ordinance of 23 November 2005 on Materials and Objects in Contact with Food (SR 817.023.21). It entered into force on 4 January 2010 and lays down the obligation for packaging inks to be manufactured only with the authorized substances. Permitted substances are defined as those listed in Annex 2 Lists I and II and in Annex 10, 1 October 2022.

The lists in the Ordinance simply states that the substances may be used in the manufacture of printing inks. To ensure safety in accordance with the law, the migration limits for substances must not be exceeded for final packaging. Guides of Good Practice for the manufacture and printing of printing inks should be followed.

Substances listed with status 'B' may be used, provided that the final packaging is in compliance with the requirements of the Ordinance, i.e. the migration of the listed substances cannot be detected using a valid and official analytical method. The migration should not be greater than 0.01 mg / kg (10 ppb).

INX carried out a review of the raw materials used in the products below to determine their status with respect to the Swiss Ordinance and found that the products below are listed in the Swiss Ordinance Annex 10.

Accordingly, it does not automatically mean that the product or substance is toxicologically suitable to be used for printing inks for all types of food packaging.

**Directive 2009/48/EC on the safety of toys - EN 71-3:2019+A1:2021 Toy Safety Standard**

The INX International Ink Co. products listed in Appendix A are formulated from ingredients whose chemistry excludes the nineteen elements regulated by EN71 Part 3 Category III (Table 1) in quantities exceeding the limits, except for the chemical compounds listed on Table 2:

Table 1: Directive 2009/48/EC requirements

Element	EN 71-3:2019+A1:2021		
	Category I (mg/kg) in dry, brittle, powder-like or pliable toy material	Category II (mg/kg) in liquid or sticky toy material	Category III (mg/kg) in scraped-off toy material
Aluminum <sup>1</sup>	2250	560	28130
Antimony	45	11.3	560
Arsenic	3.8	0.9	47
Barium	1500	375	18750
Boron	1200	300	15000
Cadmium	1.3	0.3	17
Chromium (III)	37.5	9.4	460
Chromium (VI) <sup>2</sup>	0.02	0.005	0.053
Cobalt	10.5	2.6	130
Copper	622.5	156	7700
Lead	2.0	0.5	23
Manganese	1200	300	15000
Mercury	7.5	1.9	94
Nickel	75	18.8	930
Selenium	37.5	9.4	460
Strontium	4500	1125	56000
Tin	15000	3750	180000
Organic tin	0.9	0.2	12
Zinc	3750	938	46000

Table 2: Substance's disclosure

INX Code	Product name	Value	CAS RN	Substance name	Metal
1695055	ULTRAVISION KM Flex LED UV CYAN	≤2 %	147-14-8	Pigment Blue 15	Copper

Assessment of migration shall be carried out on the finished product, not on the printing ink as such.

This certification releases INX International Ink Co. from any liability once the product is removed from its original packaging or handled in any manner that alters its original condition as supplied.

Respectfully,  
Aina Campos  
Regulatory Product Steward

<sup>1</sup> Al limits according to Directive (EU) 2019/1922, effective as from 20 May 2021

<sup>2</sup> Cr(VI) limits according to Directive (EU) 2018/725, effective as from 18 November 2019

**Appendix A: Products reviewed for this certification**

<b>INX Code</b>	<b>Description</b>
1695055	ULTRAVISION KM Flex LED UV CYAN
1695057	ULTRAVISION KM Flex LED UV YELLOW
1695058	ULTRAVISION KM Flex LED UV BLACK
1695059	ULTRAVISION KM Flex LED UV WHITE
1695056	ULTRAVISION KM Flex LED UV MAGENTA