

## **Classification of products for manual writing, drawing and painting as „article“ or „mixture“ - Contradictory statements in official guidance documents !**

EWIMA upholds its position from August 2007 (GE-03-2013, GE-08-2008, GE-10-2007):

**Writing instruments are considered as “articles”**  
(see attached technical information and table of products for details).

According to the European Regulation (EC) No.1907/2006 concerning “REACH”,

- Art. 3 (2) defines “**mixture**” as a mixture or solution composed of two or more substances.
- Art. 3 (3) defines “**article**” as an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

**The legal text neither classifies writing, painting or drawing instruments as “articles” nor as “mixtures”.**

In May 2008, the European Chemicals Agency (ECHA) published several guidance documents in order to give advice to the parties concerned to fulfil the REACH obligations. These have been revised and updated in the past years.

The interpretation whether “pens” should be regarded as “articles” or as “mixtures” is highly contradictory in several guidance documents (current version):

*Guidance on requirements for substances in articles*<sup>1</sup> – version 4.0 June 2017:

- A wax crayon consists of paraffin wax and pigments and is used for colouring and drawing on paper. As its shape/surface/design are not more relevant for the function of the crayon (to bring pigment to paper) than its chemical composition, it is to be regarded as a **mixture**. (p 22)
- The examples should be applied to guide decisions on similar borderline cases, e.g. writing materials would (in analogy with the printer cartridge) be considered as combinations of an article (functioning as a container) and a **substance/mixture**. (p 70)

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<sup>1</sup> <https://echa.europa.eu/guidance-documents/guidance-on-reach>

*Guidance on information requirements and chemical safety assessment<sup>2</sup>*

- Chapter R.15: “Consumer Exposure Assessment” – version 3.0 June 2016:

- Oral B: The substance is contained in an **article** and migrates to the surface. Licking and sucking (e.g. by children) may promote leaching of the substance from the article matrix. This option [...] is applicable for example when a substance migrates from a pen, cutlery or textiles. (p 27)
- Table R.15-8 AC13: Plastic articles, **Article Subcategory**: Plastic, small articles (ball pen, mobile phone) (p 56)

- Chapter R.16: “Environmental Exposure Assessment” – version 3.0 February 2016:

The release is controlled by the user of the **article** (e.g. release of ink from a pen) and therefore dependent on use frequency and use time per event. The release is constant over the time of use to ensure its function. (p 167)

It is clearly stated in the guidance documents that the text of the REACH regulation is the only authentic legal reference and that the information in the guidance documents does not constitute legal advice. The ECHA does not accept any liability with regard to the contents of the guidance documents.

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<sup>2</sup> <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

## Technical properties of writing, painting and drawing instruments for hand-operated / manual use

Writing, painting or drawing instruments are specifically designed and intended for hand-operated (manual) precise writing or colouring. Due to ergonomic human requirements, the specific shape of pens has been developed in the course of time and improved permanently.

All parts of a writing instrument are specifically designed purely functional to achieve a precisely defined and constant transfer of the writing media (e.g. ink) at a miniscule rate that essentially dries instantly. Every single part of a writing instrument (e.g. writing media, capillary reservoir/ink feeder, tip) has to fit in with others in a technical manner that assures the performance.

It would be mistakenly inadequate with respect to the complex function of all parts involved to consider writing, painting or drawing instruments simply as “containers” for the writing media.

It is possible to enlarge the size of a container without losing its function to contain, store or transport the ink.

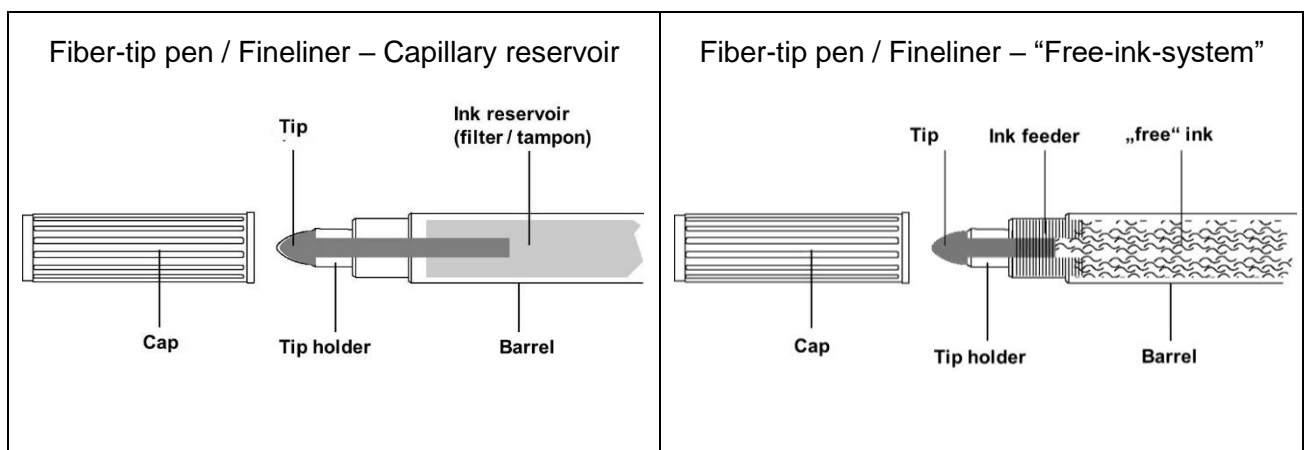
But the parts of a writing instrument incorporating the ink cannot be enlarged over a certain limit. A writing instrument will not function anymore for manual writing when the user cannot hold the writing instrument in his hand.

The function of writing instruments is determined primarily by the physical properties of the parts.

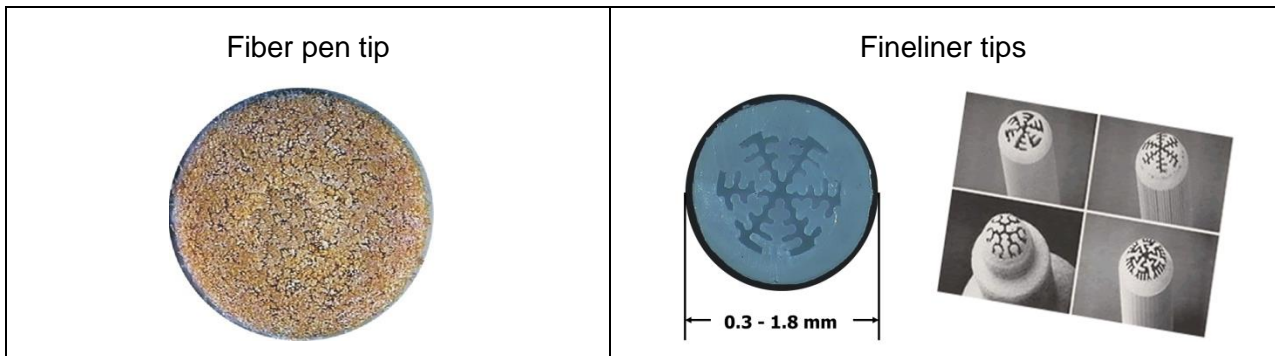
### Fiber-tip pens / fineliner and marking pens

The chemical composition influences the application of the ink, but not the function itself. When ink is dispensed, it becomes immediately incorporated with the substrate (e.g. paper, board) to become part of another article. There is never a time when the ink is used as a free chemical.

The transfer of ink from a fiber-tip pen for instance is closely related to capillary forces, increasing in a cascade from the capillary reservoir/ink reservoir to the tip and finally to paper or other suitable writing or painting carriers. Especially due to capillary forces, physically controlling the ink reservoir (filter/tampon), there is no release of ink if a pen is left cap-less in a horizontal or vertical position with the tip downwards.



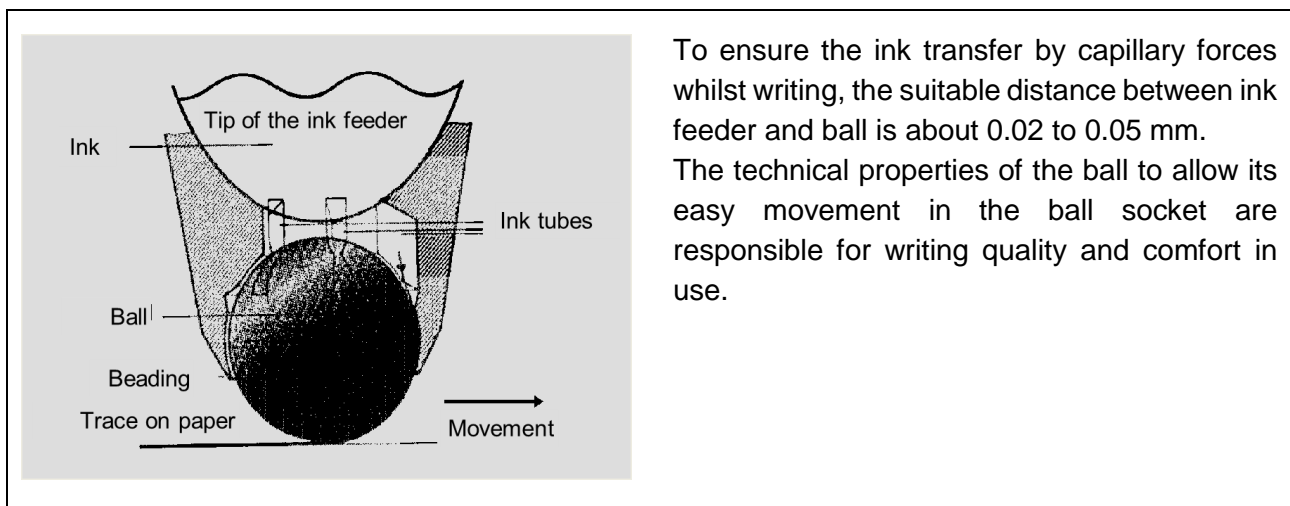
Writing instruments/marker pens designed without an ink reservoir use a complex ink feeder system combined with a tip to release a defined amount of ink on paper. A release of ink, e.g. by dropping or squirting or emitting to the environment does not take place.



Fiber-tip pens typically contain 1.5 to 2 ml ink (~ 20% of pen weight). This correlates with a writing length of about 500 m (trace on paper) and thus would lead to an **application of 4  $\mu\text{l}$  per meter**. Marking pens typically contain 5 ml ink (~ 20% of pen weight). This correlates with a writing length of about 500 m (trace on paper) and thus would result in an **application of 10  $\mu\text{l}$  per meter**.

### Ball point pens

A small movable ball at the tip of the refill provides the transfer of ink from a ball point pen. Due to the movement of the ball on the writing surface, ink is transferred to the paper.



There is no release of ink, if a pen is left in a horizontal or vertical position with the tip downwards. A release of ink, e.g. by dropping or squirting or emitting to the environment is not possible. Refills typically contain 250-1000 mg ink. This correlates with a writing length from 2000 m - 10 000 m and thus would lead to an application of 0.1 to 0.13 mg/m.

The amount of ink transferred whilst writing manually in a correct manner on paper is not comparable with the amount of ink/paint applicated with a brush from a bottle or a container. The release of ink from a writing instrument to a significant extent is only likely with massive destructive force, which eliminates the function of a product.

### **Solid materials intended to leave a precise trace**

Solid materials intended to leave a trace (e.g. wax crayons, pencils) need to have a specific shape and design to be hand-held for correct function. Therefore solid materials as such, e.g. in form of granules, flakes or powder would not allow correct writing, painting or sketching. The shape of the solid material influences the function of these writing instruments to a greater degree than the chemical composition.

We would like to mention that writing, drawing and painting instruments are considered as “articles” with intended release of substances under normal or reasonably foreseeable conditions of use (Art. 7, (EC) 1907/2006). In contrast, products as e.g. liquid paints, are considered as “mixtures”. Please find enclosed the table “Classification of products for writing, drawing and painting as „article“ or „mixture“.

Manufacturers of the European Union operate globally. In other countries (e.g. US), “articles” are defined in the respective dangerous chemicals law. For years, writing, drawing and painting instruments have been in general considered as articles. This has never been disputed. Additionally, articles are consequently in the scope of the general consumer product legislation. Manufacturers are obliged to carry out risk assessments dedicated to their products.

## Classification of products for manual writing, drawing and painting as „article“ or „mixture“ (as defined by the European regulation (EC) 1907/2006 - REACH)

According to Art. 3 (EC 1907/2006, the “REACH-Regulation”)

- “**mixture**” means a mixture or solution composed of two or more substances;
- “**article**” means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

	Definitely considered as „Article“		Definitely considered as „Mixture“
<b>Writing and drawing instruments</b>	Fiber-tip pens and fiber-tip refills (e.g. fineliner, marker, fiber-tip pens)	<b>Inks, paints</b>	Ink cartridges, ink in containers: Fountain pen ink cartridges, fountain pen ink in bottles Indian ink / China ink
	Ball-point pens and ball-point pen refills (e.g. ball-point pens, gel pens, roller ball pens)		Paint in bottles, containers, tubes, tins or tablets (e.g. finger paint, water colour, paint for use in play / didactical / creative / artistic use)
	Fountain pens		Modelling clay, modelling material, casting material for use in play / didactical / creative / artistic use
	Wood / Plastic cased pencils (e.g. black lead pencils, coloured pencils for use in play/ didactical / creative / artistic use), mechanical pencils and leads		
	Technical drawing instruments (e.g. technical pen)		
	Valve markers		
<b>Accessories</b>	Sharpener	<b>Accessories</b>	
	Eraser		
	Ruler, stencil		
	Compass		
	Correction tape		Correction fluid
	Glue tape		

This list does not claim to be exhaustive.