

PRODUKTINFORMATIONEN

DECLARATION OF COMPLIANCE

DETECTABLE RETRACTABLE PEN WITH CLIP	8800132-, 8800133-, 8800135-, 8800136-
DETECTABLE RETRACTABLE PEN WITHOUT CLIP.....	8800032-, 8800033-, 8800035-, 8800036-
DETECTABLE NO RETRACTABLE PEN WITH CLIP	8800102-, 8800103-, 8800105-, 8800106-
DETECTABLE NO RETRACTABLE PEN WITHOUT CLIP	8800002-, 8800003-, 8800005-, 8800006-
DETECTABLE RETRACTABLE PEN WITH CLIP	8800122-, 8800126-
DETECTABLE RETRACTABLE PEN WITHOUT CLIP.....	8800022-, 8800026-

REGULATIONS

We confirm that the above mentioned products fulfill the requirements on materials and articles used for food contact as described in the following rules:

- Regulation (EC) no. 1935/2004 on Materials and Articles intended to come into contact with food that cancels rules 80/590/CEE and 89/109/CEE.
- Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food
- Regulation (EU) 10/2011 on Plastic materials intended to come into contact with food including its later updates and Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011
- Regulation FDA 21 CFR 177.1520 about Olefin polymers with colorants and additives authorized for use in accordance with 178.3297 of this chapter

No recycled plastic is used in any product so Regulation (EC) n° 282/2008 on Materials on recycled plastic materials and articles intended to come into contact with foods is not applicable.

MATERIAL USED IN PEN BODY AND MECHANISM

As the information supplied by the manufacturer of the polypropylene homopolymer used in pen body and mechanism:

- All the substances used are included in the positive list of Regulation (EU) 10/2011 with the following restrictions:

MCA Substance no.	CEE ref.	CAS no.	Substance name	LME (mg/kg)
779	39815	0182121-12-6	9,9-Bis(metoximetil)fluorene	0,05
19	39090	-	N,N-Bis(2-hidroxietyl)alquil (C 8-C 18)amina	1,2
20	39120	-	Clorhidrat de N,N-bis(2-hidroxietyl)alquil(C 8-C 18)amine	1,2
433	68320	0002082-79-3	3-(3,5-Di-terc-butyl-4-hidroxifenil) octadecile propionate	6
409	62240	0001332-37-2	Iron oxide	48

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- The following substances also authorized as direct food additives (dual-use additives) are subject to restriction:

- a. Titanium dioxide (E 171)
- b. Iron oxide (E 172)
- c. Calcium salts of fatty acids (E 470a)
- d. Sorbitane monolaurate (E 493)

- The raw materials contain no Bisphenol A, nor nickel or nickel compounds intentionally added.

MIGRATION TESTS

The polypropylene homopolymer used in pen body and mechanism has been analyzed by AIMPLAS Instituto Tecnológico del Plástico Laboratory (accreditation ENAC nº 56/LE156) according to the specifications in Regulation 10/2011/EC with the following results:

Essay	Rule	Regulation	Simulant	Exposition condition	Limit ⁽¹⁾ (mg/dm ²)	Mean value ⁽²⁾ (mg/dm ²)	Conclusion
Global migration	UNE-EN 1186-1 UNE-EN 1186-3	10/2011	Simulant A (Ethanol 10%)	OM2(3)	10	<1,4	OK
Global migration	UNE-EN 1186-1 UNE-EN 1186-3	10/2011	Simulant B (Acid acetic 3%)	OM2(3)	10	<1,4	OK
Global migration	UNE-EN 1186-1 UNE-EN 1186-2	10/2011	Simulant D2 (vegetable oil)	OM2(3)	10	-(5)	-(5)
Global migration	UNE-EN 1186-1 UNE-EN 1186-14	10/2011	D2 alternative (Ethanol 95% ⁽⁶⁾)	OM2(3)	10	<1,4	OK
Global migration	UNE-EN 1186-1 UNE-EN 1186-14	10/2011	D2 alternative (Iso-octane ⁽⁶⁾)	OM2(4)	10	1,7 U=±0,7	OK

(1) According to Regulation 10/2011 on Plastic materials intended to come into contact with food the threshold limit of global migration is 10 mg/ dm²

(2) The ration of food contact surface are to volume used on essays to establish the compliance of the sample is 10 mg/ dm²

(3) Standard testing conditions for any long term storage at room temperature or below, including heating up to 70°C for up to 2 hours or heating up to 100 °C for up to 15 minutes (OM2)

(4) Equivalent conditions to migration into vegetable oil at 40°C for 10 days.

(5) It has been no possible to obtain valid results for this test due to the presence of interferences in the sample that prevents from performing a correct quantification of the absorbed oil.

(6) The determination of global migration in fat simulant has been made using alternative stimulants to fat: ethanol 95% and iso-octane

CONCLUSION: The results of the global migration tests are complying with the migration limits laid down by current legislation.

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PEN REFILLS

As per the information supplied by the refills manufacturer:

- All the raw materials used in the refills accomplish with Regulation (CE) 1907/2006 (REACH Regulation)
- All the raw materials used in the refills accomplish with Regulation EC (1272/2008) on classification, labeling and packaging of substances and mixtures
- No substances of very high concern (SVHC) are present in the materials
- TSCA: all chemical substances are listed in TSCA inventory of positive substances
- All raw materials are not listed in the California Proposition 65 regulation
- Refills comply with either ISO 12757-1 (Ball point pens and refills - Part 1: General use) or ISO 12757-2 (Ball point pens and refills – Part 2: Documentary use)

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