

## Biocompatibility and Safe drinking water

## 1. Biocompatibility

ARPRO Black meets biocompatibility requirements for contact with intact skin according to ISO 10993-1. This standard defines the biological evaluation and testing of medical devices within a risk management process.

**Test method:** The evaluations are conducted by different test methods described in the parts 5 and 10 of the ISO 10993 standard. Before testing, the specimens are sterilised at 121°C.

Tested density: ARPRO Black at 50g/l

Property	Test method	Result
Cytotoxicity		ARPRO is considered non-cytotoxic.
	ISO 10993-05	The extracts of moulded ARPRO caused no
		toxicological / biological critical cell damage or
		growth inhibition.
Skin irritation		ARPRO is considered non-irritant.
	ISO 10993-10	The extracts of moulded ARPRO caused no
		skin irritation.
		Primary Irritation Index recorded at 0, the
		lowest level.
Skin sensitisation	ISO 10993-10	ARPRO is non-sensitising.
		No sensitising effects could be detected.

## 2. Safe drinking water

ARPRO Black meets safe drinking water standards requirements for UK, France and Germany.

Tested density: ARPRO Black at 70g/l

Country	Test method	Result
UK	BS 6920 Suitability of non-metallic products for use in contact with water intended for human consumption	ARPRO has satisfied the criteria set out in BS 6920: Part 1 from 2014 "Specification" and is suitable for use with cold water (23°C) and hot water (85°C).
France	XP P 41-250-1/2/3 and NFP 41-290	ARPRO meets the requirements described in the DGS/VS n°99-217 from the 12 <sup>th</sup> of April 1999.
Germany	KTW guideline	ARPRO is fitting for pipes with DN < 80mm in contact with cold (23°C) and hot (85°C) water.

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