

	<b>Technical Information</b>	<b>730-134-EN</b>		<b>V08</b>
	<b>Safety Datasheet for GKE PCDs not necessary</b>	Created	01.06.2015	DaK
		Changed	06.05.2021	KP
		Checked	06.05.2021	UK
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<b>File no.: 0.2</b>				

## Compact-PCD, Helix-PCD, Testsets, Bio-Compact-PCD and Hollow-Flow-PCD

### Article numbers:

200-013, 200-016, 200-017, 200-020, 200-021, 200-024, 200-025, 200-026, 200-027, 200-028, 200-029, 200-030, 200-050, 200-071, 200-075, 200-081, 200-091, 200-100, 200-150, 200-153, 200-154, 200-205, 200-210, 200-211, 200-212, 200-213, 200-214, 200-215, 200-216, 200-217, 200-218, 200-219, 200-220, 200-302, 200-303, 200-304, 200-305, 200-325, 200-350, 200-425, 200-450, 200-452, 200-475, 200-510, 200-525, 200-550, 200-575, 211-121, 211-131, 211-141, 211-151, 300-031, 300-032, 300-033, 300-034, 300-035, 300-036, 300-037, 300-038, 300-039, 300-040, 300-041, 300-042, 300-028, 800-111

GKE produces and distributes Process Challenge Devices (PCD) to be used with chemical and biological indicators to monitor cleaning and sterilization processes.

According to article 31 of regulation (EG) No. 1907/2006 of the European Parliament and Council of December, 18th, 2006 to register, rating, admission and restriction chemical fabric ("REACH") suppliers of chemical substances or mixtures have to provide a safety data sheet according to attachment II of the above mentioned regulation to recipient under certain conditions.

Article 3 ("REACH") distinguishes between "substances", "mixtures" and "products".

The function of GKE PCDs is highly determined by their specific shape, material strength, surface and area distribution during production. Therefore, GKE PCDs are "products" according to "REACH" and a safety datasheet (MSDS) is – in contrast to "substances" and "mixtures" – not required for GKE PCDs.

Manufactured products with one very special exception do not require classification, marking and packaging of substances and mixtures according to regulation EG 1272/2008.

A release of harmful substances is not to be expected.

The use of GKE chemical and biological indicators in daily routine is harmless.