

REACH REGULATION

R 0007 EN

Instructions on the Safe Handling of Pressure Compensation Elements (Diaphragms in Housings) Included in Pressure Gauges According to the REACH Regulation 1907/2006 ¹⁾ and Related Requirements ²⁾

SAMSON products affected: Types 3708, 3730, 3793, 4708 and 6116 as well as other products

At the end of December 2020, SAMSON changed the materials of corresponding pressure compensation elements installed in pressure gauges. Remaining stocks will be sold off until the end of 2022 observing the legal requirements that apply to various countries and the intended purpose.

SAMSON has also stopped using these pressure compensation elements in pre-series products. In this case, alternative materials are also already used.

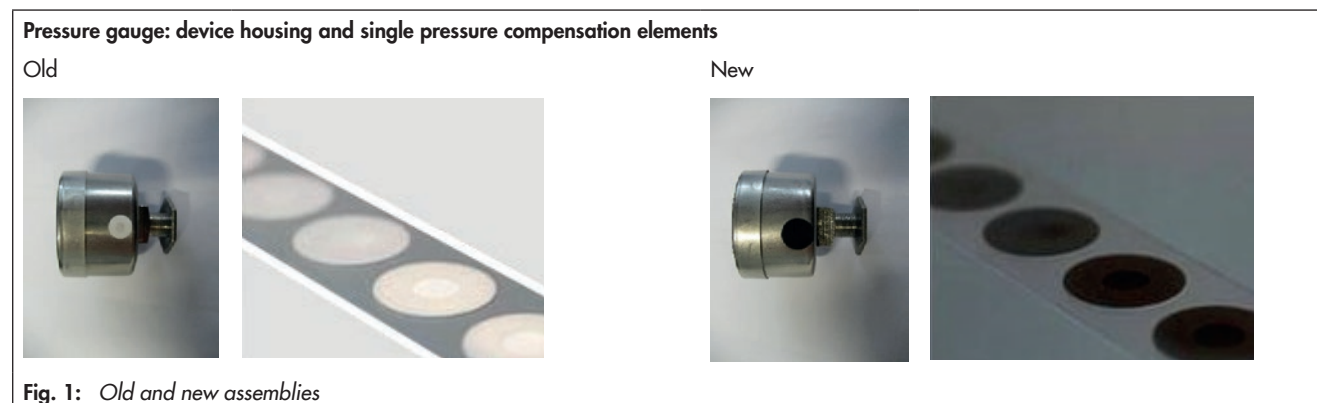


Table 1: SAMSON products and articles affected

No.	SAMSON type	Designation of SAMSON articles affected			
1	3708, 4708	0089-0026	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	Without inscription
2	3730, 3793	0080-0194	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	Supply
3	3730, 3793	0080-0195	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	Output
4	3708, 4708	0089-0025	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	Stainless steel, without inscription
5	3730, 3793	0080-0197	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	Stainless steel, supply
6	3730, 3793	0080-0198	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	Stainless steel, output
7	3730, 3793	0080-0199	Pressure gauge with borehole and pressure compensation element	0 to 6 kg/cm ²	Output
8	3730, 3793	0080-0200	Pressure gauge with borehole and pressure compensation element	0 to 6 kg/cm ²	Supply
9	3730	0080-0193	Pressure gauge with borehole and pressure compensation element	Input signal 0 to 1.2 bar	Overload protection acc. to 1.6 bar
10	3730	0080-0196	Pressure gauge with borehole and pressure compensation element	Input signal 0 to 1.2 bar	Stainless steel, overload protection acc. to 1.6 bar
11	6116	0080-0201	Pressure gauge with borehole and pressure compensation element	0 to 1.2 bar	
12	3793	0080-0209	Pressure gauge with borehole and pressure compensation element	0 to 10 bar	
13	6116	0080-0205	Pressure gauge with borehole and pressure compensation element	0 to 6 bar	

14	Various	8504-1000	Pressure compensation element Ø 7.5 mm/3 mm	Vent plug	Single part (pressure compensation element)
15	Various	8504-1008	Pressure compensation element 10/4, self-adhesive	Vent plug	Single part (pressure compensation element)

1 Legal requirements concerning perfluorooctanoic acid (PFOA)

The pressure compensation elements (diaphragm) concerned are individual articles and part of the pressure gauges. The pressure compensation elements (diaphragm) concerned are individual articles and part of the pressure gauges. The articles contain PFOA. The use of this substance is significantly restricted by law.

Table 2: Legal climate-protection requirements to control persistent organic pollutants (POPs)

Relevant legal requirements	Applies to PFOA?
POPs Regulation 2019/1021, Annex I, Part A as the EU implementation of the Stockholm Convention on persistent organic pollutants (POPs) and the Paris Agreement on climate change (2016)	Yes
REACH Regulation 1907/2006: restriction of PFOA so far applicable according to Annex XVII, entry 68, ▶ https://echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0de793f6643c In conjunction with the control of hazardous substances according to CLP 1272/2008 as the EU implementation of the United Nations Globally Harmonized System (UN GHS): for this purpose, SAMSON AG provides information to customers and recycling companies on its website ▶ https://www.samsongroup.com/en/about-samson/material-compliance/reach-regulation/	Yes
Specifications in accordance to Article 33 of the REACH Regulation (candidate list), threshold of >0.1 % (w/w) after which a substance is registered	No
Waste electrical and electronic equipment WEEE 2012/19/EU, Article 15: this document is used by SAMSON to provide information to interested recycling companies within and outside the European Economic Area (EEA; both EU and EFTA)	Yes

1.1 Foundation for calculation: list of individual articles

Following the judgment by the Court of Justice of the European Union concerning case C-106/14 of 16 October 2015, "Once an article, always an article" (O5A), we calculate the substance on the entire diaphragm with adhesive area (pressure compensation elements as commercial goods, i.e. individual articles).

Pressure compensation element (several film layers)

As a previously isolated article, the diaphragm contains the following substance in multi-layer composite (made up of several materials). This applies to the diaphragm layers with the following (pure) chemical substance:

- Diaphragm (finished article)
- Diaphragm layer that was a previously isolated article

Chemical substance: PFOA (perfluorooctanoic acid), CAS no. 335-67-1, in average concentrations of >25 ppb <50000 ppb, corresponding to >0.025 mg/kg <50 mg/kg or >0.0000025 % <0.0050 % specified as % (w/w)

2 Legislation

2.1 POPs Regulation

Table 3: Permissible use (exemption) of PFOA according to the POPs Regulation


Substance	CAS no.	EC no.	Specific exemption on intermediate use or other specification
Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds "Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds" includes: i. Perfluorooctanoic acid, including any of its branched isomers ii. Its salts; iii. PFOA-related compounds which, for the purposes of the Convention, are any substances that degrade to PFOA, including any substances (including salts and polymers) having a linear or branched perfluoroheptyl group with the moiety (C7F15)C as one of the structural elements	335-67-1 and others	206-397-9 and others	<ol style="list-style-type: none"> 1. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of PFOA or any of its salts equal to or below 0.025 mg/kg (0.0000025 % by weight) where they are present in substances, mixtures or articles. 2. For the purposes of this entry, point (b) of Article 4(1) shall apply to concentrations of any individual PFOA-related compound or a combination of PFOA-related compounds equal to or below 1 mg/kg (0.0001 % by weight) where they are present in substances, mixtures or articles. 3. (...) 4. (...) 5. (Exemptions) (...) 6. (exemptions for fire-fighting foam) (...) 7. (exemptions for the production of pharmaceutical products) (...) 8. Use of articles already in use in the Union before 4 July 2020 containing PFOA, its salts and/or PFOA-related compounds shall be allowed. Article 4(2), third and fourth subparagraphs shall apply in relation to such articles. 9. (Further exemptions) (...)
More detailed information: EN: ► https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020R0784&from=EN			

2.2 California Proposition 65³⁾

Table 4: Information about PFOA

Chemical	Application	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day) ⁴⁾
PFOA, Perfluorooctanoic acid Pentadecafluoro octanoic acid	Synthetic chemical used to make products resistant to stains, grease, soil and water.	developmental <ul style="list-style-type: none"> • low infant birth weights, • effects on the immune system, • cancer (for PFOA) 	► AB	335-67-1	November 10, 2017	–
Source: ► https://oehha.ca.gov/media/downloads/crn/noilpfoapfos.pdf						

The following applies to State of California:



Warning. This product can expose you to chemicals including Perfluorooctanoic acid (PFOA), CAS 335-67-1, which is known to the State of California to cause birth defects or cancer. For more information go to www.p65Warnings.ca.gov

Warnings on the product:

From SAMSON's point of view, the following applies if the NSRL or MADL values (µg/day) are exceeded (the two values are not specified). See Table 4:

- The diaphragms (pressure compensation elements) are made of solid, dried and hardened materials. Consequently, PFOA is specified as a contaminant and the information for the worst case at the time of manufacture of the materials is given.
- SAMSON provides details of exposure through residue in the product (contaminants) for cases involving servicing, repair or recycling.

3 Information on safe handling

The diaphragms (pressure compensation elements in film form) are already installed in the devices delivered by SAMSON or are supplied as spare parts to replace defective diaphragms. The substance is contained in the plastic of the diaphragm. As a result, any direct contact with the substance can be ruled out under normal, foreseeable conditions and when used as intended. A release of the substance is very unlikely to occur.

Pressure compensation elements are used in machinery and equipment to manufacture the following products:

- Medical devices and pharmaceuticals
 - Foodstuffs, food additives, aromas or flavors used in foodstuffs
 - Substances, mixtures or products that may later make extensive contact with skin or mucous membranes over extended periods of time
- Avoid the pressure compensation elements coming into direct contact with the above listed products.
- Immediately replace damaged pressure compensation elements.
- To prevent contact with the film and ensure the safe handling of the article, observe the following instructions on safe use (see section 3.1 to section 3.3).

3.1 Personal safety measures

- During mounting and removal, it is sufficient to use a pair of tweezers or a similar tool to handle the pressure compensation elements.
 - Avoid direct skin contact.
- Wearing gloves is impractical since the adhesive surfaces on the pressure compensation elements may stick to the gloves.
- Diaphragms must be replaced by properly trained and instructed staff only.
 - Make sure that these instructions are available to the staff before replacing any diaphragms.
 - Do not machine or heat up diaphragms before use.
 - Mount the diaphragm as specified in the applicable instructions.

3.2 Occupational health and safety measures

The occupational health and safety measures apply to substances listed in Table 3. If viewed as an individual substance, i.e. if it is not incorporated into materials, the substance type is classified according to Regulation 2019/1021 and Regulation 1272/2008 (CLP; ► <http://gestis.itrust.de>) as follows:

Perfluorooctanoic acid and its inorganic salts

Substances with carcinogenic properties; their genotoxic effects play no or only a minor role. If the levels do not exceed a MAK value available for the substance, the substance is not expected to significantly contribute to the cancer risk of humans.

- Pregnancy risk group B

According to currently available information, damage to the embryo or foetus cannot be excluded after exposure to concentrations at the level of the MAK and BAT values. Provided the Commission's assessment of the data makes it possible, the documentation indicates which concentration would correspond to the classification in pregnancy risk group C. Substances noted as such have the footnote "prerequisite for Group C, see documentation" in the list of MAK and BAT values.

Recommendations of the MAK commission (the information is merely a scientific recommendation and not applicable legislation):

- 0.005 mg/m³ measured as inhalable fraction
- Peak limitation: excursion factor 8
- Duration 15 min, mean; 4 times per shift, interval 1 h
- Category II: substances with systemic effects
- Risk of skin adsorption
- Carcinogenicity: category 4

Source: GESTIS databasis, perfluorooctanoic acid

3.3 Environmental protection measures

As a previously isolated article, the diaphragm contains the following substance in multi-layer composite (made up of several materials): PFOA, perfluorooctanoic acid, CAS no. 335-67-1, in average concentrations of **>0.025 mg/kg <50 mg/kg**

Annex IV does not specify any quantity threshold for PFOA. Therefore, SAMSON uses the value of **50 mg/kg** applicable for the related substance group PFOS:

Substance	CAS no.	EC no.	Concentration limit according to Article 7 4(a)
Perfluorooctanesulfonic acid and its derivatives (PFOS) C ₈ F ₁₇ SO ₂ X (X = OH, metal salt (O-M ⁺), halide, amide, and other derivatives including polymers)	1763-23-1, 2795-39-3, 29457-72-5, 29081-56-9, 70225-14-8, 56773-42-3, 251099-16-8, 4151-50-2, 31506-32-8, 1691-99-2, 24448-09-7, 307-35-7 and others	217-179-8, 220-527-1, 249-644-6, 249-415-0, 274-460-8, 260-375-3, 223-980-3, 250-665-8, 216-887-4, 246-262-1, 206-200-6 and others	50 mg/kg

3.4 Waste disposal measures

- ➔ Dispose of devices with pressure compensation elements through an appropriate waste disposal company for incineration plants suitable for this purpose (according to Article 7 of the POPs Regulation 2019/1021).
 - The articles are only classified as hazardous waste due to the listed ingredients if the quantity thresholds listed in Annex IV are exceeded.
Our suppliers have confirmed in writing that the values for the pressure compensation elements are below the quantity thresholds.

4 Manufacturer address

SAMSON will keep you updated on all modifications concerning restrictions, requirements or other rules and regulations in connection with the substance.

Go to the REACH page on our website:

▶ <https://www.samsongroup.com/en/about-samson/material-compliance/reach-regulation/>

In cases of doubt, contact: ▶ request-compliance-de@samsongroup.com

- 1) REACH regulation: Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
- 2) After 4 January 2021, articles that contain PFOA must not be imported into the EU anymore according to the POPs Regulation 2019/1021. Source: ► <https://echa.europa.eu/documents/10162/7a04b630-e00a-a9c5-bc85-0de793f6643c> according to REACH Annex XVII (Restricted use), see page 26, paragraph b):

6. Point 2(c) shall not apply to:
(a) articles placed on the market before 4 July 2020

Placing on the market (i.e. goods sold for the first time in the EU) Point 2(c) describes articles (i.e. concentrations and weight are clearly determinable and are more important than the chemical composition):

Article 3: New legal requirements effective as of 4 July 2020

Article 4: Exemptions from control measures

Use of articles already in use in the Union before 4 July 2020 containing PFOA, its salts and/or PFOA-related compounds shall be allowed.

Article 4(2), third and fourth subparagraphs shall apply in relation to such articles.

Source: ► <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02019R1021-20200704&qid=1598445117842>

- 3) CHAPTER 6.6. Safe Drinking Water and Toxic Enforcement Act of 1986 [25249.5 - 25249.14].
- 4) Calculation of the MADLs

The NOEL is the highest dose level which results in no observable reproductive effect, expressed in milligrams of chemical per kilogram of bodyweight per day (22 CCR 12803(a)(1)). The NOEL is converted to a milligram per day dose level by multiplying the assumed human body weight by the NOEL (22 CCR 12803(b)). For developmental toxicity, the assumed body weight is 58 kg.

Source: ► <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/nmpmadl31403.pdf>