REACH REGULATION

R 0002 EN

Instructions on the Safe Handling of SAMSON Diaphragms According to the REACH Regulation 1907/2006 [1)]

The diaphragms, as articles according to Article 33 of the REACH Regulation, contain the following (pure) chemical substance:

1-methyl-2-pyrrolidone (NMP) in average concentrations of <0.46 %

- CAS no.: 872-50-4
- EINECS no.: 212-828-1

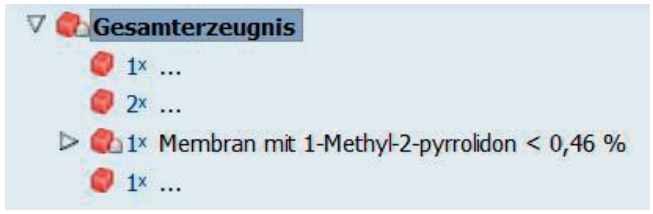

Fig. 1: *Overall structure*

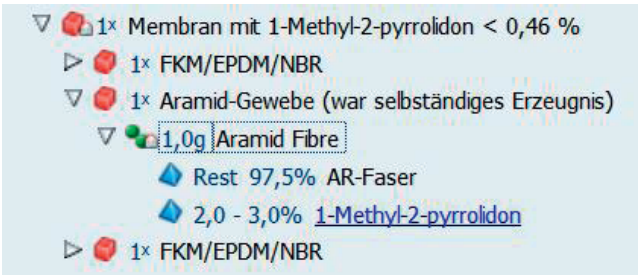

Fig. 2: *Diaphragm (article)*

Source: CDX System, Compliance Data Exchange, www.cdxsystem.com
Note: The weights vary depending on the version. Therefore, they are not listed above.

1 Note concerning Annex XVII of REACH: Restrictions

SAMSON AKTIENGESELLSCHAFT is working intensively on reducing the NMP concentrations in the affected articles and looking for materials to replace them.

The current version of the REACH annex (Entry 71) specifies the following for NMP:

1. Shall not be placed on the market as a substance on its own or in mixtures in a concentration equal to or greater than 0.3 % after 9 May 2020 unless manufacturers, importers and downstream users have included in the relevant chemical safety reports and safety data sheets, Derived No-Effect Levels (DNELs) relating to exposure of workers of 14.4 mg/m³ for exposure by inhalation and 4.8 mg/kg/day for dermal exposure.
2. Shall not be manufactured, or used, as a substance on its own or in mixtures in a concentration equal to or greater than 0.3 % after 9 May 2020 unless manufacturers and downstream users take the appropriate risk management measures and provide the appropriate operational conditions to ensure that exposure of workers is below the DNELs specified in paragraph 1.

2 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 fabric as follows:

Reinforcement fabric (aramid fibers)

As a previously isolated article, this fabric contains the following chemical substance:

1-methyl-2-pyrrolidone in average concentrations of ≤3 %

- CAS no.: 872-50-4
- EINECS no.: 212-828-1

If viewed as an individual substance, i.e. if it is not incorporated into materials, this substance is classified according to Regulation 1272/2008 (http://gestis.itrust.de) as follows:

- Irritation to the eyes, airways and skin
- Reproductive toxicity
  There is no reason to fear a risk of damage to the developing embryo or foetus when the MAK (max. concentration at the workplace) and BAT (biological tolerance at the workplace) values are observed.
  - 20 ml/m³
  - 82 mg/m³
  - Peak limitation: excursion factor 2
  - Duration 15 min, mean; 4 times per shift; interval 1 h
  - Category II: substances with systemic effects
  - BAT/German Biological Exposure Indices: parameters of 5-hydroxy-N-methyl-2-pyrrolidone
  - Limit: 150 mg/l

3 Information on safe handling

The diaphragms are already installed in the valves delivered by SAMSON or are supplied as spare parts to replace defective diaphragms. The substance is contained in the diaphragm's fabric. The largest portion of the diaphragm's fabric is covered by a rubber coating.

As a result, hardly any direct contact with the substance will occur under normal, foreseeable conditions and when used as intended. Nevertheless, contact with the fabric could occur when handling the diaphragm directly.

➔ To prevent contact with the fabric and ensure the safe handling of the article, observe the following instructions on safe use (see section 4 to section 6).

4 Personal safety measures

➔ Wear suitable protective gloves when mounting or removing the diaphragm.

Suitable protective gloves made of butyl rubber, butyl (0.5 mm, permeation breakthrough time ≥ 8 hours).

The following materials are **not suitable** due to degradation, severe swelling or low permeation breakthrough time:

- Natural rubber (NR), natural latex
- Polychloroprene (CR)
- Nitrile rubber (NBR), nitrile latex
- Fluorocarbon rubber (FKM)
- Polyvinyl chloride (PVC)

➔ Do not inhale any released dusts.

- General dust limit: 3 mg/m³ and 10 mg/m³
- Respiratory protection: FFP1 or FFP2 in case of dust formation

5 Environmental protection measures

➔ Use an extraction system if fiber dust is created during processing. Make sure the substance is not released into the sewage system.

➔ 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. Close the actuator housing afterwards.

6 Further instructions on handling the entire article (diaphragm)

Prevent the reinforcing fabric from getting into direct contact with the above listed products in cases where the diaphragms are used in machinery or systems to produce 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

➔ Immediately replace damaged diaphragms.

A layer of PTFE is additionally applied to the diaphragm in this case.

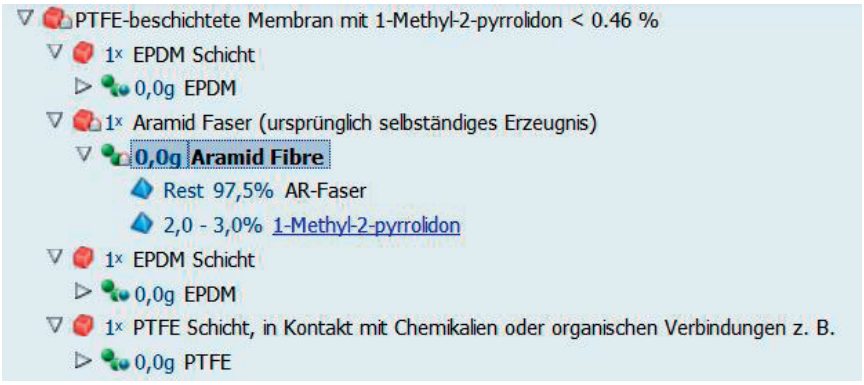

Fig. 3: *Special diaphragm design with PTFE layer (for pharmaceutical products, foodstuffs etc.)*

Source: CDX System, Compliance Data Exchange, www.cdxsystem.com
Note: The weights vary depending on the version. Therefore, they are not listed above.

7 Manufacturer address

➔ In cases of doubt, contact SAMSON's material compliance experts at: compliance@samson.de

➔ For up-to-date information: ▶ REACH pages on the SAMSON website.