

### Instructions on the Safe Handling of SAMSON Diaphragms According to the REACH Regulation 1907/2006 <sup>1)</sup>

#### Obligation to report and restriction

This document applies to certain diaphragms used in valves and pneumatic actuators.

Manufacturer information related to the REACH Regulation can be found on the SAMSON website at

► [www.samsongroup.com](http://www.samsongroup.com) > About SAMSON > Material Compliance > REACH.

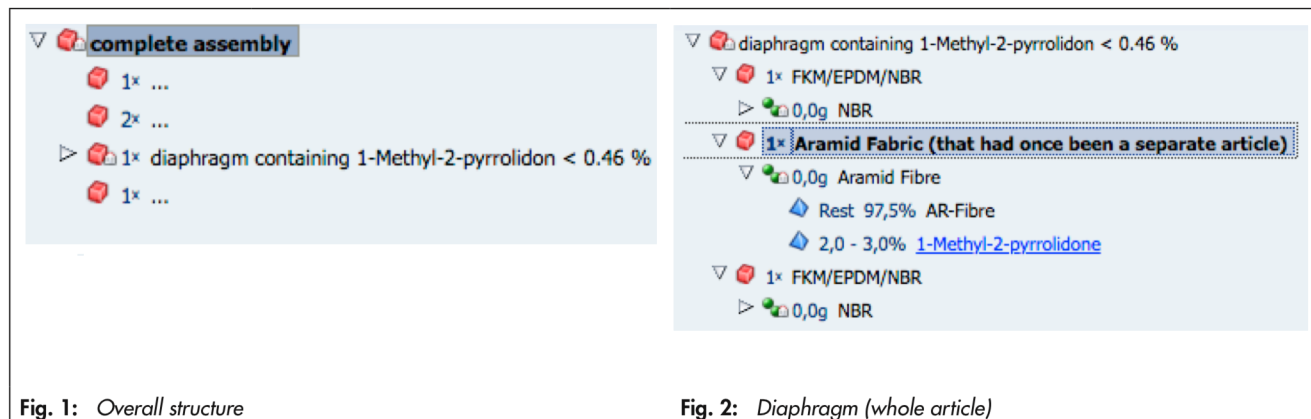
The diaphragms, as articles according to Article 33 of the REACH Regulation, contain aramid fibers as an isolated article with the following (pure) chemical substance:

#### Diaphragm (finished article)

- With the following chemical substance: NMP, 1-methyl-2-pyrrolidone (CAS no. 872-50-4, EINECS no. 212-828-1) in average concentrations of >0.1 % w/w, depending on the size of the diaphragm  $\geq 0.3$  % (Fig. 2)

#### As a previously isolated article, the reinforcing fabric (aramid fibers) contains the following chemical substance:

- NMP, 1-methyl-2-pyrrolidone (CAS no. 872-50-4, EINECS no. 212-828-1) in average concentrations of  $\geq 2.0$  % and  $\leq 3.0$  % w/w.



Source:

CDX System, Compliance Data Exchange, [www.cdssystem.com](http://www.cdssystem.com)

Note:

The weights vary depending on the version. Therefore, they are not listed above.

Product overview:

► [www.samsongroup.com](http://www.samsongroup.com) > About SAMSON > Material Compliance > REACH (sorted by diaphragm size)

<sup>1)</sup> 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 (source: ► [https://www.reach-clp-biozid-helpdesk.de/DE/Home/Home-English\\_node.html](https://www.reach-clp-biozid-helpdesk.de/DE/Home/Home-English_node.html))

## 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/m<sup>3</sup> 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:

### Reinforcing fabric (aramid fibers)

As a previously isolated article, the reinforcing fabric that we use contains the following chemical substance: NMP, 1-methyl-2-pyrrolidone in average concentrations of >2 % and ≤3 %

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

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. If viewed as an individual substance, i.e. if it is not incorporated into materials, this substance is classified according to Regulation 1272/2008 (source: ► <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/m<sup>3</sup>
  - 82 mg/m<sup>3</sup>
  - 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.

#### 3.1 Occupational health and safety

→ 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).

Information below: as of 3 March 2020

##### EU occupational exposure limits (EU OEL) according to Directive 2009/161/EU

Indicative occupational exposure limit value of the European Union:

A national indicative occupational exposure limit must be established.

- Eight-hour time-weighted average (TWA): 40 mg/m<sup>3</sup> (10 ppm)
- Short-term exposure limit (STEL): 80 mg/m<sup>3</sup> (20 ppm)

##### REACH Regulation 1907/2006

The substance is included in the REACH candidate list as a substance of very high concern.

##### Recommendations of the MAK commission

The information is merely a scientific recommendation and not applicable legislation.

- 20 ml/m<sup>3</sup>
- 82 mg/m<sup>3</sup>
- Peak limitation: excursion factor 2
- Duration 15 min, mean; 4 times per shift; interval 1 h
- Category I: Substances for which local irritant effects determine the exposure limit value, also respiratory allergens
- Risk of skin adsorption
- Pregnancy risk group C

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.

- N-methyl-2-pyrrolidone (vapor)

The substance can be present in the air both as vapor and aerosol simultaneously.

##### Biological limits (BGW)

- Parameter: 5-hydroxy-N-methyl-2-pyrrolidone
- Limit: 150 mg/l
- Material: Urine
- Sampling: End of exposure or shift

## 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  $\geq 8$  hours) or nitrile butadiene rubber (NBR). Recommended material thickness:  $\geq 0.38$  mm, min. permeation breakthrough time:  $\geq 480$  min.  
The following materials are not suitable due to degradation, severe swelling or low permeation breakthrough time:
  - Natural rubber (NR), natural latex
  - Polychloroprene (CR)
  - Nitrile butadiene rubber (NBR), material thickness:  $< 0.38$  mm, min. permeation breakthrough time:  $< 480$  min.
  - Nitrile/latex, material thickness:  $< 0.38$  mm, min. permeation breakthrough time:  $< 480$  min.
  - Fluorocarbon rubber (FKM)
  - Polyvinyl chloride (PVC)
- Do not inhale any released dusts.
  - General dust limit:  $3 \text{ mg/m}^3$  and  $10 \text{ mg/m}^3$
  - 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 valve body or actuator housing afterwards.

## 6 Further instructions on handling the whole article (diaphragm)

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

Prevent the reinforcing fabric from getting into direct contact with the above listed products.

- Immediately replace damaged diaphragms.

## 7 Manufacturer address

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

- For up-to-date information: ► REACH pages on the SAMSON website.
- In cases of doubt, contact SAMSON's material compliance experts at the e-mail address: [compliance@samson.de](mailto:compliance@samson.de)