baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

# SUBSTANCE EVALUATION CONCLUSION

# as required by REACH Article 48

# and

# EVALUATION REPORT

**for**

# trade name: WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ

**Evaluating Member State:** Germany

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# Evaluating Member State Competent Authority

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## Year of evaluation in CoRAP: 2017

Member State concluded the evaluation without any further need to ask more information from the registrants under Article 46(1) decision.

**Further information on registered substances here:**

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

# Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

# Contents

# Part A. Conclusion

## 1. CONCERN(S) SUBJECT TO EVALUATION

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ was originally selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/vPvB
- Exposure of environment

During the evaluation also other concern was identified. The additional concern was:

- High mobility

## 2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

There are no other processes known.

## 3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

**Table 1**

| CONCLUSION OF SUBSTANCE EVALUATION<br><br>Conclusions | Tick box |
|---|---|
| Need for follow-up regulatory action at EU level | |
| Harmonised Classification and Labelling | |
| Identification as SVHC (authorisation) | |
| Restrictions | |
| Other EU-wide measures | |
| No need for regulatory follow-up action at EU level | x |

# FOLLOW-UP AT EU LEVEL

## 3.1. Need for follow-up regulatory action at EU level

### 3.1.1. Harmonised Classification and Labelling

On the basis of the available information, there is currently no need for follow-up regulatory actions at EU level (see section 5).

### 3.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

On the basis of the available information, there is currently no need for follow-up regulatory actions at EU level (see section 5).

### 3.1.3. Restriction

On the basis of the available information, there is currently no need for follow-up regulatory actions at EU level (see section 5).

### 3.1.4. Other EU-wide regulatory risk management measures

On the basis of the available information, there is currently no need for follow-up regulatory actions at EU level (see section 5).

# 4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

No need for regulatory follow-up at EU level.

**Table 2**

| REASON FOR REMOVED CONCERN<br><br>The concern could be removed because | Tick box |
|---|---|
| Clarification of emission/exposure. | x |
| Actions by the registrants to ensure safety, as reflected in the registration dossiers(e.g. change in supported uses, applied risk management measures, etc. ) | |

There is currently no need for follow-up action at EU level with respect to the environment and the evaluated concern. This is due to the low probability of environmental releases from the currently registered use of the substance. WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is used as an isolated transported intermediate for the manufacture of another substance in a closed system. Handling of the substance by the registrant ensures that exposure to the environment is not expected.

The substance possesses hazardous properties (it is persistent, potentially mobile and potentially toxic) and further information would have been necessary to clarify the concern. If new registrations or relevant uses became available, the substance should be included in the CoRAP again for a further assessment.

## 5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

Not applicable, see section 5.

# Part B. Substance evaluation

## 6. EVALUATION REPORT

### 6.1. Overview of the substance evaluation performed

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ was originally selected for substance evaluation in order to clarify concerns about:

- Suspected PBT/vPvB
- Exposure of environment

During the evaluation also other concern was identified. The additional concern was:

- High mobility

**Table 3**

| EVALUATED ENDPOINTS<br><br>**Endpoint evaluated** | **Outcome/conclusion** |
|---|---|
| Suspected PBT | Persistency is confirmed and bioaccumulation potential cannot be excluded.<br>Based on self-classification the T-criterion is expected to be fulfilled (STOT RE 1). The substance does not fulfil the T-criterion based on environmental toxicity. |
| Exposure of environment | Actions by the registrants are considered as important risk management measures by the eMSCA to ensure a low risk of environmental exposure.<br><br>No further action. |
| Mobility | The low adsorption potential of the substance indicates a high mobility in water and soil. |

Even if the substance has hazardous properties (persistent, mobile, potentially toxic), no futher action is needed due to negligible exposure to the environment.

## 6.2. Procedure

The substance evaluation started in March 2017.

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ was originally selected for substance evaluation in order to clarify concerns about its suspected PBT/vPvB and the potential exposure of the environment.

The evaluation was conducted by assessing the registration data and by performing an own literature search.

In June 2017 the eMSCA invited the registrant for an expert meeting in order to discuss the current state of the evaluation and on-going tasks. In the course of the discussion the registrants provided further information on uses and toxicity.

Moreover, the substance was discussed on the 16th Meeting of the PBT Expert Group.

## 6.3. Identity of the substance

The substance is a perfluoroalkoxycarboxylate salt. Its composition is claimed as confidential business information.

**Table 4**

| SUBSTANCE IDENTITY | |
|---|---|
| **Public name:** | WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ |
| **EC number:** | 444-340-1 |
| **CAS number:** | - |
| **Index number in Annex VI of the CLP Regulation:** | - |
| **Molecular formula:** | confidential |
| **Molecular weight range:** | confidential |
| **Synonyms:** | |

Type of substance X Mono-constituent ☐ Multi-constituent ☐ UVCB

**Structural formula: confidential**

## 6.4. Physico-chemical properties

The given physico-chemical properties are for the dried salt with a purity of 88%. However MV31-K-salt is sold as an aqueous solution for reason of stability.

Table *5*

| OVERVIEW OF PHYSICOCHEMICAL PROPERTIES | |
|---|---|
| **Property** | **Value** |
| Physical state at 20°C and 101.3 kPa | grey granular solid. |
| Vapour pressure | < -10E-06 hPa at 20 °C (no further infomation regarding the used method) |
| Water solubility | 345 g/L at 20°C (flask method) |
| Partition coefficient n-octanol/water (Log Kow) | log Pow is -0.78 (based on the equation: Pow = C (octanol)/C (water); where C(octanol) is the saturation concentration of test substance in n-octanol; C (water) is the saturation concentration in water. |
| Flammability | idem |
| Explosive properties | idem |
| Oxidising properties | idem |
| Granulometry | Not applicable – substance is sold as aqueous solution |
| Stability in organic solvents and identity of relevant degradation products | idem |
| Dissociation constant | idem |
| [enter other property, if relevant, or delete irrelevant rows] | idem |

## 6.5. Manufacture and uses

### 6.5.1. Quantities

**Table 6**

| AGGREGATED TONNAGE (PER YEAR) | | | | |
|---|---|---|---|---|
| ☐ 1 – 10 t | ☐ 10 – 100 t | ☐ 100 – 1000 t | ☐ 1000- 10,000 t | ☐ 10,000-50,000 t |
| ☐ 50,000 – 100,000 t | ☐ 100,000 – 500,000 t | ☐ 500,000 – 1000,000 t | ☐ > 1000,000 t | ☒ Confidential |

### 6.5.2. Overview of uses

**Table 7**

| USES | Use(s) |
|---|---|
| **Uses as intermediate** | Synthesis of MV31 from MV31-K-Salt<br>MV31-K salt is used as an isolated intermediate for the manufacture of MV31 (ERC 6a). The process categories covers use in closed process with no likelihood of exposure (PROC 1). Furthermore, the substance is transferred from/to vessels/large containers at dedicated facilities (PROC 8b). |
| **Formulation** | - |
| **Uses at industrial sites** | |
| **Uses by professional workers** | The substance is used as laboratory reagent (PROC 15) |
| **Consumer Uses** | - |
| **Article service life** | - |

## 6.6. Classification and Labelling

### 6.6.1. Harmonised Classification (Annex VI of CLP)

No entry in Annex VI of CLP Regulation available.

### 6.6.2. Self-classification

- In the registration(s):

- Acute Tox. 4 (H302)
- Acute Tox. 4 (H312)
- Skin Corr. 1B (H314)
- Acute Tox. 4 (H332)
- STOT SE 3 (H335) (respiratory tract)
- STOT RE 1 (H 372)

- The following hazard classes are in addition notified among the aggregated self-classifications in the C&L Inventory:

-

## 6.7. Environmental fate properties

### 6.7.1. Degradation

6.7.1.1. Abiotic degradation

6.7.1.1.1 Hydrolysis

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is hydrolytically stable at pH 4, 7 and 9.

Table 8: Summary of studies on hydrolysis

| Method | Results | Reliability | Reference |
|---|---|---|---|
| OECD Guideline 111 (Hydrolysis as a Function of pH) | Preliminary test (50°C)<br>% decomposition after 5 days:<br>pH 4: ≤ 0.3 %<br>pH 7: ≤ 0.64 %<br>pH 9: ≤ 0.66 %<br><br>half-life > 1 year | 2 (key study) | Registration dossier |
| No guideline followed | 20°C<br>% recoveries after 15 days: 91.0-105.0<br>pH value was not monitored | eMSCA: 3 (no guideline, pH-value not monitored)<br>Registrant: 2 (supporting study) | Registration dossier |

6.7.1.2.1 Phototransformation / photolysis

No relevant information available.

6.7.1.2. Biodegradation

Biodegradation of WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ was tested in one screening test. No simulation test is available. The substance is not readily biodegradable.

Table 9: Summary of screening tests

| Method | Results | Reliability | Reference |
|---|---|---|---|
| OECD Guideline 301 F (Ready Biodegradability: Manometric Respirometry Test)<br>Non-adapted inoculum | % degradation of test substance:<br><br>0 after 28 days ($O_2$ consumption)<br><br>Toxicity control: 56% degration in 14 days<br>Reference substance: 84% degradation by day 14 | 1 (key study) | Registration dossier |

In conclusion, WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is not readily biodegradable.

6.7.1.3 Summary and discussion on degradation

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is hydrolytically stable at pH 4, 7, and 9.

The substance is not readily biodegradable as shown by a screening test. No degradation was shown within 28 days.

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ belongs to the group of perfluoroether carboxylic acids. These substances are structurally similar to perfluoralkyl carboxylic acids (e.g. perfluorooctanoic acid), with an acidic functional group attached to a per- and

polyfluoroether chain instead of a perfluoroalkyl chain. Under environmentally relevant conditions perfluoroether chains are similarly resistant to abiotic (photolysis, reactions with OH radicals, and hydrolysis) and biotic degradation as the perfluoroalkyl chains (Wang et al., 2015).

## 6.7.2. Environmental distribution

The adsorption of WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ was determined according to OECD 121 guideline using the HPLC method. The log $K_{oc}$ was estimated to be 1.83 at 20°C (Registration dossier). The value indicates that the substance has a low adsorption potential to organic carbon in soil and sewage sludge.

## 6.7.3. Bioaccumulation

Since the structural formula is confidential, a detailed assessment of the bioaccumulation potential is presented in the confidential annex of this report. A bioaccumulation potential cannot be excluded. An OECD 305 study with carp on a structurally similar substance does not indicate a bioaccumulation potential in fish. However, bioconcentration values in gill breathing organisms may not be the most relevant endpoint to consider. In absence of data on the human clearance time for WÄSSRIGE LOESUNG des MV31-KALIUMSALZ it is however impossible to draw a definitive conclusion. See also chapter 7.11 on PBT and VPVB assessment

## 6.8. Environmental hazard assessment

### 6.8.1. Aquatic compartment (including sediment)

#### 6.8.1.1. Fish

Table 10: Summary of toxic effects on fish

| Method | Results | Reliabilty | Reference |
|---|---|---|---|
| OECD Guideline 203 (Fish, Acute Toxicity Test)<br>Danio rerio<br>Limit test | 96h-$LC_{50}$ > 100 mg/L (nominal) | 1 (key study) | Registration dossier |

#### 6.8.1.2. Aquatic invertebrates

Table 11: Summary of toxic effects on aquatic invertebrates

| Method | Results | Reliability | Reference |
|---|---|---|---|
| OECD Guideline 202 (Daphnia sp. Acute Immobilisation Test)<br>Static;<br>Limit test | 48h-$EC_{50}$ > 100 mg/L (mean meas., mobility) | eMSCA: 3 (no data on validity criteria, mortality in control not stated)<br><br>Registrant: 2 (key study) | Registration dossier |

#### 6.8.1.3. Algae and aquatic plants

Table 12: Summary of toxic effects on algae

| Method | Results | Reliability | Reference |
|---|---|---|---|
| OECD Guideline 201 (Alga, Growth Inhibition Test)<br>Static;<br>Limit test<br>*Desmodesmus subspicatus* | 72h-$EC_{50}$ > 100 mg/L (nominal, growth rate); 4% inhibition<br>72h-$EC_{50}$ > 100 mg/L (nominal, biomass); 14% inhibition | 1 (key study) | Registration dossier |

#### 6.8.1.4. Sediment organisms

No relevant information available.

#### 6.8.1.5. Other aquatic organisms

No relevant information available.

### 6.8.2. Terrestrial compartment

No relevant information available.

### 6.8.3. Microbiological activity in sewage treatment systems

Table 13: Summary of toxicity to microorganisms

| Method | Results | Reliabilty | Reference |
|---|---|---|---|
| OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test) static | 3h-$EC_{50}$ > 1000 mg/L (nominal) | 1 (key study) | Registration dossier |

### 6.8.4. PNEC derivation and other hazard conclusions

Not evaluated.

### 6.8.5. Conclusions for classification and labelling

The acute toxic effects for fish, daphnia and algae are all above 100 mg/L. No chronic aquatic toxicity data are available. Classification and labelling for aquatic environment is not justified.

## 6.9. Human Health hazard assessment

Not evaluated.

## 6.10. Assessment of endocrine disrupting (ED) properties

Not evaluated.

## 6.11. PBT and VPVB assessment

Persistence:

WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is hydrolytically stable and not readily biodegradable. No simulation test is available.

The substance belongs to the group of perfluoroether carboxylic acids. These substances are structurally similar to perfluoralkyl carboxylic acids (e.g. perfluorooctanoic acid), with an acidic functional group attached to a per- and polyfluoroether chain instead of a perfluoroalkyl chain. Under environmentally relevant conditions perfluoroether chains are similarly resistant to abiotic and biotic degradation as the perfluoroalkyl chains. Hence, WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is expected to be very persistent.

Bioaccumulation:

It cannot be concluded that the substance is not bioaccumulative. An OECD 305 study with carp on a structurally similar substance does not indicate a bioaccumulation potential in fish. However, bioconcentration values in gill breathing organisms may not be the most relevant endpoint to consider. As shown for PFOA there is a low bioaccumulation potential in fish but elevated levels of PFOA in human blood and a half life in humans of 2-4 years were observed. In absence of data on the human clearance time for WÄSSRIGE LOESUNG des MV31-KALIUMSALZ it is however impossible to draw a definitive conclusion. Observations with PFAAs show a chain length dependent binding to proteins. The substance may bind to proteins similarly. It may be potentially re-absorbed and may thus have a slower elimination half live and may accumulate in human blood.

Toxicity:

Only screening information is available. The short-term toxic effects are all above 100 mg/L. Hence, the screening threshold value of 0.1 mg/L is not fulfilled. The substance does not fulfil the T-criterion based on environmental toxicity.

Based on self-classification the T-criterion is expected to be fulfilled (STOT RE 1).

Mobility:

Based on the $K_{OC}$ value given in the registration dossier the substance has a low adsorption potential to organic carbon in soil and sewage sludge. The substance may thus reach groundwater which is used as a drinking water source.

Overall conclusion:

The PBT criteria of REACH Annex XIII are not fulfilled based on the currently available data. However, the substance is very persistent and it may be biaccumulative. Furthermore the substance is expected to be T based on self-classification as STOT RE 1. Additionally, WÄSSERIGE LOESUNG DES MV31-KALIUMSALZ is mobile in soil and water.

However, due to the low potential of environmental exposure of the substance, no further information is requested at this point to further clarify the hazard.

If new registrations or relevant uses became available, the substance should be included in the CoRAP again for a further assessment a clarification of the PBT concern.

## 6.12. Exposure assessment

### 6.12.1. Human health

Not evaluated.

### 6.12.2. Environment

Assessment of exposure was conducted based on information in the registration dossier and information provided by the registrant. Given the substance is used as an intermediate, no CSR was provided. However, the registrant provided a short description of risk management measures including information on technological processes and means of rigorous containment and minimisation technologies. In conclusion, handling of the substance by the registrant ensures that exposure to the environment is not expected for the uses mentioned in the registration dossier.

### 6.12.3. Combined exposure assessment

Not evaluated.

## 6.13. Risk characterisation

Not evaluated.

## 6.14. References

Wang Z., Cousins I.T., Scheringer M., and Hungerbuhler K. (2015): Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids (PFAAs) and their precursors: status quo, ongoing challenges and possible solution. Environment International 75, 172-179

## 6.15. Abbreviations

| | |
|---|---|
| BCF | bioconcentration factor |
| CSR | Chemical Safety Report |
| $EC_{50}$ | Half maximal effective concentration |
| EFSA | European Food Safety Authority |
| eMSCA | evaluating member state competent authority |
| $LC_{50}$ | Half maximal lethal concentration |
| NOEC | no observed effect concentration |
| PBT | persistent, bioaccumulative, toxic |
| PFAA | perfluoroalkyl acids |
| PFCA | perfluoroalkyl carboxylic acid/ perflouroalkyl carboxylates |
| PFSA | perfluoroalkyl sulfonic acid/ perfluoroalkyl sulfonates |
| PFOA | Perfluorooctanoic acid |
| SVHC | Substance of very high concern |
| vPvB | very persistent, very bioaccumulative |