

Substance Name: 1,4-dioxane

EC Number: 204-661-8

CAS Number: 123-91-1

MEMBER STATE COMMITTEE SUPPORT DOCUMENT  
FOR IDENTIFICATION OF

1,4-DIOXANE

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE  
OF ITS HAZARDOUS PROPERTIES WHICH CAUSE  
PROBABLE SERIOUS EFFECTS TO HUMAN HEALTH  
AND THE ENVIRONMENT WHICH GIVE RISE TO AN  
EQUIVALENT LEVEL OF CONCERN TO THOSE OF CMR<sup>1</sup>  
AND PBT/VPVB<sup>2</sup> SUBSTANCES (ARTICLE 57F)

Adopted on 17 June 2021

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<sup>1</sup> CMR means carcinogenic, mutagenic or toxic for reproduction

<sup>2</sup> PBT means persistent, bioaccumulative and toxic; vPvB means very persistent and very bioaccumulative

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### ABBREVIATIONS:

$C_{max}$	maximum concentration
CAKE	Computer Assisted Kinetic Evaluation
DOC	dissolved organic carbon
DFOP	Double first-order in parallel
$DT_{50}$	Half-live
DWT	drinking water treatment
FDW	finished drinking water
FOMC	First-order multi-compartment
GAC	granular activated carbon
HS	Hockey-Stick
$K_{OC}$	normalised organic carbon to water partition coefficient
LOD	limit of detection
LOQ	limit of quantification
LRTP	long range transport potential
$P_{ov}$	overall persistence
PWS	public water systems
SFO	Single first-order

STP	sewage treatment plant
TCA	1,1,1-trichloroethene
TCE	trichloroethylene
VHC	volatile chlorinated hydrocarbon

# IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: 1,4-dioxane

EC Number: 204-661-8

CAS number: 123-91-1

- The substance is identified as a substance meeting the criteria of Article 57 (a) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class carcinogenicity category 1B.
- The substance is identified as a substance of equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 (REACH) according to Article 57(f) of REACH Regulation.

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Carcinogenic - Article 57 (a)

1,4-Dioxane is covered by index number 603-024-00-5 of Regulation (EC) No 1272/2008. Pursuant to Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 1,4-dioxane will be classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer")<sup>3</sup>.

Therefore, this classification of the substance shows that it meets the criteria for classification in the hazard class:

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH

Equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 – Article 57(f)

1,4-Dioxane is identified as substance of very high concern according to Article 57(f) of regulation 1907/2006 (REACH) due to scientific evidence of probable serious effects to the environment and human health (man via environment). The scientific evidence gives rise to an equivalent level of concern to substances covered by Article 57 (a) to (e).

*Intrinsic properties*

Abiotic degradation of 1,4-dioxane by hydrolysis and phototransformation in air and water is regarded as negligible. Based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions. Degradation of

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<sup>3</sup> Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 17<sup>th</sup> ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation this new harmonised classification applies from 17 December 2022. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

1,4-dioxane was investigated in surface water according to OECD TG 309, showing no degradation of the substance. Therefore, the degradation half-life of 1,4-dioxane is obviously higher than 60 days. Considering the data on abiotic and biotic degradation, 1,4-dioxane is considered to fulfil the P/vP criteria (half-life in water >60 days) of REACH Annex XIII.

The substance is completely miscible with water (water solubility used for assessment = 1000 g/L) and has a log  $K_{oc}$  of 0.85 indicating a low potential for adsorption on organic matter and clay minerals. These intrinsic substance properties lead to a high mobility in water. Additionally, the intrinsic substance properties indicate that the substance will partition primarily to the water compartment and will undergo environmental distribution via aqueous media, easily reaching groundwaters.

The high water solubility and low sorption potential of 1,4-dioxane make the substance difficult to remove from water as it only has a low potential to adsorb to materials and prefers to remain in the water phase.

Because of 1,4-dioxane's high water solubility, low volatility from water and low potential for adsorption, water will be the dominant transport media in the environment once the substance is released. In combination with its long environmental half-life, there is a potential for widespread contamination of the water environment.

The OECD tool for Long Range Transport Potential (LRTP) predicts a characteristic travel distance (CTD) of 1384 km together with an overall persistence ( $P_{ov}$ ) of 820 days for 1,4-dioxane. This indicates that 1,4-dioxane is capable of reaching regions far away from the point of initial emission.

The Risk Assessment Committee (RAC) has concluded that 1,4-dioxane fulfils the criteria for classification as carcinogenic Carc. 1B. The classification has been included in the 17th ATP to CLP<sup>4</sup>. This classification is of relevance for the assessment of 1,4-dioxane as a substance of very high concern according to Article 57 (f), i.e. under the T-criterion of REACH Annex XIII; Section 1.1.3 b).

#### *Concerns arising from the substance properties*

Available information on persistency, mobility and potential for being transported in the water phase over long distances of 1,4-dioxane, gives rise to the concern, that once the substance is released to the environment, the contamination will hardly be reversible. This assumption is supported by a study that analysed the behaviour of 1,4-dioxane during river bank filtration and filtration with activated carbon at the drinking water production facility. The analysis showed that only a small portion of 1,4-dioxane is removed via river bank filtration and filtration with activated carbon. The result indicates, that the substance will not be removed from water by these purification techniques, which are generally applied across Europe. Furthermore, a temporal and spatial distribution from the point of release is to be considered. It needs to be considered that as long as 1,4-dioxane is released to the environment, the environmental levels might increase.

The concern raised by 1,4-dioxane is triggered by individual properties as well as by combination of its properties. Persistence and mobility allow the substance to be dispersed far beyond the sites of release via transport in the water environment. The substance stays in the environment even if releases of the substance have already ceased, as can be concluded from the substance

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Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 17<sup>th</sup> ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation, this new harmonised classification applies from 17 December 2022. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

properties and the recurring findings in groundwater samples. The persistency, mobility and toxicity (carcinogenicity) and in addition the irreversibility of the contamination of the aquatic compartment compromise the quality of drinking water resources.

The substance properties and the irreversibility of the contamination give rise to the concern of increasing exposure to wildlife and man via environment due to contaminated water.

The very high persistency and its mobility result in an increasing pollution of the aquatic environment. 1,4-Dioxane is difficult to remove once emitted to the aquatic environment. 1,4-Dioxane poses a threat to the resources of our drinking water, as due to its persistency and mobility, 1,4-dioxane can bypass river bank filtration and filtration with activated carbon, raising the concern of a continuous exposure of humans via drinking water. Any remediation efforts of contaminated drinking water resources will cause high costs to society. As the substance is very mobile causing a rapid distribution from the point source, remediation measures become even more difficult. Furthermore, 1,4-dioxane is carcinogenic and humans will be exposed to it via consumption and use of drinking water. Consequently, there is societal concern due to the presence of 1,4-dioxane in drinking water that requires immediate action. The environment provides natural drinking water sources, whose integrity needs to be ensured for future generations.

Due to the properties of 1,4-dioxane (persistency, mobility, potential for being transported in the water phase over long distances and carcinogenicity) it is not possible to derive a safe concentration limit for the environment. Monitoring data demonstrate the presence of 1,4-dioxane in surface water, groundwater and even drinking water across the globe. Sources of emission in the vicinity are seldom apparent.

The substance properties like persistency and mobility suggest that the substance might pose a risk on a global scale. It follows that human health and the environment might be affected by 1,4-dioxane on a global scale.

A supporting concern is that although available aquatic studies do not show effects or only at high concentrations, no information is available about other effects to the environment, e.g. on ecotoxic effects to non-model species. Therefore, the substance properties raise the concern of yet unknown effects on the environment.

#### *Equivalent level of concern*

The level of concern is considered very high in particular due to the combination of the following concern elements:

- Concern for an irreversible and increasing presence in the environment, in particular to the aquatic environment
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B and is included in the 17<sup>th</sup> ATP to CLP
- High societal concern for the presence of 1,4-dioxane in drinking water sources
- Continuous presence in water results in continuous exposure of humans and environment
- Yet unknown environmental and human health effects

#### *Conclusion*



Although the carcinogenic properties of 1,4-dioxane alone are sufficient to assess it as a substance of very high concern, it is the combination of its substance properties causing higher concern to the environment and human health (man via environment). The combined intrinsic properties which demonstrate scientific evidence of probable serious effects to human health and the environment and which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity and yet unknown environmental effects. Together, these elements lead to a very high potential for irreversible effects.

Registration dossiers submitted for the substance? Yes

## Justification

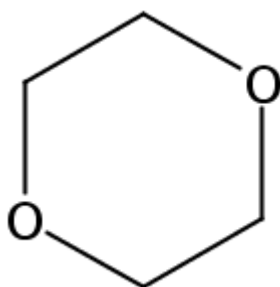
### 1. Identity of the substance and physical and chemical properties

#### 1.1. Name and other identifiers of the substance

Table 1: Substance identity

EC number:	204-661-8
EC name:	1,4-dioxane
CAS number (in the EC inventory):	123-91-1
CAS number: Deleted CAS numbers:	123-91-1
CAS name:	1,4-dioxane
IUPAC name:	1,4-dioxane
Index number in Annex VI of the CLP Regulation	603-024-00-5
Molecular formula:	C <sub>4</sub> H <sub>8</sub> O <sub>2</sub>
Molecular weight range:	88.12 g/mol
Synonyms:	<i>p-Dioxane</i> , <i>1,4-Diethylene dioxide</i>

Structural formula:



#### 1.2. Composition of the substance

Name: 1,4-dioxane

Substance type: mono-constituent

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
<i>1,4-dioxane</i> <i>EC number 204-661-89</i>		≥80 - ≤100%	

### 1.3. Physicochemical properties

Table 3: Overview of physicochemical properties

Property	Description of key information	Value	Reference/source of information
Physical state at 20°C and 101.3 kPa	<i>Data from data base and ATSDR report</i>	<i>Colourless liquid</i>	<i>ATSDR 2012; Gestis data base</i>
Melting/freezing point	<i>handbook data</i>	<i>11.8°C at 1013 hPa</i>	<i>O'Neil MJ. 2001. Dioxane. In: The Merck index. An encyclopedia of chemicals, drugs, and biologicals. Whitehouse Station NJ: Merck &amp; Co., Inc., (referenced in ATSDR 2012)</i>
Boiling point	<i>handbook data</i>	<i>101.1°C at 1013 hPa</i>	<i>O'Neil MJ. 2001. Dioxane. In: The Merck index. An encyclopedia of chemicals, drugs, and biologicals. Whitehouse Station NJ: Merck &amp; Co., Inc., (referenced in ATSDR 2012)</i>
Vapour pressure	<i>handbook data</i>	<i>38.1 mm Hg, 50.8 hPa at 25°C</i>	<i>Daubert TE, Danner RP. 1985. 1,4-Dioxane. In: Physical and thermodynamic properties of pure chemicals. New York, NY: Taylor &amp; Francis. (referenced in ATSDR 2012)</i>
	<i>measured</i>	<i>35.6 mm Hg at 25°C; 47.5 hPa</i>	<i>Francesconi R., Comelli F., J. Chem. Eng. Data, Vol. 33, No.2, p. 80 - 83, 1988</i>
Density	<i>handbook data</i>	<i>relative density 1.03</i>	<i>O'Neil MJ. 2001. Dioxane. In: The Merck index. An encyclopedia of chemicals, drugs, and biologicals. Whitehouse Station NJ: Merck &amp; Co., Inc., (referenced in ATSDR 2012)</i>
Water solubility	<i>measured</i>	<i>miscible; for assessments in coherence with registration data a water solubility of 1000 g/L at a temperature of 25°C is assumed</i>	<i>Riddick JA, Bunger WB, Sakano TK. 1986. 1,4-Dioxane. In: Organic solvents. Physical properties and methods of purification. New York, NY: John Wiley &amp; Sons, 312, 938. (referenced in ATSDR 2012)</i>
Partition coefficient n-octanol/water (log value)	<i>estimated</i>	<i>log K<sub>ow</sub> -0.27 (temperature not known)</i>	<i>Hansch C, Leo A, Hoekman D. 1995. Exploring QSAR: Hydrophobic, electronic, and steric constants. Washington, DC: American Chemical Society. (referenced in ATSDR 2012)</i>
Partition coefficient organic carbon / water K <sub>oc</sub> (log value)	<i>estimated</i>	<i>log K<sub>oc</sub> 0.85</i>	<i>EU RAR, 2002</i>
Partition coefficient air / water K <sub>AW</sub> (log value)	<i>estimated</i>	<i>Log K<sub>AW</sub> -3.69 at 12°C</i>	<i>Own calculation, see section 3.2.2.</i>

## 2. Harmonised classification and labelling

1,4-Dioxane is covered by Index number 603-024-00-5 in part 3 of Annex VI to the CLP Regulation as follows:

Table 4: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
603-024-00-5	1,4-dioxane	204-661-8	123-91-1	Carc. 2	H351	GHS02	H351	EUH019		
				Eye Irrit. 2	H319	GHS08	H319	EUH066		
				STOT SE 3	H335	GHS07	H335			
				Flam. Liq. 2	H225	Dgr	H225			

New classification:

The Risk Assessment Committee (RAC) adopted an opinion on 15 March 2019 to classify 1,4-dioxane as Carc. 1B<sup>5</sup>, H350, instead of the current classification as Carc. 2, H351. The classification has been included in the 17<sup>th</sup> ATP to CLP<sup>6</sup>.

Table 5: Classification according to the 17<sup>th</sup> ATP to CLP

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
603-024-00-5	1,4-dioxane	204-661-8	123-91-1	Carc. 1B	H350	GHS02	H350	EUH019		D
				Eye Irrit. 2	H319	GHS08	H319	EUH066		
				STOT SE 3	H335	GHS07	H335			
				Flam. Liq. 2	H225	Dgr	H225			

<sup>5</sup> <https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18075db7f>; date of access: 28.01.2021

<sup>6</sup>

Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 17<sup>th</sup> ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation this new harmonised classification applies from 17 December 2022. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

### 3. Environmental fate properties

Only studies are listed that are available in the registration dossier, on the ECHA dissemination site or in the European risk assessment report (EU-RAR, 2002). Unless otherwise stated the information presented in this SVHC dossier is taken from the registration dossier as published on the ECHA dissemination site<sup>7</sup>.

#### 3.1. Degradation

1,4-Dioxane is a heterocyclic ring containing four carbon and two oxygen atoms and belongs to the group of cyclic ethers. This heterocyclic ether structure is highly stable and results in high resistance to biodegradation (Sei et al., 2010; Zenker et al., 2003).

##### 3.1.1. Abiotic degradation

###### 3.1.1.1. Hydrolysis

There is no standard hydrolysis test according to OECD 111 available. In Kollig et al. (1993) it is stated that 1,4-dioxane does not hydrolyse because no hydrolysable functional groups are present. This assumption is supported by a study by Wolfe and Jeffers (2000), stating that 1,4-dioxane does not have functional groups that are susceptible to hydrolysis.

The QSAR model HYDROWIN v2.00 of the EPISuite tool (US EPA, 2002-2012) predicts rates and half-lives for hydrolysis. 1,4-Dioxane does not contain any functional groups for which hydrolysis can be estimated by HYDROWIN v2.00.

###### 3.1.1.2. Phototransformation/photolysis

###### 3.1.1.2.1. Phototransformation in air

No experimental data on direct or indirect phototransformation in air was available for 1,4-dioxane.

The ECHA dissemination site reports a QSAR model AOPWIN v1.92 of the EPISuite tool (US EPA, 2002-2012) which predicts degradation rates and half-lives for indirect photolytic degradation in the atmosphere and predictions were run for 1,4-dioxane. For 1,4-dioxane a half-life of 13.7 h was calculated assuming indirect photolysis via OH-radicals,  $0.5 \times 10^6$  OH/cm<sup>3</sup>, 24 h day. Also, Maurer et al. (1999) reported a half-life of 22.4 h for 1,4-dioxane in the presence of OH-radicals in a concentration of  $1 \times 10^6$  OH/cm<sup>3</sup>. Fast degradation of 1,4-dioxane in the presence of hydroxyl radicals (initial H<sub>2</sub>O<sub>2</sub> concentration was 15 mM) was also reported by Stefan and Bolton (1998) and achieved a 90% reduction in 1,4-dioxane in 5 min.

1,4-Dioxane is not expected to be susceptible to direct photolysis under environmental conditions since this compound lacks functional groups that absorb light at visible-ultraviolet (UV) light wavelengths (US EPA, 2018; Zenker et al., 2003).

###### 3.1.1.2.2. Phototransformation in water

No experimental and calculated data on phototransformation in water was available for 1,4-dioxane. According to Mohr et al. (2016), aqueous photo-oxidation half-life in water of 1,4-dioxane via hydroxyl radicals ranged between 67 days and 9.1 years, depending on the degree of light penetrating the surface water governing the concentration of OH-radicals and thus the photo-oxidation rate.

1,4-Dioxane and other ethers are weak absorbers of UV light in the wavelength range that

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<sup>7</sup> <https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15842/1>; date of access: 02.02.2021

persists through the troposphere and penetrates surface water (Mohr et al., 2016) and thus does not undergo direct photolysis in water.

The technical guidance document R.11 (ECHA, 2017a) states regarding the consideration of photochemical degradation processes in water: *“Due to the large variation in the light available in different environmental compartments, the use of photolysis data is not generally recognised for persistence assessment.”* In final conclusion, the contribution of photolytic degradation in the water phase to the total degradation in this compartment is expected to be negligible. In addition, due to the lack of UV-adsorbing functional groups in the molecular structure, 1,4-dioxane is not expected to be directly photolysed in water. Major releases of 1,4-dioxane will occur into surface waters that show only little potential for aquatic photolytic degradation due to depth of the water column, turbidity and presence of suspended matter that hamper the photolytic degradation potential.

#### 3.1.1.2.3. Phototransformation in soil

No experimental or calculated data on phototransformation in soil was available for 1,4-dioxane.

#### 3.1.1.3. Summary on abiotic degradation

Due to the structural properties, hydrolysis is not expected to be an important fate pathway. After evaporation or exposure to air, 1,4-dioxane will be rapidly degraded by photochemical processes. However, volatilisation to the air is not a major pathway for removal of 1,4-dioxane from the water phase (see 3.2.2.). Thus, abiotic degradation of 1,4-dioxane by phototransformation in air is regarded as negligible. Photolytic degradation in the aquatic compartment is expected to be negligible on basis of the current ECHA guidelines for assessment of degradation and environmental fate of chemicals, too (see 3.1.1.2.2).

In overall conclusion, abiotic degradation is not a relevant pathway for removal of 1,4-dioxane from air or the aquatic environment.

### 3.1.2. Biodegradation

#### 3.1.2.1. Biodegradation in water

##### 3.1.2.1.1. Estimated data

According to common knowledge, the heterocyclic structure is regarded as rather stable due to the two ester linkages (Zenker et al., 2003), leading to the resistance of 1,4-dioxane to microbial mineralisation (White et al., 1996).

The QSAR model BIOWIN v4.10 of the EPISuite tool (US EPA, 2002-2012) includes several QSARs for estimating intrinsic substance properties and environmental fate and behaviour of chemicals, providing degradation timeframes for primary and ultimate degradation of chemicals. BIOWIN also provides an estimate whether a substance fulfils the criteria of being rated as “readily biodegradable”.

QSAR calculations (BIOWIN v4.11) for 1,4-dioxane lead to inconsistent results regarding screening information on P and vP set out in ECHA R.11 guidance. According to the estimation of biodegradation, 1,4-dioxane “does not biodegrade fast” because the probability is lower than 0.5 (Biowin2 = 0.0061). Ultimate biodegradation timeframes for 1,4-dioxane indicate ultimate degradation within weeks (Biowin3 = 2.9871), with a slight trend to ultimate degradation within months. MITI non-linear model prediction results (Biowin6) indicates that 1,4-dioxane is readily biodegradable, because the probability is greater than or equal to 0.5 (estimated value = 0.5539).

The inconsistent results from the BIOWIN QSAR predictions mentioned above could be attributed to the different rating of the substance fragments within the models applied. In Biowin2 and Biowin3, the 1,4-dioxane structure is rated as two aliphatic ether fragments and therefore the prediction is highly dependent on that fragment. However, in Biowin6, the 1,4-dioxane structure is rated as two aliphatic ether fragments as well as four -CH<sub>2</sub>- cyclic fragments. In contrast to the aliphatic ether fragment, these -CH<sub>2</sub>- cyclic fragments have a positive coefficient improving the biodegradability of 1,4-dioxane in the Biowin6 model. ..

#### 3.1.2.1.2. Screening tests

Several standard or non-standard studies on ready biodegradability were available for 1,4-dioxane.

In an OECD 301 F test for ready biodegradability using non-adapted inoculum (activated sludge) as inoculum, degradation of 1,4-dioxane amounted to <10% (O<sub>2</sub> demand) at a test concentration of 100 mg/L after 29 days of incubation. The positive control using the substance aniline showed 92% degradation after 29 days. The test substance had no inhibitory effects on the degradation of the positive control substance. The reliability of the data is considered to be high. From these results it is concluded that the substance is not readily biodegradable.

An OECD 310 test using non-adapted inoculum (activated sludge) and applying enhanced conditions (prolonged test duration) at an initial concentration of 37.1 mg/L shows <5% mineralisation (CO<sub>2</sub> formation) after 60 days of incubation. The positive control using the substance aniline showed 74% degradation after 14 days. The test substance had no inhibitory effects on the degradation of the positive control substance. The reliability of the data is considered to be high. From these results it is concluded that the substance is not readily biodegradable.

A study according to OECD 302 B using industrial activated sludge and a test concentration of 400 mg/L shows a 1,4-dioxane degradation of 40% (DOC removal) after 10 days. However, measurement of the oxygen demand suggests that decline in 1,4-dioxane concentration is based on elimination instead of degradation. The reliability of the data is considered to be limited. From these results it is concluded that the substance is not inherently biodegradable.

The ECHA dissemination site mentions a non-standard test investigating the degradation of 1,4-dioxane in river water originating from Korea (Kim, 2007). Degradation amounted to 5% (test material analysis) at a concentration of 10 mg/L after 25 days of incubation. The test substance was analysed by means of HPLC.

In a study by Sei et al. (2010) using river water samples from 3 different rivers, the initial concentration of 100 mg/L 1,4-dioxane remained constant over the course of time (29 days), indicating that no degradation occurs. In a test on the toxicity of 1,4-dioxane to microorganisms according to test guideline DIN 38412-8 (bacterial inhibition test with *Pseudomonas*), EC<sub>10</sub> or NOEC value for microorganisms amounted to 2,700 mg/L. The reliability of the data is considered to be high. Based on the results, the test concentrations used in both OECD screening tests on ready biodegradation are considered to have no impact on the vitality of the inoculums in the tests.

According to a study by Sei et al. (2010) using activated sludge from a domestic and industrial waste water source, no degradation of 100 mg/L 1,4-dioxane could be observed analytically.

In conclusion 1,4-dioxane is evaluated to not be readily biodegradable.

#### 3.1.2.1.3. Simulation tests (water and sediments)

No standard simulation tests with 1,4-dioxane or other cyclic ethers in water and sediments are available on ECHA's dissemination site.



In a study (Hofman-Caris and Claßen, 2020) according to OECD TG 309, degradation of unlabelled 1,4-dioxane was investigated in surface water without the addition of suspended sediment. The test was performed using stationary biometer test systems using 300 mL of surface water. After collection, the surface water was cooled at 13 °C for 7 days prior to the test. 1,4-Dioxane was dissolved in water resulting in a concentration of 96 mg/L and was added in a concentration of 100 µg/L to the test system. Duplicate samples were incubated for 0, 7, 15, 30, 45, and 60 days, respectively at 13 ± 1 °C in darkness. As reference substance, unlabelled aniline was used. The application rate was 1.0 µg/L. Besides the reference substance, the microbial activity of the water was also investigated by determining the amount of adenosine triphosphate (ATP). Degradation was evaluated based on the concentration of reference substance and 1,4-dioxane detected in the water phase using GC-MS. The amount of ATP in the surface water without the addition of 1,4-dioxane at day 0 was 86 ± 1.2 pg/mL, after autoclaving ATP concentration was reduced (<1 ± 0.44 pg/mL), indicating that the ATP assay is able to reflect the microbial activity of the surface water.

In the presence of 1,4-dioxane, the ATP concentration was equal to those measured in surface water without any addition, meaning that 1,4-dioxane has no negative effect on the microbial population. The concentration of aniline decreased over the course of the study. After 15 days of incubation, the concentration was 0.418 ± 0.1 µg/L. At the end of the study (day 60), the aniline concentration amounted to <0.01 µg/L in the surface water. Degradation of aniline based on the concentration observed amounted to 52% and >98% after 15 and 30 days of incubation. Based on the results it is concluded that the surface water used in the test contained an active microbial population.

Recovery of the 1,4-dioxane concentration applied to test ranged between 71-93%. According to OECD 309, initial recovery should be between 70% and 110% for non-labelled substances. Thus, the study is regarded as valid.

The 1,4-dioxane concentration remained stable over the course of time and ranged between a minimum value of 71.1 ± 5.5 µg/L at day 15 and a maximum value of 93.3 ± 0.4 µg/L at day 30 (Figure 1). At the end of the study (day 60), 85.8 ± 3.2 µg/L 1,4-dioxane could be detected in the surface water. As unlabelled 1,4-dioxane was used in this study, ultimate degradation of the substance could not be determined. Nevertheless, as no decline in test concentration was detected during the study, no ultimate degradation of 1,4-dioxane took place in the test system.

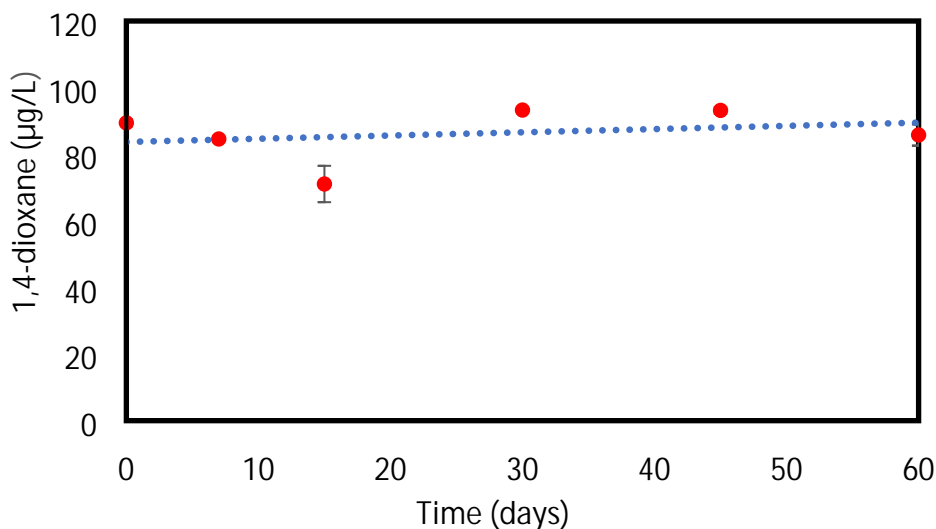


Figure 1: Concentration of 1,4-dioxane ( $\mu\text{g/l}$ ) in a surface water test system in course of time (days). Data were shown as mean value of two individual bottles for each sampling point with error bars indicating standard deviation.

The determination of half-life of 1,4-dioxane was calculated based on the amount of 1,4-dioxane detected in the water phase using the software Computer Assisted Kinetic Evaluation (CAKE, Tessella, Version 3.1). The software CAKE applies the kinetic models SFO (Single first-order), FOMC (First-order multi-compartment), DFOP (Double first-order in parallel) and HS (Hockey-Stick) to deviate half-lives whereas the latter ones describe biphasic kinetics characterized by a quick initial decrease in test compound concentration ( $k_1$ ) followed by a slow phase ( $k_2$ ). Calculated half-lives ( $DT_{50}$ ) of 1,4-dioxane are shown in Table 6. The SFO model is the best fit model (lowest Chi2 error value which is below 15%). Results of the t-test reveal that the parameter  $k$  of the SFO model, as well as the  $k_1$  and  $k_2$  of the DFOP and HS models, are not significantly different from zero at the significance level of 5% ( $p < 0.05$ ). Therefore, it is concluded that there is no significant measurable degradation over 60 days. A half-life  $> 10,000$  days (default value) was derived from the SFO model. However, as no degradation of the substance appears during the study, the calculated half-lives are considered uncertain. Thus, the respective  $DT_{50}$  should be interpreted with care. Nevertheless, it is possible to conclude on reaching certain trigger values, even though it is impossible to define exact values. Thus, the  $DT_{50}$  of 1,4-dioxane is regarded to be over 60 days.

Table 6: Kinetic calculations of half-lives ( $DT_{50}$ ) based on the amount of parent detected in the water phase

Model	$DT_{50}$ (days)	Chi2 Error	Result t-test	Visual fit
SFO	$> 10,000$	7%	$k = 0.5$	medium
DFOP	$DT_{50\ k_1} = 0.584$ $DT_{50\ k_2} = > 10,000$	9%	$k_1 = 0.4928$ $k_2 = 0.5$	medium
HS	$DT_{50\ k_1} = 86.1$ $DT_{50\ k_2} = > 10,000$	9%	$k_1 = 0.4366$ $k_2 = 0.5$	medium
FOMC		Not applicable as no visual assessment of the fit and residuals as well as		

		estimation of the error percentage was possible.
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The reliability of the data is considered to be high. In conclusion, 1,4-dioxane is evaluated as not degradable in surface water.

### 3.1.2.2. Biodegradation in soil

No standard simulation tests with 1,4-dioxane or other cyclic ethers in soil are available.

After release into soil, degradation of 1,4-dioxane can be strongly influenced by the presence of microorganisms which are capable of degrading 1,4-dioxane and other cyclic ethers.

In a study using a soil suspension (Kelley et al., 2001) periodically aerated with sterile air, 1,4-dioxane was not degraded during a period of 120 days. The activity of soil microorganisms was not monitored. In case a dioxane-degrading actinomycete strain were added to the soil suspension, 1,4-dioxane degradation amounted to 60% in 120 days. The soil suspension contained 20 g of soil dissolved in 200 mL basal salt media and 25 mg/L 1,4-dioxane was added. Degradation was monitored using GC-FID analysis.

Using garden soil suspension, no degradation of 1,4-dioxane within 39 days of incubation was detected (Sei et al., 2010). The soil suspension contained 3 g of soil dissolved in 100 mL basal salt media and 100 mg/L 1,4-dioxane was added. Test concentrations used in this test are quite high compared to concentrations applied in standard simulation tests and may challenge the detection of small changes in the concentration of the test item. Degradation was monitored using GC-FID analysis with LOD of 0.8 mg/L.

In a study with <sup>14</sup>C-1,4-dioxane at a concentration of 10 mg/kg soil, 3-8% of the applied radioactivity were converted to <sup>14</sup>CO<sub>2</sub> after 18-28 days of incubation in a test system containing 185 g soil and 90 mL nutrient solution (Kelley et al., 2001), indicating that ultimate degradation is not a main route of 1,4-dioxane after entering the soil compartment.

In contrast, in contaminated soil suspensions spiked with 100 mg/L of 1,4-dioxane, the concentration was reduced within 33 days to below its detection limit (0.8 mg/L), indicating primary degradation of the compound (Sei et al., 2010). Degradation was monitored using GC-FID analysis with LOD of 0.8 mg/L.

All of the soil degradation studies described above have significant deviations from standard soil simulation tests, e.g., due to the use of soil suspensions, high test substance concentrations, or addition of nutrients.

(He et al., 2018) reported that although 1,4-dioxane is relatively recalcitrant, a number of strains capable of degrading 1,4-dioxane have been isolated. According to the authors, most of these strains degrade dioxane co metabolically, meaning that 1,4-dioxane degradation is induced by another substrate, and it does not serve as carbon or energy source to support bacterial growth. Nearly all of these strains were isolated from wastewater treatment plants or dioxane-impacted sites. Many of the strains originate from soil.

Some non-standard studies with isolated bacteria in pure or mixed culture from different locations (soil, sediment, aquifer) indicate some potential for biodegradation of 1,4-dioxane under aerobic (Barajas-Rodriguez and Freedman, 2018; Bernhardt and Diekmann, 1991; Burbach and Perry, 1993; Inoue et al., 2016; Mahendra and Alvarez-Cohen, 2005; Parales et al., 1994; Pugazhendi et al., 2015; Sales et al., 2013; Sei et al., 2013; Sock, 1993; Li et al., 2017) and anaerobic conditions (Ramalingam and Cupples, 2020; Shen et al., 2008). Degradation of 1,4-dioxane by cultures enriched from uncontaminated soil was dominated by *Rhodanobacter*, *Pseudomonas*, *Mycobacterium*, and *Acinetobacter* (He et al., 2018; Ramalingam

and Cupples, 2020; Sei et al., 2013). Degradation was monitored by either decrease in 1,4-dioxane concentration, the formation of CO<sub>2</sub> or the presence of transformation products (Chen et al., 2016; Huang et al., 2014; Mahendra et al., 2007; Pugazhendi et al., 2015; Zenker et al., 2000). However, as isolated microorganism strains were used, the studies are only applicable to show that 1,4-dioxane is biodegradable under specific conditions.

Many studies reported the cometabolic transformation of 1,4-dioxane in pure or mixed cultures in the presence of primary substrates, e.g. tetrahydrofuran. In a study on the biodegradability of 1,4-dioxane, Zenker et al. (2002) showed that when tetrahydrofuran is added to the test medium 1,4-dioxane is subject to cometabolic degradation (test material analysis) in a relatively short period. In a study according to (Hatzinger et al., 2017) cometabolic transformation of 1,4-dioxane with ethane was reported. However, the results of this study do not allow extrapolation to degradation under environmental conditions due to the lack of degradation when no primary substrate is present, a microbial population composition enriched from a 1,4-dioxane contaminated aquifer is used and under the specific test conditions. The study is therefore only applicable to show that 1,4-dioxane is biodegradable under specific conditions.

In conclusion, based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions.

### 3.1.2.3. Summary and discussion on biodegradation

Based on the low degradation in water as shown in the screening tests available and other studies on biodegradation, including the OECD TG 309 surface water simulation test,, it is concluded that the biodegradation of 1,4-dioxane in the aquatic environment is very slow or negligible.

For degradation in soil, no studies following (or equivalent to) OECD test guidelines are available. In conclusion, based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions.

### 3.1.3. Field data

Stepien et al. (2014) studied 1,4-dioxane concentration in the influent and effluent of four domestic sewage treatment plants (STP) and found no removal of 1,4-dioxane through the STPs. This suggests that degradation of 1,4-dioxane under environmental conditions will be very limited, as for STPs.

Adamson et al. (2015) performed a comprehensive evaluation of California state (GeoTracker) and Air Force monitoring records. California's GeoTracker database contains data from over 12 000 sites where groundwater impacts are being monitored (Adamson et al., 2015). For the survey Adamson et al. evaluated groundwater concentration data for the period between February 2000 and December 2013. Dioxane analysis was completed at 589 individual sites and 191 of these sites contained 1,4-dioxane. As a second dataset served a set of dioxane-impacted monitoring records based on the Environmental Restoration Program Information Management System (ERPIMS) database that is maintained by the United States Air Force. A total of 441 independent monitoring wells were observed since 1990. The authors mention at least 4 independent dioxane detections over time, across 14 installations and at least 92 "sites". The authors declare that in the case of the Air Force data set it was generally not feasible to segregate to individual sites due to complexity of installation. Therefore, the analysis is well-based. Temporal changes in the site-wide maximum concentrations were used to estimate source attenuation rates at the GeoTracker sites. While attenuation could not be established at all sites, statistically significant positive attenuation rates were confirmed at 22 sites. Dioxane attenuation rates were positively correlated with rates for 1,1-DCE (1,1-dichloroethylene) and TCE (trichloroethylene) but not 1,1,1-TCA (1,1,1-trichloroethane). At this set of sites, there was little

evidence that chlorinated solvent remedial efforts (e.g., chemical oxidation, enhanced bioremediation) impacted dioxane attenuation. Further Adamson et al. report that attenuation rates based on well-specific records from the Air Force data set revealed a significant dioxane attenuation (131 out of 441 wells) at a similar frequency and extent (median equivalent half-life = 48 months) as observed at the California sites. For the well-by-well based attenuation rates, a positive correlation could be established with factors that promoted biodegradation (dissolved oxygen concentration). The authors state, however, that dioxane is expected to be more mobile due to its high solubility and lack of sorption, and these characteristics may contribute to the observed concentration changes. For sites and wells, where significant attenuation was established, the half-lives of 1,4-dioxane were in the range of 2 to 5 years.

Gedalanga et al. (2016) developed a multiple lines of evidence (MLOE) framework to evaluate the biodegradation potential of 1,4-dioxane based on a former landfill site in the US which accepted industrial waste from 1968 to 1979 (Gedalanga et al., 2016). The groundwater at this site is impacted by 1,4-dioxane with up to 420 µg/L (2015) and Tetrahydrofuran (THF) with up to 340 µg/L (2015). As a result of the MLOE analysis, which included molecular biological analysis, compound-specific isotope analysis, concentration trend analysis, spatial distribution, temporal changes, modelling and others, the authors concluded that 1,4-dioxane attenuation was occurring across the groundwater plume and that non-destructive physical processes alone did not account for the observed 1,4-dioxane attenuation. The authors observed a decrease of the 1,4-dioxane plume mass in total by 38 percent and provide evidence that a TFH-driven cometabolism is possible.

Field data indicate, that attenuation of 1,4-dioxane in groundwater sites might occur under specific conditions (presence of chlorinated solvents, THF, aerobic conditions). However, it is important to note that natural attenuation was identified for a limited number of sites/wells.

#### 3.1.4. Summary and discussion of degradation

Based on its chemical structure, 1,4-dioxane is expected to be highly stable due to the heterocyclic ether structure. Abiotic degradation of 1,4-dioxane by hydrolysis and phototransformation in air and water is expected to be negligible based on the chemical structure and QSAR predictions.

In screening tests regarding ready degradability negligible mineralisation occurred, even after an extended study period or utilisation of adapted inoculum. In other studies on degradation of 1,4-dioxane in water (Kim, 2007; Sei et al., 2010), no degradation of 1,4-dioxane was detected. This data demonstrates that the substance is potentially persistent / potentially very persistent in water according to the screening criteria of REACH Annex XIII.

On the basis of a OECD TG 309 surface water simulation test with surface water (Hofman-Caris and Claßen, 2020) showing no degradation of the substance within 60 days, DT<sub>50</sub> of 1,4-dioxane is regarded to be over 60 days. This result confirms that the substance qualifies as very persistent in water according to the persistency criteria of REACH Annex XIII.

For degradation in soil, no studies following (or equivalent to) OECD test guidelines are available. In conclusion, based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions.

Considering the data on abiotic and biotic degradation, it is concluded that 1,4-dioxane is persistent and very persistent in the aquatic compartment.

### 3.2. Environmental distribution

#### 3.2.1. Adsorption/desorption

On the ECHA dissemination website, the result of two QSAR estimations are available for the

substance. These were conducted with the computer program KOCwin (v2.00; part of EPIsuite v4.10, US EPA (2012)). The log  $K_{OC}$  was calculated by utilizing the Molecular Connectivity Index (MCI) in the first study and an estimate for the log  $K_{OC}$  on basis of the octanol/water partition coefficient (log  $K_{OW}$ ) in the second one. The results are log  $K_{OC}$  = 0.42 (2020, MCI method) and log  $K_{OC}$  = 0.51 (2020,  $K_{OW}$  method). A value for log  $K_{OC}$  of 0 is also reported for 1,4-dioxane. This value was calculated with EPIWIN SRC PCKOCWIN v1.66 in 2007.

In the EU Risk Assessment Report for 1,4-dioxane a  $K_{OC}$  of 7.1 L/kg, respectively log  $K_{OC}$  = 0.85 calculated with QSAR for non-hydrophobics from log  $K_{OW}$  = -0.32 according to the EU TGD (1996) was reported (EU-RAR, 2002).

Arp and Hale (2019) evaluated for all substances registered as of May 2017 whether or not they fulfil the criteria for PMT/vPvM as defined in the published UBA assessment scheme (Neumann and Schliebner, 2019). For their evaluation Arp and Hale not only used registration data available via ECHA's dissemination site but also additional data from other sources. For 1,4-dioxane they found that the lowest experimentally derived value for the substance was log  $K_{OC}$  = -0.5 (Arp and Hale, 2019).

DiGuseppi et al. (2016) analysed the adsorption behavior of 1,4-dioxane. They concluded that with a log  $K_{OC}$  = 0.42 the substance will only weakly adsorb to organic matter.

QSAR calculations conducted with the model KOCwin v2.01 from EPI Suite v4.11 (US EPA, 2002-2012) and the SMILES code as input for the purpose of the report resulted in a log  $K_{OC}$  = 0.595 ( $K_{OW}$  method) respectively log  $K_{OC}$  = 0.421 (MCI method) for 1,4-dioxane.

The chemical structure of 1,4-dioxane reveals the non-ionic nature of the substance. Therefore, binding processes on non-organic soil constituents such as clay minerals are unlikely.

According to Zenker et al. (2003) sorption is not expected to be a significant attenuation process for 1,4-dioxane due to its miscibility with water. Further information is available from the study by Stepien et al. (2014), which showed only very low concentration decline after a filtration step with activated carbon. This study confirms the low sorption potential of 1,4-dioxane.

In conclusion, the available data for the substance provides clear evidence that adsorption will not be a relevant pathway of removal of 1,4-dioxane. This refers to removal from aqueous media in the environment, but also refers to removal from aqueous media in technical environments such as sewage treatment plants or drinking water purification installations. Once emitted to the water cycle, the major amount of the substance is expected to remain in it.

For the purpose of further assessments of environmental distribution and fate the value of log  $K_{OC}$  = 0.85 from the EU Risk Assessment Report (EU-RAR, 2002) was used.

### 3.2.2. Volatilisation

Volatilisation describes the tendency of a substance to evaporate from the water phase.

Volatility in general is calculated by using the equation R.16-4 for the Henry's Law constant according to Guidance Document R.16 (ECHA, 2016):

$$HENRY = \frac{VP * MOLW}{SOL}$$

Table 7: Volatilisation

Variable	Expression	Unit	Value
VP(*)	Vapour pressure	[Pa]	4745.5
MOLW	Molecular weight	[g/mol]	88.12
SOL(*)	Water solubility	[g/L]	1000
HENRY	Henry's law constant	[Pa*m <sup>3</sup> /mol]	0.418

(\*) values taken from Table 3 and extrapolated from the individual test temperature of the specific endpoint to European average environmental temperature of 12 °C by applying the Arrhenius equation.

During the public consultation of the Annex XV dossier, arguments were provided that this result might be inaccurate because this method is rated to be not valid for substances that are completely miscible with water. In those cases, ECHA Guidance R.7a (ECHA, 2017b) suggests to apply group and bond contribution based QSAR models instead, respectively gives a favour to measured values.

The module HENRYwin v3.21 being part of EPIsuite (US EPA (2002-2012)) provides the following results for the Henry's Law constant of 1,4-dioxane for a temperature of 25 °C:

- Experimental database match: 0.486 Pa\*m<sup>3</sup>/mol
- Bond estimation method: 0.599 Pa\*m<sup>3</sup>/mol
- Group estimation method: 0.011 Pa\*m<sup>3</sup>/mol

Commonly, slightly volatile substances are defined by falling below the threshold of 0.1 Pa\*m<sup>3</sup>/mol, whereas highly volatile substance are expected to exceed the threshold of 100 Pa\*m<sup>3</sup>/mol, as reported in OECD TG 309 "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test".

All values indicate that the substance has a low volatility from water, trending to slightly volatile. For further assessments the measured value of 0.486 Pa\*m<sup>3</sup>/mol was applied.

Another parameter describing the distribution of a substance between air phase and water phase is the partition coefficient air-water ( $K_{AW}$ ). This can easily be calculated by using the equation R.16-5 as set out in ECHA Guidance Document R.16:

$$K_{AW} = \frac{HENRY}{R * T} = -3.69 \text{ (@12°C; displayed here as log } K_{AW})$$

with R being the gas constant (8.314 Pa\*m<sup>3</sup>\*mol<sup>-1</sup>\*k<sup>-1</sup>) and T the temperature at the air-water interface (285 K; European average temperature).

In conclusion the available data clearly indicates that volatilisation is not a major pathway of removal of 1,4-dioxane from the water phase.

### 3.2.3. Distribution modelling

#### *Distribution in sewage treatment plants*

The Simple Treat model predicts the share of degradation of a substance in a municipal STP together with the ratio of substance being released to surface waters, respectively the ratio emitted to air or retained in sewage sludge. The Simple Treat distribution model is generally accepted and included in various standard computerised models, such as EPISuite, EUSES and Chesar.

Using water solubility, vapour pressure from Table 3 together with the data on adsorption behaviour from section 3.2.1 and applying an elimination rate constant  $k=0/h$  for biodegradation of "not readily biodegradable" substances in the STP following the requirements of Table R.16-10 set out in ECHA Guidance R.16. Simple Treat provides the following distribution pattern for a municipal STP:

Table 8: Distribution pattern for a municipal STP

Summary of distribution (*)	(%)
to air	1.0
to water	99.0
via primary sludge	0.1
via surplus sludge	0.0
degraded	0.0
total	100.0

(\*) Distribution according to SimpleTreat 3.0 (debugged version, Feb 1997); exceedance of 100 percent for sum of the single values caused by rounding errors.

The outcome of the distribution modelling suggests that currently applied standard waste water treatment processes in principle have no influence on the concentration of 1,4-dioxane in sewage water. Virtually the whole amount of 1,4-dioxane entering the sewer system is emitted to surface water in the follow-up. Only a small amount (0.8%) is emitted to air, where transport is assumed to occur via aerosol particles.

#### *Distribution processes between environmental compartments*

The generally accepted distribution model is the MacKay Level III fugacity model covering the environmental compartments air, water, sediment and soil. The model is for example included in the EPI Suite-Toolbox, developed by the U.S. Environmental Protection Agency (US EPA, 2002-2012). The model offers the option to calculate the distribution between different compartments starting with one or several compartments of initial release (air, water, soil), but also to assume multiple combinations by runs using permutations of air, water and soil release rates as either 0 or 1000 kg/h.

The outcome of the Level III distribution predictions is provided below. Input parameters for water solubility, vapour pressure and  $\log K_{OW}$  calculated internally by EPI Suite were overwritten with the corresponding physical-chemical parameters from Table 3 in this document. The data of the mass amount provided in the following tables represents the distribution in equilibrium state.

Table 9: Initial release to soil only

	Mass amount (percent)
Air	0.53



Water	18.8
Soil	80.7
Sediment	0.036

Table 10: Initial release to water only

	Mass amount (percent)
Air	0.16
Water	99.6
Soil	0.044
Sediment	0.19

Table 11: Initial release to air only

	Mass amount (percent)
Air	65.3
Water	16.2
Soil	18.5
Sediment	0.031

Table 12: Multiple Level III release

	Mass amount (percent)
Air	3.46
Water	44.3
Soil	52.1
Sediment	0.086

Distribution modelling predicts that once released to a specific single compartment, the substance will predominantly remain in it. The calculation for multiple level III releases shows that the substance will predominantly end up in the water and soil compartment.

#### *Mobility in the environment*

As explained in section 3.2.1 with  $\log K_{OC} = 0.85$  (EU-RAR, 2002) the substance has a low potential for adsorption on organic matter and clay minerals.

As consequence of the conclusions drawn by Zenker et al. (2003) and Stepien et al. (2014) regarding the high water solubility and low sorption potential to organic and inorganic matter, it becomes obvious that the primary pathway of environmental distribution is via aqueous media. With this in mind the logical consequence is that 1,4-dioxane in air is washed out from the atmosphere due to precipitation and will reach the soil compartment or surface water. Due to low sorption of the substance there will be no retention in soil and the substance will easily reach groundwater which is widely used as source for raw water processed for drinking water production.

#### 3.2.4. Field data

##### *Findings in drinking water*

Studies investigating 1,4-dioxane levels in Europe's drinking waters are rare.

1,4-Dioxane was addressed in a drinking water monitoring campaign in Frankfurt/Main (Magg et al., 2013). In total, 12 samples were analysed, 7 samples contained 1,4-dioxane with an average concentration of  $>0.22 \mu\text{g/L}$  ( $c_{\text{max}} = 0.58 \mu\text{g/L}$ ).

Recently, the study by Karges et al. (2018) published a German-wide survey of 1,4-dioxane contamination in finished drinking water (FDW) obtained by managed aquifer recharge systems. 80% of the FDW samples, collected from April 2015 to February 2016, contained 1,4-dioxane in concentrations between  $0.034 \mu\text{g/L}$  to  $2.05 \mu\text{g/L}$ .

The efficiency of the Sant Joan Despí drinking water treatment plant in Catalonia, Spain (mouth of Llobregat river) was investigated between March 2015 and January 2018. The plant supplies drinking water to a population of more than three million people with an average production of  $450,000 \text{ m}^3/\text{day}$ . The authors reported an average concentration of 1,4-dioxane in finished drinking water of  $1062 \pm 923 \text{ ng/L}$  between March 2016 and January 2018, with a maximum value of  $4356 \text{ ng/L}$  ( $n=89$ ) (Carrera et al., 2019).

In the scope of the Unregulated Contaminant Monitoring Rule (UCMR3) 1,4-dioxane occurrence was examined in U.S. public drinking water systems from January 2013 to December 2015<sup>8</sup>. The substance was detected in 21% of the 4864 public water systems (PWS) and exceeded the health-based reference concentration ( $0.35 \mu\text{g/L}$ ) at 6.9% of these systems. In terms of the source water types the authors reported a detection frequency of 1,4-dioxane in samples from groundwater sources of 12% and in samples from surface water sources 10% (Adamson et al., 2017).

Tap water from 6 cities in Kanagawa Prefecture in Japan collected in 1995 to 1996 was analysed for its contamination with 1,4-dioxane. The author of the study reported concentrations of 1,4-dioxane in all tap water samples ( $n=12$ ) between  $0.2 \mu\text{g/L}$  to  $1.5 \mu\text{g/L}$  (Abe, 1997).

Although current detailed knowledge on the occurrence of 1,4-dioxane in drinking waters is limited, it is evident that the substance is found in drinking water in Europe, U.S. and Japan. It is well known that 1,4-dioxane is difficult to remove from water due to common water processing techniques (Carrera et al. (2019) and references within). Therefore, findings of 1,4-dioxane in drinking waters usually originate either from contaminated surface water or from contaminated ground water used in drinking water production.

##### *Findings in groundwater*

75% of EU inhabitants depend on groundwater for their drinking water supply (EU COM, 2019). However, only few data are available on occurrence of 1,4-dioxane in groundwater bodies across

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<sup>8</sup> <https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule>

Europe.

Due to its high solubility in water and its low log  $K_{OC}$ , 1,4-dioxane easily migrates to groundwater and matrix diffusion processes in aquifers take place (see chapter 3.2.1). 1,4-Dioxane was used in the past as a stabiliser for chlorinated solvents (e.g. 1,1,1-trichloroethene (TCA) and others). Therefore, 1,4-dioxane is found in groundwater from industrial areas with historic contaminations of chlorinated solvents (Adamson et al. (2014); Carrera et al. (2019); Pollitt et al. (2019) and references within these). The use of TCA has been banned since 1996 (Karges et al., 2020), so that a decrease in concentrations of 1,4-dioxane over time could be expected. However, there appear to be no studies available that prove this trend.

A recent study investigated groundwater samples from selected sites in Germany, where the authors suspected the occurrence of 1,4-dioxane. The authors collected groundwater samples downstream of a detergent manufacturing plant, from landfill sites and sites with known volatile chlorinated hydrocarbon (VCH) pollution. In total, 44 groundwater samples were analysed during October and November 2014. In all samples 1,4-dioxane was detected in levels above the limit of quantification (LOQ) in a concentration range between 0.04 µg/L to 152.11 µg/L (Karges et al., 2018). Although none of the sampled ground water sites is used for the drinking water production directly, the authors critically note the proximity between three of the investigated sites to drinking water catchment sites.

OVAM<sup>9</sup> commissioned a study on the presence of 1,4-dioxane and other additives of 1,1,1-trichloroethane in groundwater in Flanders. The study was performed on the basis of random sampling measurements of 1,4-dioxane at sites in Flanders with known 1,1,1-trichloroethane groundwater contamination between August to September 2016 and between February to May 2017. Amongst others it was concluded that 1,4-dioxane was identified in groundwater at all 16 measurement locations with a maximum of 1,4-dioxane concentration of 26,000 µg/L, and at 13 out of 16 sites the 1,4-dioxane limit in groundwater (50 µg/L) was exceeded (OVAM, 2017).

The study by (Carrera et al., 2017) investigated the occurrence of 1,4-dioxane at the lower Llobregat River basin (Spain). The authors collected 70 samples from 5 groundwater wells during October and November 2015 and found increasing concentrations of 1,4-dioxane downstream at the left side of the Llobregat river. Measured mean levels ranged from 1.68 µg/L to 50.5 µg/L with a maximum of 241 µg/L.

Monitoring data on findings from groundwater for 149 samples were collected by the Austrian Environment Agency in 2019. 1,4-Dioxane concentrations within the samples ranged from 0 µg/L to 14 µg/L, with 95% of the samples having a concentration of 0.25 µg/L or lower. In 111 samples, 1,4-dioxane concentration was below the LOD and in 12 samples below the LOQ (UBA AT, 2020).

1,4-Dioxane contaminations in groundwater are mainly investigated in US and Japan (e.g. Abe (1999); Adamson et al. (2014); Anderson et al. (2012); Zenker et al. (2003)). These reports demonstrate the co-occurrence of 1,4-dioxane contamination with 1,1,1-trichloroethane (TCA) and trichloroethylene (TCE) release/presence in groundwater bodies. Historical emission sources for those groundwater contaminations are US Air Force sites and chemical plants, where 1,4-dioxane was used as solvent, or as stabilising agent for TCA and other chlorinated solvents (Abe, 1999; Anderson et al., 2012).

Interesting to note is that (Adamson et al., 2017) investigated the factors influencing the frequency of 1,4-dioxane detections in the U.S. As one of those factors the source water type (groundwater source and surface water source) was identified. A more even distribution of samples containing 1,4-dioxane from the different source water types (12% of groundwater samples and 10% of surface water samples) is reported. The authors state that "*the ratio for source water type based on detection frequency (1.25 in favor of groundwater) is relatively*

<sup>9</sup> Flemish public service authority with responsibility for aspects of circular economy policies and monitoring the soil quality in Flanders.

*modest*". Two explanations were given:

1. *"the releases to surface water from wastewater and industrial discharges provide a greater loading to the environment than is often assumed"*
2. *"portion of the 1,4-dioxane released to groundwater is reaching surface water"*.

### *Findings in Surface Waters*

River bank filtration water has a remarkable share of the total water used for drinking water production (e.g. Germany 17% (Karges et al., 2018), the Netherlands: 5-6% (Geudens and van Grootveld, 2017)).

For 1,4-dioxane, the concentration of the substance in surface water impacts the concentration of the river bank filtrate, which is used for the production of drinking water. In line with this, Stepien et al. (2014) demonstrated for Rhine water samples that neither bank filtration nor purification of raw water was capable of removing 1,4-dioxane. Surface water monitoring results are available for the river Rhine (Fleig et al., 2017; RIWA, 2016; RIWA, 2018; Röden et al., 2016). Measurements since 2011 indicate that the concentration of 1,4-dioxane in Rhine river water and its tributary remain at a constant level over the years (Fleig et al., 2017; LANUV, 2019; RIWA, 2016; RIWA, 2018). Measured concentrations are above the target value, proposed by the European River Memorandum (ERM), of 0.1 µg/L (IAWR et al., 2013). A current report by LANUV (2019) reported basal levels of 1,4-dioxane between 1 to 2 µg/L near Lobith (Rhine, DE), and maximum levels above 5 µg/L in rivers Rhine and Lippe.

Stepien et al. (2014) studied 1,4-dioxane concentration in the influent and effluent of four domestic sewage treatment plants (STP), 111 surface water samples and bank filtrate and drinking water of two drinking water facilities. The authors found no removal of 1,4-dioxane through the STPs. Further, Stepien et al. (2014) reported concentrations of 1,4-dioxane in the river Oder reached 2.2 µg/L, and 0.86 µg/L in both the rivers Main and Rhine during 2012-2013. The concentrations of 1,4-dioxane increased with increasing distance from the spring.

Motivated by recent findings of 1,4-dioxane in German river waters, the Bavarian Environment Agency initiated an ongoing monitoring campaign in 2016. For the river Lech and one tributary, concentrations of up to 5.5 µg/L, and for the river Inn and one tributary concentrations of up to 4.9 µg/L and 100 µg/L, respectively, were found. Analysis of raw water, obtained from wells strongly influenced by Lech bank filtrate, revealed 1,4-dioxane concentrations of up to 3.3 – 5.0 µg/L (Rüdel et al., 2020).

Monitoring data comprising 31 samples of selected surface waters in Austria were collected by the Austrian Environment Agency in 2019. 1,4-Dioxane concentrations within the samples ranged from 0 µg/L to 1.6 µg/L, with 95% of the samples having a concentration of 0.25 µg/L or lower. In 20 samples 1,4-dioxane concentration was below the LOD and in two samples below the LOQ (UBA AT, 2020).

### 3.2.5. Summary and discussion of environmental distribution

The available information on adsorption/desorption behaviour of the substance predominantly consists of QSAR information. The results are in the range of  $\log K_{oc} = -0.5$  (Arp and Hale, 2019) to  $\log K_{oc} = 0.85$  (EU-RAR, 2002). Together with the results of Zenker et al. (2003) and Stepien et al. (2014) the data is sufficient to prove that the substance will not adsorb at organic matter and clay minerals.

With a Henry's Law constant of  $0.486 \text{ Pa}\cdot\text{m}^3\text{mol}^{-1}$  at 25 °C the substance has a moderate

trending to low volatility from aqueous media.

Once reaching the water compartment, the substance will predominantly remain in it as adsorption, volatilisation and - as explained in section 3.1 - degradation processes have only little effect on the substance concentration once it is emitted into the environment.

Distribution modelling with SimpleTreat indicates that there will be in principle no retention of the substance in sewage treatment plants. Fugacity level III distribution modelling indicates that the substance to a large extent may remain in the compartment of its initial release. But due to the high water solubility (1000 g/L) and the very low adsorption potential the substance will be washed out from the atmosphere and from soil and is finally expected to remain in the water compartment.

Based on this evidence it becomes obvious that the substance is capable to accumulate not only in surface waters but also in groundwater. Both are sources of raw water used for drinking water production. Indeed, the available monitoring data show that 1,4-dioxane has been detected in groundwater, surface water and drinking water in Europe.

### 3.3. Removal from the environment, decontamination and purification

Techniques to remove 1,4-dioxane from environmental media are important in order to have the possibility to reduce contamination and lower environmental and human exposure. As 1,4-dioxane tends to partition to the aqueous phase due to its properties of high water solubility and low adsorption potential, purification techniques for water are most relevant. 1,4-Dioxane has been detected in surface water, groundwater and in treated drinking water. Removal techniques suitable for drinking water treatment plants are therefore essential, while the purification of wastewater is equally important.

Stepien et al. (2014) measured 1,4-dioxane concentrations in the influent and effluent of four domestic sewage treatment plants (STP) during 2012-2013. No removal of 1,4-dioxane by STP treatment was observed. The STPs all treated household sewage and indirect discharges from industries and served populations between 73 000 and 750 000. For three STPs, the average concentration of 1,4-dioxane in the influent was 0.262 – 0.516 µg/L and the concentrations in the effluents were comparable, showing that there was no removal of 1,4-dioxane. These three STPs used mechanical, biological, nitrification and phosphorus removal treatment techniques. For the fourth STP, the average concentration of 1,4-dioxane in the influent was 0.833 µg/L and the average effluent concentration increased dramatically to 62 µg/L. This STP used an additional denitrification treatment step and the increase in 1,4-dioxane was due to impurities in the methanol used in the postanoxic denitrification process.

Stepien et al. (2014) also investigated the efficiency of bank filtration. In 2012 and 2013, two drinking water treatment (DWT) facilities that utilise bank filtered surface water from the Rhine River for drinking water production were investigated for the presence of 1,4-dioxane. Sample collection of the DWT 1 was performed in 2012. A total of 11 water samples were obtained: 9 from multilevel wells, one raw water sample after bank filtration, and a drinking water sample. The raw water at the DWT 1, consisting of 75% bank filtration water and 25% groundwater from natural groundwater recharge, contained 670 ng/L of 1,4-dioxane. Once the water passed through the treatment process (ozonation, aeration, and a two-layer activated carbon filtration) the concentration decreased to 490 ng/L.

DWT 2 was sampled in 2013. One river sample, a raw water sample, and two drinking water samples were obtained. At the DWT 2, the concentration of 1,4-dioxane in the raw water sample (following ozonation, aeration, and gravel filtration) was 650 ng/L. Once the water passed through another filtration step with activated carbon, the average concentration of 1,4-dioxane dropped to 600 ng/L (n=2) in the drinking water. At the same time as the sampling in DWT 2, two Rhine River samples were obtained in which an average concentration of 1,4-dioxane of 770 ng/L was determined. These results demonstrate that neither bank filtration nor purification

of the raw water was capable of removing 1,4-dioxane significantly.

Röden et al. (2016) investigated the efficiency of 1,4-dioxane removal of bank filtration and filtering with activated carbon filters (Röden et al., 2016). The authors used a well-characterised bank filtration site at the lower river Rhine. Samples of river water (n=55) were taken from November 2014 to June 2015 and samples of bank filtrate (n=17) from January 2015 to September 2015. On average the river samples contained 0.6 µg/L and the bank filtrate samples 0.45 µg/L 1,4-dioxane, leading the authors to conclude that the substance is only marginally removed during subsurface passage.

To analyse the efficiency of a granular activated carbon filter the authors collected samples from the inlet (n=4) and outlet (n=4) of the granular activated carbon (GAC) filter at a DWT plant at lower Rhine region from January 2015 to June 2015. Concentrations of 1,4-dioxane in the influent to the activated carbon filter stage averaged 0.33 µg/L. In the effluent, only a marginally lower concentration with a somewhat smaller fluctuation range could be determined. The authors concluded that removal of 1,4-dioxane during activated carbon filtration does not occur in practice.

Carrera et al., 2019 investigated the efficiency of the Sant Joan Despí drinking water treatment plant in Catalonia, Spain (mouth of Llobregat river). The plant supplies drinking water to a population of more than three million people with an average production of 450,000 m<sup>3</sup>/day. Four seasonal sampling campaigns were carried out during 2015 to determine the removal efficiency at each treatment step including ozonation, granular activated carbon filters, ultrafiltration and reverse osmosis. The authors report a removal of 1,4-dioxane using ozonation by 32 ± 18%, GAC filtration by 12%, ultrafiltration by 4 – 9%, and reverse osmosis by 70 – 85% (Carrera et al., 2019).

Broughton et al, compares three different treatment technologies for removal of 1,4-dioxane from water (Broughton et al., 2019): advanced oxidation processes (AOPs), granular activated carbon (GAC), and synthetic media. AOPs were shown to be effective in reducing 1,4-dioxane in water. However, applying AOPs can result in the formation of various by-products. These reaction by-products might compete at the subsequent scavenging resulting in more energy consumption and the need for higher scavenger capacities and therefore higher operation and maintenance costs. Additionally, potentially toxic compounds might be formed in incomplete oxidation processes.

GAC was proven to be efficient at reducing high concentrations of 1,4-dioxane from 100s to 10 µg/L. Due to the chemical properties and GACs physical characteristics, the authors conclude that GAC filtration cannot achieve 1,4-dioxane concentrations below 10 µg/L.

For a synthetic adsorbent a high removal efficiency of 1,4-dioxane to concentrations below 0.04 µg/L is described. Further, the authors indicate, that no undesirable by-products are formed when using the synthetic adsorbent. The practical applicability was demonstrated in a single case study for remediation of contaminated groundwater in the U.S.

### 3.4. Data indicating potential for long-range transport

The intrinsic substance behaviour of mobility in aquatic environments is already evaluated in section 3.2. For deciding about the Long Range Transport Potential (LRTP) of a substance, different information can be used. This includes data about the overall half-life in the environment ( $P_{OV}$ ) and the characteristic travel distance (CTD). For decision making, whether 1,4-dioxane is capable to reach remote areas the OECD LRTP Tool (version 2.2; OECD 2009) was utilised.

The  $P_{OV}$  boundary is 195 days ( $P_{OV}$  of  $\alpha$ -HCH) and the LRTP boundaries are 5097 km (CTD of PCB 28) and 2.248 % (Transfer Efficiency, TE of PCB-28) as defined by Scheringer (Scheringer et al., 2009).

Since no information about degradation half-lives in each different environmental compartment is available from simulation studies, an estimate was undertaken by utilising the tables R.16-11 and R.16-12 from the REACH technical guidance R.16 (ECHA, 2016) for environmental exposure assessment. These tables provide half-lives for biodegradation in surface water, bulk soil and sediment respectively. The predicted half-lives are based on results of standardised (screening) tests on biodegradability.

Common to both applied tables, these do not provide any specific half-life values for substances concluded to be “not biodegradable” on the basis of screening biodegradation tests. Since no value equals “infinite” in the tables the guidance suggests to use various values for the prediction and provides information that the upper boundary for half-lives, that should be applied is 10,000 days (boundary of the inputs for the EUSES model).

Three different calculations were conducted. The first one is a ‘best-case’ calculation assuming that 1,4-dioxane is able to fulfil the criteria for being “inherently biodegradable”, although various information in section 3.1 shows this is not the case. The second calculation is expected to represent a ‘pragmatic worst-case’ for the substance being “not biodegradable” according to the results from screening tests only. For this calculation, the ‘best-case’ half-lives were multiplied with a factor of 10.

The last calculation (‘upper limit’) takes into account the degradation half-life (DegT<sub>50</sub>) extrapolated by SFO kinetics from the result of the OECD 309 test for the water compartment (please see discussion in section 3.1.2.1.3). Because no definite half-life could be derived from this test, the upper boundary from EUSES was applied as input value. The DegT<sub>50</sub> applied for soil is the upper boundary half-life for EUSES for pragmatic reasons too because applying this value in case of an unconfined upper DT<sub>50</sub> is widely accepted.

Input parameters being identical in all calculations have been: log K<sub>OW</sub> = -0.27 (see Table 3); distribution coefficient air-water log K<sub>AW</sub> = -3.69 (see section 3.2.2); degradation half-life in the atmosphere 13.7 h (see section 3.1.1.2.1).

Table 13: LRTP modelling

Scenario	DegT <sub>50</sub> (water) for calculation	DegT <sub>50</sub> (soil) for calculation	Characteristic travel distance	Overall half-life (P <sub>ov</sub> )	Transfer efficiency (%)
‘Best-case’: “inherently biodegradable”	150 days (extrapolated)	300 days (extrapolated)	298 km	173 days	0.069
‘pragmatic worst-case’: “not biodegradable”	1500 days (extrapolated)	3000 days (extrapolated)	1052 km	620 days	0.0730
‘upper limit’: DegT <sub>50</sub> (water) / “not biodegradable” (soil)	10000 days (extrapolated; upper limit of EUSES)	10000 days (extrapolated; upper limit of EUSES)	1384 km	820 days	0.0754

With an estimated atmospheric half-life of 13.7 hours the substance does not induce a concern for long range transport at screening level. Applying the overall half-life (P<sub>ov</sub>), 1,4-dioxane exceeds the corresponding boundary for POP substances (195 days), except for the ‘best-case’ calculation. The Characteristic Travel Distance (CTD) of 1,4-dioxane on the other hand only counts for about 27 percent of the threshold for a substance qualifying as POP, even when

assuming no degradation over a long period ('upper limit' calculation).

Bearing in mind the low tendency for volatilisation from water, data shows that the substance is capable to be transported over long distances in aquatic media and that it might be found far away from the point of release into the environment. In comparison the calculation for the abovementioned second case ('pragmatic worst-case') results in a CTD of 1052 km whereas the Rhine river has an official length of 1232.7 km<sup>10</sup>.

The OECD LRTP Tool also provides a graphical output for the relationship of the calculated values CTD and overall Persistency in the environment ( $P_{ov}$ ). The tool compares the outcome with the criteria for long range transport of POPs. In case the substance fits in the lower left sector of the graph, the substance clearly does not show POP-like behaviour. If the substance fits in the upper right sector, then it would show POP-like behaviour, whereas fitting into the two other remaining sectors would require further expert judgement but definitely showing potential for being transported over a longer distance from the point of emission to the place of final deposition. The graphical output of the three runs for 1,4-dioxane are provided in the three figures below.

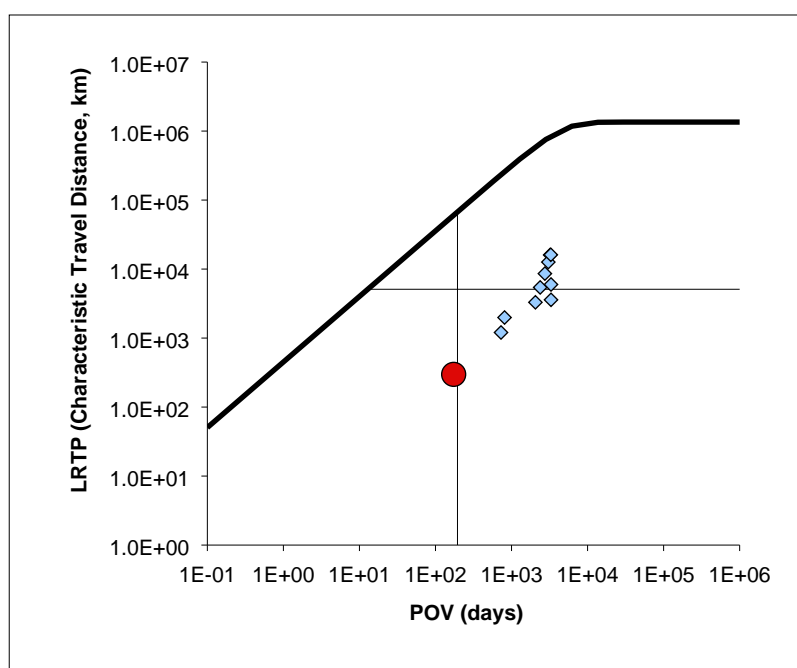


Figure 2: Graphical output for CTD of 1,4-dioxane assuming substance being "inherently biodegradable"; output in comparison to 'Generic PCB homologues'.

<sup>10</sup> According to the International Commission for the Hydrology of the Rhine basin, 2015.



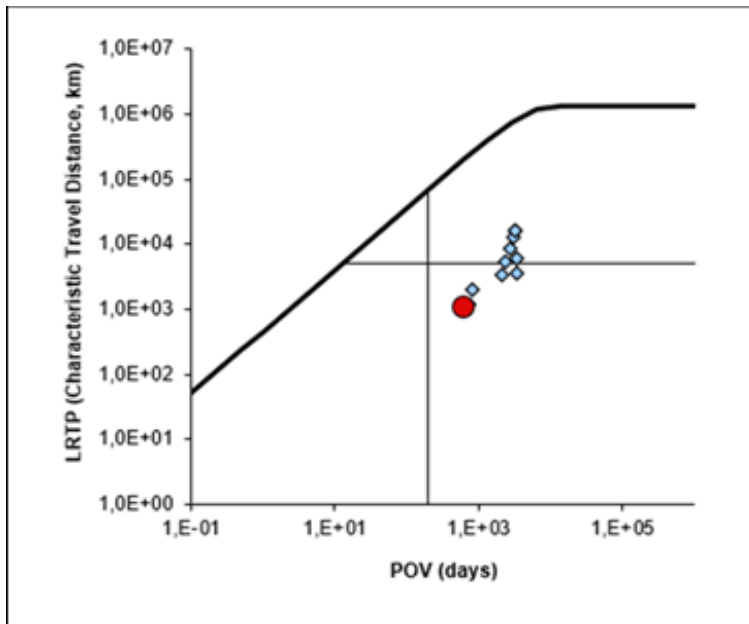


Figure 3: Graphical output for CTD of 1,4-dioxane assuming substance being "not biodegradable"; output in comparison to 'Generic PCB homologues'.

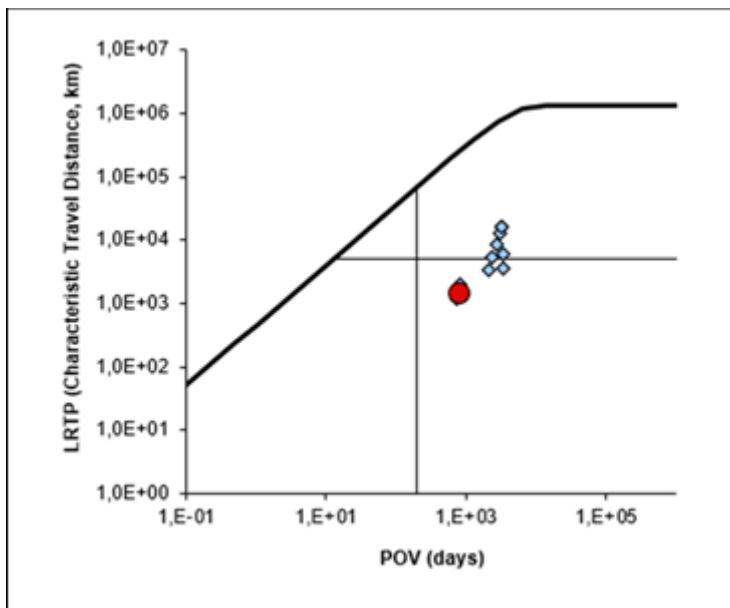


Figure 4: Graphical output for CTD of 1,4-dioxane for measured degradation half-life in water and estimated value for soil; output in comparison to 'Generic PCB homologues'.

When looking at Figure 2, 1,4-dioxane would be exactly at the threshold between "no POP-like behaviour" (lower left sector) and the potential for being transported in the environment over larger distances. In Figure 3 and Figure 4 the results of the calculations with the assumed degradation half-lives for "not biodegradable" and the estimate applying the EUSES upper half-life of 10,000 days in water and soil ('upper limit' calculation). In both cases the substance remains in the lower right sector.

Having in mind that the substance has a low tendency to volatilise from aqueous media due to the low Henry constant it can be concluded, that 1,4-dioxane will not necessarily follow the behaviour of the "classic" POPs which typically are "hoppers". For those "hoppers" the long-

range transport is the result of a repetitive process of volatilisation and deposition allowing them to reach remote areas.

Quite the contrary, it is noticeable that 1,4-dioxane seems to be able to travel more than 1000 km while predominantly staying in the water phase.

### *Summary*

Because of the substance's high water solubility, the low volatility from water and the low potential for adsorption, the water body is expected to be the dominant transport medium in the environment once the substance is released. In a worst-case approach the OECD tool for Long Range Transport Potential (LRTP) predicts a characteristic travel distance (CTD) of 1384 km together with an overall persistence ( $P_{ov}$ ) of 820 days for 1,4-dioxane. This prediction is based on the extrapolated biodegradation half-life of 10,000 days in the aquatic compartment (upper limit of respective EUSES input) and worst-case half-life of 10,000 days for environmental half-life in soil (upper limit of respective EUSES input). Even when considering this LRTP prediction as a rough and over-conservative estimate because no result from environmental simulation tests for biodegradation in soil are available as input parameter, the results indicate that 1,4-dioxane is capable to reach regions far away from the point of initial emission.

### 3.5. Bioaccumulation

#### 3.5.1. Bioaccumulation in aquatic organisms (pelagic and sediment organisms)

One study on bioaccumulation of 1,4-dioxane in *Cyprinus carpio* according to OECD Guideline 305C is available, utilising the data out of the European Risk Assessment Report for 1,4-dioxane (EU-RAR, 2002). According to this information in a flow-through study, individual *Cyprinus carpio* were tested with two concentrations of 1,4-dioxane for a period of 42 days. The test concentrations were 1 and 10 mg/L. Depending on the test concentration the BCF value in the EU-RAR ranges from 0.2 - 0.7 (mean BCF = 0.45; MITI, 1992), indicating that 1,4-dioxane is not bioaccumulative. However, study details are limited, e.g. duration of uptake phase and depuration were not reported.

#### 3.5.2. Bioaccumulation in terrestrial organisms (soil dwelling organisms, vertebrates)

No standard study on bioaccumulation of 1,4-dioxane or other cyclic ethers in terrestrial organisms are available.

#### 3.5.3. Field data

No field data on bioaccumulation of 1,4-dioxane or other cyclic ethers are available.

#### 3.5.4. Summary and discussion of bioaccumulation

According to the obtained BCF values bioaccumulation in fish is low. However, details on the study are lacking. The log  $K_{ow}$  of 1,4-dioxane was -0.27, indicating that the substance has a low bioaccumulation potential.

In conclusion, 1,4-dioxane is evaluated as not bioaccumulative.

## 4. Human health hazard assessment

Information on hazard to human health relevant for the identification of the substance as SVHC in accordance with Article 57 (a) of the REACH Regulation is provided in Section 2 of this report.

The classification as carcinogenic Carc. 1B; H350 is also of relevance for the assessment of 1,4-dioxane as a substance of very high concern according to Article 57 f), i.e. under the T-criterion of REACH Annex XIII; Section 1.1.3 b).

## 5. Environmental hazard assessment

Only studies are listed that are available in the registration dossier, on the ECHA dissemination site or in the European risk assessment report (EU-RAR, 2002). No study reports were available for the ecotoxicity studies. Unless otherwise stated the information presented in this SVHC dossier is taken from the registration dossier as published on the ECHA dissemination site<sup>7</sup>.

### 5.1. Aquatic compartment (including sediment)

#### 5.1.1. Fish

##### 5.1.1.1. Short-term toxicity to fish

There are several studies available about exposure of fish to 1,4-dioxane.

An acute test was conducted with the test organism *Menidia beryllina* (tidewater silversides), a salt water fish and testing duration of 96 h. No guideline was followed. The LC<sub>50</sub> was not reached at the highest test concentration of 320 mg/L (LC<sub>50</sub> is >320 mg/L (nominal), a theoretical LC<sub>50</sub> (by extrapolation) would be 6,700 mg/L, this value was given on the ECHA dissemination site and in the EU-RAR (EU-RAR, 2002). However, an extrapolation 20 times higher than the highest test concentration is not realistic.

A test similar to OECD 203 was conducted with *P.promelas* and a testing duration of 96 h. The LC<sub>50</sub> was 13,000 mg/L nominal. The test is also listed in the EU-RAR (EU-RAR, 2002).

A study with *P.promelas* and a testing duration of 96 h and an LC<sub>50</sub> of 10,800 mg/L (nominal) was reported. The method specified a special acute fish toxicity test system by the Center for Lake Superior Environmental Studies (University of Wisconsin-Superior). The test is also listed in the EU-RAR (EU-RAR, 2002).

Furthermore, there is a third acute test with *P.promelas* with an exposure duration of 96 h. The testing method is the same as in the test above. The LC<sub>50</sub> reported is 9,850 mg/L. The test is also listed in the EU-RAR (EU-RAR, 2002).

A prolonged toxicity test with *Oryzias latipes* (rice fish) according to OECD TG 204 is available. The testing duration is 21 days. The effect concentration is LC<sub>50</sub> >100 mg/L (nominal, analytically verified).

Seven more acute toxicity fish tests with several species, partly with testing duration lower than 96 h, are listed in the EU-RAR (EU-RAR, 2002) with effect values LC<sub>50</sub> > 100 mg/L.

##### 5.1.1.2. Long-term toxicity to fish

The chronic fish test was conducted according to an internal test method "ET-15-1987-1 Embryo-larval-toxicity test", equivalent to OECD 210. The test began with embryos of *Pimephales promelas*. The testing duration was 32 d in a flow-through design. Analytical verification of test concentrations showed that measured concentrations were in the range of 96 to 102% of the nominal concentration. The nominal//measured (mean) concentrations were: 150 mg/L//145 mg/L; 100 mg/L//99.7 mg/L; 65 mg/L//65.3 mg/L; 42 mg/L//40.3 mg/L; 27 mg/L//27.6 mg/L (sampling days for analytic: 0, 4, 5, 11, 15, 18, 22, 26, 29). No effects on hatching, day of hatch, number of deformed larvae, larvae survival and weight were seen. The NOEC is specified to be ≥145 mg/L (initially measured, however in the IUCLID the measured concentrations were specified to be mean concentrations). In the EU-RAR the NOEC for this test is reported to be >103 mg/L, recalculated from a "maximum acceptable toxicant concentration" (MATC/√2=NOEC), (EU-RAR, 2002).

## 5.1.2. Aquatic invertebrates

### 5.1.2.1. Short-term toxicity to aquatic invertebrates

The study was conducted according to OECD TG 202 with *D. magna* in a semi-static test and duration of 48 h. The EC<sub>50</sub> was >1000 mg/L (nominal, analytically verified). In the EU-RAR (EU-RAR, 2002) three other short-term toxicity tests with aquatic invertebrates are listed with EC<sub>50</sub> > 100 mg/L. Two of them only have a testing duration of 24 h.

### 5.1.2.2. Long-term toxicity to aquatic invertebrates

A test with *Ceriodaphnia dubia* according to guideline EPA-600/4-85-014 is available (EU-RAR, 2002). The testing duration is 7 d. The nominal concentrations are 625; 1,250; 2,500; 5,000; 10,000 mg/L in a semi-static test. Analytical monitoring is not specified. The NOEC is reported as 625 mg/L and the LOEC is 1,250 mg/L (nominal).

A *Daphnia magna* reproduction test according to OECD TG 211 was conducted with a duration of 21 d. No information about the testing regime is available (Japanese study). According to this study the NOEC is 1000 mg/L.

## 5.1.3. Algae and aquatic plants

A toxicity test on *Pseudokirchneriella subcapitata* was conducted according to guideline OECD 201 with a duration of 72 h. The ErC<sub>50</sub> was >1000 mg/L and the NOErC ≥ 1000 mg/L.

An alga test according to ISO 8692 with the test organism *Scenedesmus quadricauda* showed after 8 d testing duration an EC<sub>50</sub> of 5,600 mg/L (growth rate or biomass not specified), reported as toxic threshold concentration. This test was also reported in the European risk assessment report (EU-RAR, 2002).

Another algae test was conducted with the species *Scenedesmus quadricauda* with a testing duration of 8 days. The test result was an EC<sub>50</sub> of 575 mg/L (nominal) for biomass, reported as toxic threshold concentration (as the effect value only for biomass is given it was not further considered). This test was also reported in the European risk assessment report (EU-RAR, 2002).

## 5.1.4. Sediment organisms

No information on toxicity to sediment organisms were available.

## 5.1.5. Other aquatic organisms

No information on toxicity to other aquatic organisms were available.

## 5.2. Terrestrial compartment

### 5.2.1. Toxicity to terrestrial plants

A toxicity test on seed germination/root elongation using the species lettuce (*Lactuca sativa*) with duration of 3 d was conducted. A guideline was not followed and only this one species was tested. The substrate type was agar (0.5%). An EC<sub>50</sub> (1,450 mg/L) was determined for water. Since the proportion of agar in the test substrate was negligible, this value for water was multiplied with the factor for standard soil density of 1.5. The EC<sub>50</sub> was 2,175 mg/kg soil dw. The range of concentration tested was not specified. The test serves as basis for the endpoint summary at ECHA's dissemination website and is also reported in the European risk assessment report (EU-RAR, 2002).

### 5.2.2. Toxicity to soil micro organisms

No information on toxicity to soil micro-organisms were available.

### 5.2.3. Toxicity to terrestrial invertebrates

In the European risk assessment report (EU-RAR, 2002) information on a test with the pupae of the flesh fly *Sarcophaga crassipalpis* is available. 1,4-Dioxane (5 µL) was applied topically to the pupal cutical. No mortality appeared during diapause. Development and termination of the diapause was monitored based on the oxygen consumption. 32% of the organisms terminated the diapause prematurely. Out of these, 56% developed normally to adult insects. The EU-RAR referred to (Denlinger, 1980).

## 5.3. Atmospheric compartment

No information on hazards posed to the atmospheric compartment was available.

## 5.4. Microbiological activity in sewage treatment systems

The European Risk Assessment Report for 1,4-dioxane (EU-RAR, 2002) reports a 16h NOEC for *Pseudomonas putida* of 2,700 mg/L and a short-term respiration inhibition test with industrial activated sludge in which no effects were found up to a concentration of 2000 mg/L.

## 5.5. Toxicity to birds

No information on toxicity to birds were available.

## 5.6. Summary and discussion of toxic effects

On aquatic organisms effects were only observed at high concentrations >100 mg/L. The NOEC in a long-term toxicity test with aquatic invertebrates was 625 mg/L.

The T-criterion of REACH Annex XIII is considered to be fulfilled based on the RAC opinion concluding that 1,4-dioxane should be classified as Carc 1B. This classification was also included in the 17<sup>th</sup> ATP to CLP.

## 6. Conclusions on the SVHC Properties

### 6.1. CMR assessment

1,4-Dioxane is covered by index number 603-024-00-5 of Regulation (EC) No 1272/2008. Pursuant to Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 1,4-dioxane will be classified in the hazard class carcinogenicity category 1B (hazard statement H350: "May cause cancer")<sup>11</sup>.

### 6.2. PBT and vPvB assessment

Section is not relevant for the identification of 1,4-dioxane as SVHC in accordance with Article 57 (f) REACH.

### 6.3. Equivalent level of concern assessment

#### 6.3.1. Summary of the data on hazardous properties

##### 6.3.1.1. Persistency/Degradation

Abiotic degradation of 1,4-dioxane by hydrolysis and phototransformation in air and water is regarded as negligible. Screening tests regarding ready degradability show negligible mineralisation, even after an extended study period and utilisation of adapted inoculum. In other studies on degradation of 1,4-dioxane in water (Kim, 2007; Sei et al., 2010), no degradation of 1,4-dioxane was detected. This data demonstrates that the substance is to be evaluated as potentially persistent / potentially very persistent in water according to the screening criteria of REACH Annex XIII.

For degradation in soil, no studies following (or equivalent to) OECD test guidelines are available. In conclusion, based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions

On the basis of a surface water simulation test (Hofman-Caris and Claßen, 2020) showing no degradation of the substance within 60 days, the DT<sub>50</sub> of 1,4-dioxane is regarded to be over 60 days. This result confirms that the substance qualifies as very persistent in water according to the persistency criteria of REACH Annex XIII.

In overall conclusion and considering the available data on abiotic and biotic degradation, it is concluded that 1,4-dioxane is persistent and very persistent in the water compartment according to the criteria of REACH Annex XIII.

##### 6.3.1.2. Mobility in the environment

The substance is completely miscible with water (water solubility used for assessment = 1000 g/L) and has a log K<sub>OC</sub> of 0.85 (EU-RAR, 2002) indicating a low potential for adsorption on organic matter and clay minerals and a high water solubility. These intrinsic substance properties

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<sup>11</sup> Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 17<sup>th</sup> ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation compliance with this new harmonised classification applies from 17 December 2022. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.



indicate that the substance will partition primarily to the water compartment and will undergo environmental distribution via aqueous media, easily reaching groundwaters. The substance is regarded as mobile based on the intrinsic properties, water solubility and adsorption behaviour, together with the knowledge about potential for passing natural and technical barriers. The available monitoring data show that 1,4-dioxane has been detected in groundwater, surface water and drinking water in Europe.

#### 6.3.1.3. Decontamination and removal of 1,4-dioxane from the environment and from drinking water

Due to the preference for the aqueous phase in the environment, the most important compartment for 1,4-dioxane decontamination is water. 1,4-Dioxane is not readily removed with conventional water purification techniques. The high water solubility and low sorption potential of 1,4-dioxane make the substance mobile in water and also difficult to remove from water as it only has a low potential to adsorb to materials and prefers to remain in the water phase. This makes it difficult to remove from drinking water, contaminated groundwater, wastewater and industrial effluents. Elaborated measures, like advanced oxidation processes, subsurface heating, bio-/phytoremediation were applied in pilot studies on contaminated groundwater sites. The available methods to remove 1,4-dioxane from drinking water to lower human exposure to this carcinogen are expensive and energy intensive and are not common in drinking water plants.

#### 6.3.1.4. Potential for long-range transport via water

Because of 1,4-dioxane's high water solubility, low volatility from water and low potential for adsorption, water will be the dominant transport media in the environment once the substance is released. In combination with its long environmental half-life, there is a potential for widespread contamination of the water environment.

The OECD tool for Long Range Transport Potential (LRTP) predicts a characteristic travel distance (CTD) of 1384 km together with an overall persistence ( $P_{ov}$ ) of 820 days for 1,4-dioxane. This indicates that 1,4-dioxane is capable of reaching regions far away from the point of initial emission.

#### 6.3.1.5. Human Health effects

The Risk Assessment Committee (RAC) has concluded that 1,4-dioxane fulfils the criteria for classification as carcinogenic Carc. 1B. This classification was also included in the 17th ATP to CLP<sup>12</sup> and is of relevance for the assessment of 1,4-dioxane as a substance of very high concern according to Article 57 (f), i.e. under the T-criterion of REACH Annex XIII; Section 1.1.3 b).

### 6.3.2. Concerns arising from the substance properties

#### 6.3.2.1. Concern for an irreversible and increasing presence in the environment

The properties of 1,4-dioxane of persistency, mobility and potential for being transported in the water phase over long distances lead to an irreversible presence in the environment and in particular cause contamination of the aquatic environment.

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<sup>12</sup> Commission Delegated Regulation (EU) 2021/849 of 11 March 2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (the 17th ATP to CLP). Pursuant to the second paragraph of Article 2 of this Regulation compliance with this new harmonised classification applies from 17 December 2022. However, pursuant to the third paragraph of that provision substances and mixtures may already be classified, labelled and packaged in accordance with this classification.

Due to the lack of abiotic and biotic degradation potential of 1,4-dioxane and typically a co-presence of substances being degradable more easily, it is expected that there is no removal by the sewage treatment plants and the overall amount of 1,4-dioxane releases to the environment is not reduced in sewage treatment plants.

A study by Stepien et al. (2014) investigated the removal of 1,4-dioxane from waste water in four sewage treatment plants. These plants received between 30% and 50% waste water from indirect industrial emitters. In none of them there was any relevant decrease of the 1,4-dioxane concentration observed in the effluent, when compared with the corresponding influent concentrations. In contrast, in one sewage treatment plant, concentration of 1,4-dioxane in the effluent was 100 times higher than in the influent.

No information is available from studies that specifically investigate the degradation of 1,4-dioxane in industrial sewage treatment plants, which in general receive a mixture of various chemicals, too. A screening test on inherent biodegradation (OECD TG 302B) utilizing inoculum from an industrial sewage treatment plant showed removal of the substance from the test media (DOC monitoring), but this was a side effect of stripping the test vessels to determine the oxygen demand. Therefore, no evidence is available that biodegradation is a relevant step for removing 1,4-dioxane from waste water. Only those techniques which are also applied for drinking water purification seem to have some capacity to reduce the release of the substance into the environment (please see section 6.3.2.2).

Monitoring programs show a constant, if not increasing, contamination of surface waters in Europe. As explained in chapter 3.2.4, background concentrations above the limit value derived at the European River Memorandum (ERM) of 0.1 µg/L are exceeded in areas of the rivers Rhine, Main, Lech and Oder. In a monitoring campaign done in Bavaria in the year 2016, surface water of the rivers Lech and Inn were analysed for their 1,4-dioxane concentrations. In the study concentrations up to 5.5 µg/L and 4.9 µg/L were found, respectively. The concentration in the rivers seems to increase with increasing anthropogenic influence on the water quality of the rivers by discharges.

1,4-Dioxane is reported in groundwaters sampled in Germany, Belgium and Spain at concentrations between 0.04 µg/L and 241 µg/L.

Due to the global water cycle and the fact that the aqueous compartments are all well connected, the high persistency and the high mobility of 1,4-dioxane lead to long distance transport processes in the environment. The properties of 1,4-dioxane of high persistency and mobility are likely to cause a transport across water bodies to pristine oceans and groundwaters raising the concern that any effects caused by the substance might also occur at remote locations from the origin of release.

Some studies show, that isolated bacteria strains which can be found in the soil of contaminated sites have the potential to degrade 1,4-dioxane under very specific, artificial conditions. However, REACH aims for a high level of environmental protection. Therefore, it cannot be expected that microorganisms already have the enzymatic ability, nor them being able to adapt to the substance to degrade it within a reasonably short time frame, so that an increasing presence in the environment does not result.

#### 6.3.2.2. Decontamination of 1,4-dioxane from the environment and from drinking water resources

It is known that it is difficult to remove 1,4-dioxane from the water cycle. Studies described by Röden et al. (2016) and Stepien et al. (2014), analysed the behaviour of 1,4-dioxane during river bank filtration and filtration with activated carbon at the drinking water production facility. The analysis showed that only a small portion of 1,4-dioxane is removed via river bank filtration and filtration with activated carbon does not remove the substances from water.

Four seasonal sampling campaigns were carried out over a year to determine the removal efficiency of the dioxanes and dioxolanes at each step of a drinking water treatment process including ozonation, granular activated carbon filters (GAC filters), ultrafiltration and reverse osmosis treatments were carried out in Spain. The authors report a removal of 1,4-dioxane using ozonation by  $32 \pm 18\%$ , GAC filtration by 12%, ultrafiltration by 4 – 9%, and reverse osmosis by 70 – 85% (Carrera et al., 2019).

Although some techniques have been shown to reduce 1,4-dioxane concentrations in a drinking water treatment plant, it should be noted that these techniques are not commonly used and are highly energy demanding.

Elaborate measures, like advanced oxidation processes, subsurface heating, bio-/phytoremediation were applied in pilot studies on contaminated groundwater sites. Further, evidences for natural attenuation of 1,4-dioxane on groundwater under specific conditions (e.g. presence of chlorinated solvents, THF, aerobic conditions) have been provided. These methods, procedures and processes are resource-intensive or only happen under specific conditions. Therefore any contamination of any potential drinking water resource with 1,4-dioxane needs to be avoided proactively.

#### 6.3.2.3. Human Health effects

Water is used for drinking and cooking each day and it is the basis of all food over the whole life of humans. According to the German Association for Nutrition (DGE) the water intake for adolescents and adults is approximately 1500 mL per day (DGE, 2020). Furthermore 1,4-dioxane can also be taken up by inhalation, for example when showering. This substance is classified as carcinogenic for humans (Carc. 1B), that is why its presence in drinking water is of high concern.

#### 6.3.2.4. Societal concern

Article 7.3 of the Water Framework Directive (2000/60/EC) stipulates that "Member States shall ensure the necessary protection for the bodies of water identified with the aim of avoiding deterioration in their quality of water to reduce the level of purification treatment required in the production of drinking water." Due to its mobility and persistence, 1,4-dioxane is found in surface water, groundwater and produced drinking water. Decontamination can only be achieved at high societal costs, if at all. Furthermore, 1,4-dioxane is carcinogenic for humans who will be exposed via consumption and use of drinking water. Consequently, there is societal concern for the presence of 1,4-dioxane in drinking water that requires immediate action.

#### 6.3.2.5. Continuous presence in water results in continuous exposure of humans and environment

The presence of 1,4-dioxane in surface waters is expected to predominantly result from releases from sewage treatment plants into receiving water because the techniques applied in sewage treatment plants are not capable to remove 1,4-dioxane from the waste water due to its high persistency and low adsorption potential.

As explained in section 3.4 the characteristic travel distance (CTD) of 1,4-dioxane calculated with the OECD LRTP tool is 1384 km with a  $P_{ov}$  of 820 days. Even when not fulfilling CTD of POPs

because 1,4-dioxane predominantly remains in the water phase instead of being subject to a repeated process of volatilisation and deposition, it is clear from this estimate that 1,4-dioxane is capable to reach regions far away from the point of initial release by aqueous distribution, for example via surface waters.

The use of surface water as a source for drinking water production is not uncommon. The application of this raw water source depends on the local conditions, for example a lack of ground water in areas with karst geohydrology or the need for deep injection for the purpose of groundwater infiltration. Due to the substance's intrinsic lack of degradability and lack of adsorption potential, 1,4-dioxane is capable to permeate bank filtration (direct use in case of bank filtration) and soil horizons (indirect use in case of deep injection). This hypothesis is confirmed by field data as presented in section 3.2.4.

As explained in section 3.2.4., the various standard purification techniques do not affect the residual concentration of 1,4-dioxane in drinking water at the end. By using surface water as raw water sources directly or indirectly and due to the continuous presence of 1,4-dioxane in those, the drinking water purification installations are continuously stressed due to the difficulty and costs of decontamination and remediation techniques.

If release of 1,4-dioxane to the environment continues, the concentration of 1,4-dioxane in groundwater and surface water (both drinking water resources) may increase over time due to high persistency. Data show that after release to the environment 1,4-dioxane reaches the drinking water. Humans could be exposed to 1,4-dioxane over their whole life which is of high concern, as the substance is classified as a carcinogen category 1B. For these reasons, the release of 1,4-dioxane to the environment should be prevented.

#### 6.3.2.6. Concern for yet unknown effects and inability to derive a safe concentration in the environment

Once 1,4-dioxane is in the environment, it is hard to remove due to high persistency and the lack of natural removal processes. Contaminated areas might be sources of continued releases into the environment long after phase-out of 1,4-dioxane and the high mobility of 1,4-dioxane leads to wide distribution in the water body. These substance properties raise the concern of yet unknown effects on the environment that were not observed in the standard toxicity tests or may only develop after life-long exposure.

Indeed, the concern for effects that may emerge only after lifetime exposure is part of the concern for PBT/vPvB substances. ECHA Guidance R11, page 11 states "vPvB substances are characterised by a particular high persistence in combination with a high tendency to bioaccumulate, which may, based on experience from the past with such substances, lead to toxic effects and have an impact in a manner which is difficult to predict and prove by testing, regardless of whether there are specific effects already known or not."

The same concern applies for 1,4-dioxane. Due to its high persistence, it will remain in the environment for a long time and due to its high water solubility and low adsorption potential, it will remain in the water compartment and be bioavailable for uptake by wildlife or humans.

Furthermore, environmental concentrations will inevitably increase with continued release. However, there are currently no test systems available that are capable of detecting effects which may appear in long-living wildlife only after lifelong (i.e. potentially decades of) exposure. Additionally mixture effects with other stressors are possible resulting in higher synergistic or additive toxicity of the substances. In addition, due to the high persistence and low adsorption potential (which prevents decreasing bioavailability of the substance over time by sorption to particles and sedimentation) the environmental concentrations will rise with continued emissions and may sooner or later reach exposure levels sufficient to trigger the already identified severe effects but potentially also further adverse effects which are not currently known.

Hence, high persistence in combination with low adsorption potential and high water solubility is in terms of the associated risks for human health and the environment comparable with vPvB

properties of a substance in that there are the same difficulties to cease exposure and remove the substances from the environment. Further, there are the same difficulties to quantify with sufficient certainty the development of exposure in the long-term and the related risks, as for PBT/vPvB substances.

Humans are exposed via contamination of the environment. Therefore it is a basic objective to protect the environment. As explained above, exposure of humans will proceed long after cessation of emissions, hence posing an irreversible threat to future generations and illustrating the need to act now. Furthermore, other long-term effects on humans may be detected after low-level, long-term exposure in drinking water. Due to persistency of the substance, intergenerational effects may be possible. Drinking water protection requires protection of the water sources. For these reasons a safe concentration of 1,4-dioxane cannot be derived and a quantitative risk assessment cannot be performed.

### 6.3.3. Equivalent level of concern assessment

The level of concern is considered very high in particular due to the combination of the following concern elements:

- Concern for an irreversible and increasing presence in the environment, in particular in the aquatic environment
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B and is included in the 17<sup>th</sup> ATP to CLP
- High societal concern for the presence of 1,4-dioxane in drinking water sources
- Continuous presence in water results in continuous exposure of humans and environment
- Yet unknown environmental and human health effects

### 6.3.4. Conclusion on hazard properties and ELoC assessment

1,4-Dioxane is identified as substance of very high concern according to Article 57(f) of regulation 1907/2006 (REACH) due to scientific evidence of probable serious effects to the environment and human health (man via environment). The scientific evidence gives rise to an equivalent level of concern to substances covered by Article 57 (a) to (e).

#### *Intrinsic properties*

Abiotic degradation of 1,4-dioxane by hydrolysis and phototransformation in air and water is regarded as negligible. For degradation in soil, no studies following (or equivalent to) OECD test guidelines are available. In conclusion, based on the weight of evidence, the degradability of 1,4-dioxane is considered to be relatively low in soils under relevant environmental conditions. Degradation of 1,4-dioxane was investigated in surface water according to OECD TG 309, showing no degradation of the substance. Therefore, the degradation half-life of 1,4-dioxane is obviously higher than 60 days. Considering the data on abiotic and biotic degradation, 1,4-dioxane is considered to fulfil the P/vP criteria (half-life in water >60 days) of REACH Annex XIII.

The substance is completely miscible with water (water solubility used for assessment = 1000 g/L) and has a log  $K_{oc}$  of 0.85 indicating a low potential for adsorption on organic matter and clay minerals. These intrinsic substance properties lead to a high mobility in water. Additionally, the intrinsic substance properties indicate that the substance will partition primarily

to the water compartment and will undergo environmental distribution via aqueous media, easily reaching groundwaters.

The high water solubility and low sorption potential of 1,4-dioxane make the substance difficult to remove from water as it only has a low potential to adsorb to materials and prefers to remain in the water phase.

Because of 1,4-dioxane's high water solubility, low volatility from water and low potential for adsorption, water will be the dominant transport media in the environment once the substance is released. In combination with its long environmental half-life, there is a potential for widespread contamination of the water environment.

The OECD tool for Long Range Transport Potential (LRTP) predicts a characteristic travel distance (CTD) of 1384 km together with an overall persistence ( $P_{ov}$ ) of 820 days for 1,4-dioxane. This indicates that 1,4-dioxane is capable of reaching regions far away from the point of initial emission.

The Risk Assessment Committee (RAC) has concluded that 1,4-dioxane fulfils the criteria for classification as carcinogenic Carc. 1B. The classification has been included in the 17th ATP to CLP. This classification is of relevance for the assessment of 1,4-dioxane as a substance of very high concern according to Article 57 (f), i.e. under the T-criterion of REACH Annex XIII; Section 1.1.3 b).

#### *Concerns arising from the substance properties*

Available information on persistency, mobility and potential for being transported in the water phase over long distances of 1,4-dioxane, gives rise to the concern, that once the substance is released to the environment, the contamination will hardly be reversible. This assumption is supported by a study that analysed the behaviour of 1,4-dioxane during river bank filtration and filtration with activated carbon at the drinking water production facility. The analysis showed that only a small portion of 1,4-dioxane is removed via river bank filtration and filtration with activated carbon. The result indicates, that the substance will not be removed from water by these purification techniques, which is generally applied across Europe. Furthermore, a temporal and spatial distribution from the point of release is to be considered. It needs to be considered that as long as 1,4-dioxane is released to the environment, the environmental levels might increase.

The concern raised by 1,4-dioxane is triggered by individual properties as well as by combination of its properties. Persistence and mobility allow the substance to be dispersed far beyond the sites of release via transport in the water environment. The substance stays in the environment even if releases of the substance have already ceased, as can be concluded from the substance properties and the recurring findings in groundwater samples. The persistency, mobility and toxicity (carcinogenicity) and in addition the irreversibility of the contamination of the aquatic compartment compromise the quality of drinking water resources.

The substance properties and the irreversibility of the contamination give rise to the concern of increasing exposure to wildlife and man via environment due to contaminated water.

The very high persistency and its mobility result in an increasing pollution of the aquatic environment. 1,4-Dioxane is difficult to remove once emitted to the aquatic environment. 1,4-Dioxane poses a threat to the resources of our drinking water, as due to its persistency and mobility, 1,4-dioxane can bypass river bank filtration and filtration with activated carbon, raising the concern of a continuous exposure of humans via drinking water. Any remediation efforts of contaminated drinking water resources will cause high costs to society. As the substance is very mobile causing a rapid distribution from the point source, remediation measures become even more difficult. Furthermore, 1,4-dioxane is carcinogenic and humans will be exposed to it via consumption and use of drinking water. Consequently, there is societal concern due to the presence of 1,4-dioxane in drinking water that requires immediate action. The environment

provides natural drinking water sources, whose integrity needs to be ensured for future generations.

Due to the properties of 1,4-dioxane (persistence, mobility, potential for being transported in the water phase over long distances and carcinogenicity) it is not possible to derive a safe concentration limit for the environment. Monitoring data demonstrate the presence of 1,4-dioxane in surface water, groundwater and even drinking water across the globe. Sources of emission in the vicinity are seldom apparent.

The substance properties like persistence and mobility suggest that the substance might pose a risk on a global scale. It follows that human health and the environment might be affected by 1,4-dioxane on a global scale.

A supporting concern is that although available aquatic studies do not show effects or only at high concentrations, no information is available about other effects to the environment, e.g. on ecotoxic effects to non-model species. Therefore, the substance properties raise the concern of yet unknown effects on the environment.

#### *Equivalent level of concern*

The level of concern is considered very high in particular due to the combination of the following concern elements:

- Concern for an irreversible and increasing presence in the environment, in particular to the aquatic environment
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B and is included in the 17<sup>th</sup> ATP to CLP
- High societal concern for the presence of 1,4-dioxane in drinking water sources
- Continuous presence in water results in continuous exposure of humans and environment
- Yet unknown environmental and human health effects

#### *Conclusion*

Although the carcinogenic properties of 1,4-dioxane alone are sufficient to assess it as a substance of very high concern, it is the combination of its substance properties causing higher concern to the environment and human health (man via environment). The combined intrinsic properties which demonstrate scientific evidence of probable serious effects to human health and the environment and which give rise to an equivalent level of concern are the following: very high persistence, high mobility in water, potential for being transported in the water phase over long distances, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity and yet unknown environmental effects. Together, these elements lead to a very high potential for irreversible effects.

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