Annex XV report

PROPOSAL FOR 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

Submitted by: Germany

Date: 2 March 2021

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TABLES

ABBREVIATIONS:

c_{max}	maximum concentration
CAKE	Computer Assisted Kinetic Evaluation
D_{OC}	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-trichloroehtene
TCE	trichloroethylene
VHC	volatile chlorinated hydrocarbon

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- It is proposed to identify the substance 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

1,4-Dioxane is proposed to be 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 (men 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, 1,4-dioxane is evaluated as not capable to undergo noticeable biodegradation in soil under environmentally relevant conditions. Degradation of 1,4-dioxane was investigated in surface water according to OECD 309 TG, resulting in a calculated DT_{50} (SFO) ≥10,000 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 2917 km together with an overall persistence (P_{ov}) of 1771 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 draft 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 long range transport 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. 1,4-Dioxane was not removed from water. 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 compromises 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 men 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.

Due to the properties of 1,4-dioxane (persistency, mobility, long-range transport 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.

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 and humans 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.

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, keeping also in mind the classification as Carc. 1B. Long term effects of the substance at low levels are possible but unknown, yet.

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
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- Potential for irreversible and increasing contamination of surface water and groundwater
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B
- 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
- Long-term effects are unknown

Conclusion

Although the carcinogenic properties of 1,4-dioxane alone would be 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 (men 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 long-range transport in water, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity. Together, these elements lead to a very high potential for irreversible effects.

Registration dossiers submitted for the substance? Yes

PART I

Justification

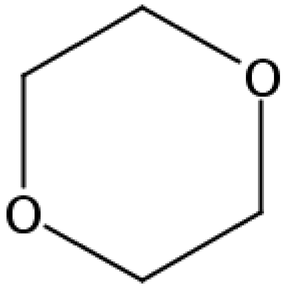
1. Identity of the substance and physical and chemical properties

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:	$C_4H_8O_2$
Molecular weight range:	88.12 g/mol
Synonyms:	*p-Dioxane,* *1,4-Diethylene dioxide*

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
1,4-dioxane *EC number 204-661-89*		≥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	*Data from data base and ATSDR report*	*Colourless liquid*	*ATSDR 2012; Gestis data base*
Melting/freezing point	*handbook data*	*11.8°C at 1013 hPa*	*O'Neil MJ. 2001. Dioxane. In: The Merck index. An encyclopedia of chemicals, drugs, and biologicals. Whitehouse Station NJ: Merck & Co., Inc.,* *(referenced in ATSDR 2012)*
Boiling point	*handbook data*	*101.1°C at 1013 hPa*	*O'Neil MJ. 2001. Dioxane. In: The Merck index. An encyclopedia of chemicals, drugs, and biologicals. Whitehouse Station NJ: Merck & Co., Inc., (referenced in ATSDR 2012)*
Vapour pressure	*handbook data*	*38.1 mm Hg, 50.8 hPa at 25°C*	*Daubert TE, Danner RP. 1985. 1,4-Dioxane. In: Physical and thermodynamic properties of pure chemicals. New York, NY: Taylor & Francis. (referenced in ATSDR 2012)*
	measured	*35.6 mm Hg at 25°C; 47.5 hPa*	*Francesconi R., Comelli F., J. Chem. Eng. Data, Vol. 33, No.2, p. 80 - 83, 1988*
Density	*handbook data*	*relative density 1.03*	*O'Neil MJ. 2001. Dioxane. In: The Merck index. An encyclopedia of chemicals, drugs, and biologicals. Whitehouse Station NJ: Merck & Co., Inc., (referenced in ATSDR 2012)*
Water solubility	*measured*	*miscible;* *for assessments in coherence with registration data a water solubility of 1000 g/L at a temperature of 25°C is assumed*	*Riddick JA, Bunger WB, Sakano TK. 1986. 1,4-Dioxane. In: Organic solvents. Physical properties and methods of purification. New York, NY: John Wiley & Sons, 312, 938. (referenced in ATSDR 2012)*
Partition coefficient n-octanol/water (log value)	*estimated*	*log* K_{ow} *-0.27* *(temperature not known)*	*Hansch C, Leo A, Hoekman D. 1995. Exploring QSAR: Hydrophobic, electronic, and steric constants. Washington, DC: American Chemical Society. (referenced in ATSDR 2012)*
Partition coefficient organic carbon / water K_{OC} (log value)	*estimated*	*log Koc 0.85*	*EU RAR, 2002*
Partition coefficient air / water K_{AW} (log value)	*estimated*	*-4.1*	*Own calculation, see section 3.2.2.*

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 GHS08 GHS07 Dgr	H351	EUH019 EUH066		
				Eye Irrit. 2	H319		H319			
				STOT SE 3	H335		H335			
				Flam. Liq. 2	H225		H225			

New classification:

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

Table 5: Classification according to the draft 17th 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 GHS08 GHS07 Dgr	H350	EUH019 EUH066		
				Eye Irrit. 2	H319		H319			
				STOT SE 3	H335		H335			
				Flam. Liq. 2	H225		H225			

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[1] https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18075db7f; date of access: 28.01.2021

[2] https://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=729&dspLang=en&basdatedeb=&basdatefin=&baspays=EU&basnotifnum=&basnotifnum2=&bastypepays=&baskeywords; date of access: 28.01.2021

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[3].

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, $0.5x10^6$ OH/cm^3, 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 $1x10^6$ OH/cm^3. Fast degradation of 1,4-dioxane in the presence of hydroxyl radicals (initial H_2O_2 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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[3] 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, 2017) 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 very small size of the molecule, which causes the (low) molecular weight parameter in the BIOWIN equation. This strongly influences the degradation prediction, because low molecular weight is considered to be easier biodegradable then high molecular weight. Furthermore, the contribution of the aliphatic ether fragment could be an explanation for the result "readily biodegradable" (Biowin6). In Biowin2 and 3 this fragment is rated negative (aliphatic ether is considered to make biodegradation slower), but in the Biowin6, this fragment has a positive contribution, meaning that the aliphatic ether is in this model considered to improve biodegradability. However, as explained above in general the aliphatic ether bonds are considered to be difficult to biodegrade in the literature, making the reliability of the Biowin6 prediction (readily biodegradable) questionable.

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 1,4-dioxane, degradation of the test compound amounted to <10% (O_2 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 and applying enhanced conditions (prolonged test duration) at an initial concentration of 37.1 mg/L shows <5% mineralisation (CO_2 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. Measurement of the oxygen demand suggests that decline in 1,4-dioxane concentration is based on elimination. The reliability of the data is considered to be limited. From these results it is concluded that the substance is not inherently biodegradable.

In a test on the toxicity of 1,4-dioxane to microorganisms using activated sludge according to test guideline DIN 38412-8 (bacterial inhibition test with *Pseudomonas*), EC_{10} 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.

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.

Using waste water, the concentration of 1,4-dioxane (initial concentration 100 mg/L) did not decline within 24 hours of incubation (Klečka and Gonsior, 1986), indicating that no degradation occurs.

In a study (Hofman-Caris and Claßen, 2020) according to OECD 309 TG, 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. 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. 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 (k1) followed by a slow phase (k2). The half-life (DT_{50}) of 1,4-dioxane was calculated to be as follows (Table 6):

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	Visual fit
SFO	>10,000	7%	good
DFOP	$DT_{50\ k1}$=0.584 $DT_{50\ k2}$=>10,000	9%	medium

HS	$DT_{50\ k1}$=86.1 $DT_{50\ k2}$=>10,000	9%	medium
FOMC	Not applicable as no visual assessment of the fit and residuals as well as estimation of the error percentage was possible.		

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 general, soil microbes at contaminated sites are considered to be incapable of degrading 1,4-dioxane under ambient conditions (Lesage et al., 1990).

In a study using soil microcosms (Kelley et al., 2001), 1,4-dioxane was not degraded during a period of 120 days. The microcosms 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, no degradation of 100 mg/L 1,4-dioxane within 39 days of incubation was detected (Sei et al., 2010).

In a study with ^{14}C-1,4-dioxane at a concentration of 10 mg/kg soil, 3-8% of the applied radioactivity were converted to $^{14}CO_2$ 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 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).

Some non-standard studies with isolated soil bacteria in pure or mixed culture from different locations indicate some potential for biodegradation of 1,4-dioxane (Bernhardt and Diekmann, 1991; Burback and Perry, 1993; Inoue et al., 2016; Parales et al., 1994; Pugazhendi et al., 2015; Sales et al., 2013; Sei et al., 2013; Sock, 1993). However, not all of these studies investigated the identity of the degradation products – only the disappearance of the parent compound was analysed. Therefore, it is not clear whether the decrease in 1,4-dioxane concentration was caused by dissipation or degradation of the parent compound.

The 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 co-metabolic degradation (test material analysis) in a relatively short period. However, the results of this study do not allow extrapolation to degradation under environmental conditions due to the lack of degradation when no tetrahydrofuran is added, 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, 1,4-dioxane is evaluated as not capable to undergo noticeable biodegradation in soil under environmentally relevant conditions.

3.1.2.3. Summary and discussion on biodegradation

Based on the lack of any primary degradation in water as shown in the screening tests available and other studies on biodegradation and the very high DT_{50} value of 1,4-dioxane in surface water, it is concluded that the biodegradation of 1,4-dioxane in the aquatic environment is very slow or negligible.

For the soil compartment, based on the weight of evidence, 1,4-dioxane is evaluated as not capable to undergo noticeable biodegradation in soil under environmentally relevant 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.

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. This data demonstrates that the substance is potentially persistent / potentially very persistent according to the screening criteria of REACH Annex XIII.

On the basis of the observed lack of any primary degradation in water (Kim, 2007; Klečka and Gonsior, 1986; Sei et al., 2010) and soil (Kelley et al., 2001; Sei et al., 2010), there is already very strong evidence, that the substance might be rated to be persistent or even very persistent in water and soil. This hypothesis was confirmed by the very high DT_{50} (SFO) ≥10,000 days of 1,4-dioxane in a surface water simulation test with surface water (Hofman-Caris and Claßen, 2020). This result confirms that the substance qualifies as very persistent in water according to the persistency criteria of REACH Annex XIII.

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

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 acc. 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).

DiGuiseppi 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 was 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] (@12 °C)	1890
MOLW	Molecular weight	[g/mol]	88.12
SOL$^{(*)}$	Water solubility	[g/L] (@12 °C)	891.2
HENRY	Henry's law constant	[Pa*m^3/mol] (@12 °C)	0.187

$^{(*)}$ 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.

With a Henry's Law constant of 0.187 Pa*m^3/mol the substance qualifies as moderately volatile from water at the averaged European temperature of 12 °C. The uncertainty for this result by applying temperature correction for the input parameters is expected to be negligible. Commonly, slightly volatile substances are defined by falling below the threshold of 0.1 Pa*m^3/mol, whereas highly volatile substance are expected to exceed the threshold of 100 Pa*m^3/mol, as reported in OECD TG 309 "Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test".

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:

$$K_{AW} = \frac{HENRY}{R * T} = -4.1 \text{ (displayed here as log } K_{AW}\text{)}$$

with R being the gas constant (8.314 Pa*m^3*mol^{-1}*k^{-1}) and T the temperature at the air-water interface (285 K).

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	0.8
to water	99.1
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)

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	0.4
Water	18.8
Soil	80.8
Sediment	0.036

Table 10: Initial release to water only

	Mass amount (percent)
Air	0.12
Water	99.7
Soil	0.034
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	2.65
Water	44.7
Soil	52.6
Sediment	0.087

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. This log K_{OC} is far below the proposed vM criteria (log $K_{OC} \leq 3$; Neumann and Schliebner (2019)), suggesting that 1,4-dioxane is very mobile in the environment.

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 µg/L (c_{max} = 0.58 µg/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 µg/L to 2.05 µg/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 m^3/day. The authors reported an average concentration of 1,4-dioxane in finished drinking water of 1062 ± 923 ng/L between March 2016 and January 2018, with a maximum value of 4356 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[4]. The substance was detected in 21% of the 4864 public water systems (PWS) and exceeded the health-based reference concentration (0.35 µg/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 µg/L to 1.5 µg/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 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[5] 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

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[4] https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule

[5] Flemish public service authority with responsibility for aspects of circular economy policies and monitoring the soil quality in Flanders.

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 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 0.187 $Pa*m^3mol^{-1}$ at the European annual average temperature of 12 °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^3/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 CAG 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 decision making, whether 1,4-dioxane is capable to reach remote areas the OECD LRTP Tool (version 2.2; OECD 2009) was utilised.

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 being “not biodegradable”. 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-life in the EUSES model is 10,000 days.

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. The last one utilises the DegT(50) determined from the result of the OECD 309 test for the water compartment, whereas the DegT(50) applied for soil is the upper boundary half-life for EUSES because applying this value in case of an unconfined upper DT_{50} is widely accepted.

Input parameters being identical in all calculations have been: log K_{OW} = -0.27 (see Table 3); distribution coefficient air-water log K_{AW} = -4.1 (see section 3.2.2); degradation half-life in the atmosphere 13.7 h (see section 3.1.1.2.1). It needs to be mentioned that the degradation half-life for water used in the worst-case scenario LRTP modelling is much lower than an experimentally determined DT_{50} > 10,000 days obtained in a simulation test according to OECD 309 (detailed in 3.1.2.1.3).

Table 13: LRTP modelling

Scenario	DegT50(water) for calculation	DegT50(soil) for calculation	Characteristic travel distance	Overall half-life (P_{ov})	Transfer efficiency (%)
“inherently biodegradable”	150 days (extrapolated)	300 days (extrapolated)	335 km	195 days	0.078
“not biodegradable”	1000 days (extrapolated)	3000 days (extrapolated)	1420 km	841 days	0.081

DegT50(water) / “not biodegradable” (soil)	10000 days (measured; OECD 309)	10000 days (extrapolated; upper limit of EUSES)	2917 km	1771 days	0.086

The P_{OV} boundary is 195 days (P_{OV} of α-HCH) and the LRTP boundaries are 5097 km (CTD of PCB 28) and 2.248 % (TE of PCB-28).

It seems that the overall persistence (P_{ov}) of 1,4-dioxane is comparable to POP substances.

The OECD LRTP Tool also provides a graphical output for the relationship of the calculated values Characteristic Travel Distance (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.

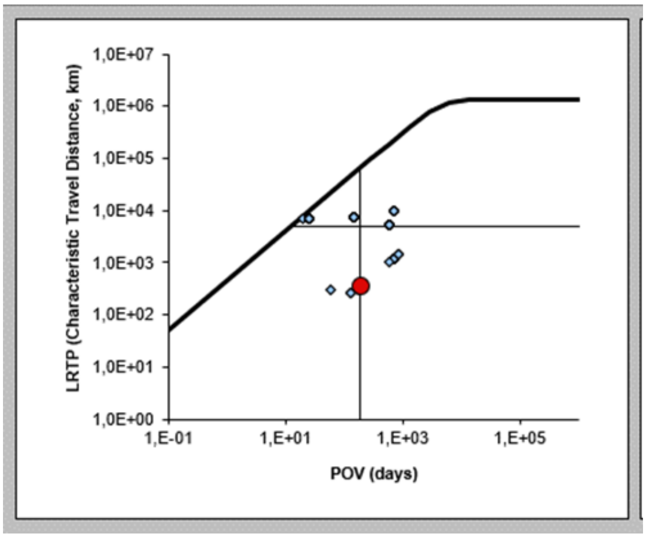

Figure 1: Graphical output for CTD of 1,4-dioxane assuming substance being "inherently biodegradable".

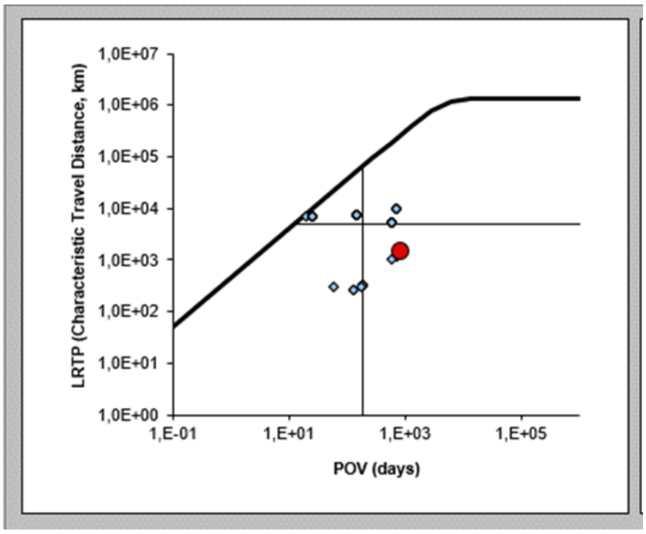

Figure 2: Graphical output for CTD of 1,4-dioxane assuming substance being "not biodegradable".

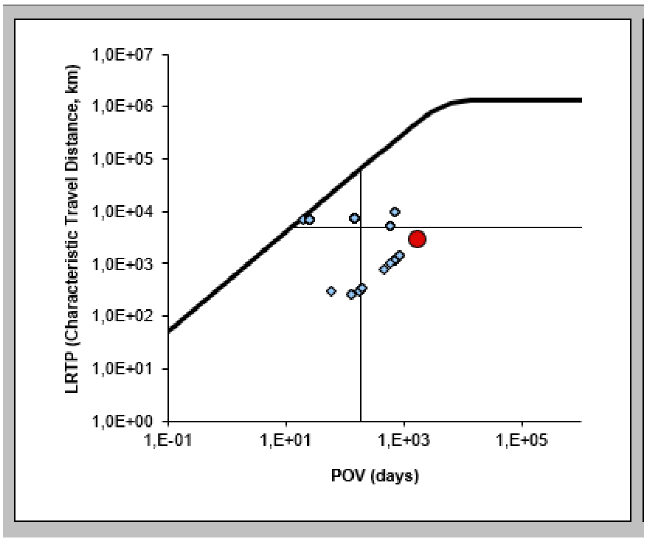

Figure 3: Graphical output for CTD of 1,4-dioxane for measured degradation half-life in water and estimated value for soil.

When looking at Figure 1, 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 2 and Figure 3 the results of the calculations with the assumed degradation half-lives for “not biodegradable” and the hybrid of measured and estimated values trend towards the “POP-like behaviour” (upper 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 is still able to travel nearly 3000 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, water will be the dominant transport media in the environment once the substance is released. The OECD tool for Long Range Transport Potential (LRTP) predicts a characteristic travel distance (CTD) of 2917 km together with an overall persistence (P_{ov}) of 1771 days for 1,4-dioxane, using the outcome from the OECD 309 for the degradation half-life of the substance in the aquatic compartment and the recommendations of REACH guidance R.16 for the proxy for environmental half-life in soil. Even when considering this LRTP prediction as a rough estimate because no results from environmental simulation tests in soil are available as input parameters, the results indicate that 1,4-dioxane is capable to reach regions far away from the point of initial emission, thus indicating the concern for this substance to be subject to long range transport.

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

The Risk Assessment Committee (RAC) has concluded that 1,4-dioxane fulfils the criteria for classification as carcinogenic Carc. 1B; H350 (see section 2), based on evidence of carcinogenicity in different tissues observed in two species at reasonable dose levels. The classification has been included in the draft 17th ATP to CLP[2]. It 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).

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[3].

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_{50} was not reached at the highest test concentration of 320 mg/L (LC_{50} is >320 mg/L (nominal), a theoretical LC_{50} (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_{50} 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_{50} 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_{50} 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_{50} >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_{50} > 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” ($MATC/\sqrt{2}=NOEC$), (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_{50} 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_{50} > 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 ErC50 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_{50} 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_{50} 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_{50} (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_{50} 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 recently adopted RAC opinion concluding that 1,4-dioxane should be classified as Carc 1B. This classification was also included in the draft 17th ATP to CLP[2].

6. Conclusions on the SVHC Properties

6.1. CMR assessment

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

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. This data demonstrates that the substance is to be evaluated as potentially persistent / potentially very persistent according to the screening criteria of REACH Annex XIII.

There is a lack of any primary degradation in water (Kim, 2007; Klečka and Gonsior, 1986; Sei et al., 2010) and soil (Kelley et al., 2001; Sei et al., 2010). Even while no specific degradation half-lives under environmental conditions were provided in these studies, they provide very strong evidence, that the substance can be rated as very persistent according to the criteria of REACH Annex XIII.

This previous hypothesis was confirmed by a simulation test on degradation in surface water (Hofman-Caris and Claßen, 2020), where a very high DT_{50} (SFO) ≥10,000 days was obtained for 1,4-dioxane. This value exceeds the threshold for very persistent substances in water (half-life in water >60 days) according to the criteria of REACH Annex XIII by several orders of magnitude.

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 environment 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_{OC} 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 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 criteria defined in Neumann and Schliebner (2019), suggesting that 1,4-dioxane is very mobile in the environment. 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 2917 km together with an overall persistence (P_{ov}) of 1771 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 draft 17th ATP to CLP[2] 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 long range transport lead to an irreversible presence in the environment and in particular cause contamination of the aquatic environment.

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.

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 ± 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. 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.

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 2917 km with a P_{ov} of 1771 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 the whole life which is highly alarming as the substance is classified as carcinogenic. For these reasons and in application of the precautionary principle the release of 1,4-dioxane to the environment should be prevented.

6.3.2.6. Long term effects are unknown

Once 1,4-dioxane is in the environment it is hard to remove. Contaminated areas might be sources of continued releases into the environment long after phase-out of 1,4-dioxane, resulting in long-lasting or even irreversible exposure of wildlife of all trophic levels. 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, keeping also in mind the classification as Carc. 1B. Long term effects of the substance at low levels are possible but unknown, yet. 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 should be considered. Mixture toxicity effects with other stressors cannot be ruled out. 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
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- Potential for irreversible and increasing contamination of surface water and groundwater
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B
- 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
- Long-term effects are unknown

6.3.4. Conclusion on hazard properties and ELoC assessment

1,4-Dioxane is proposed to be 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 (men 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, 1,4-dioxane is evaluated as not capable to undergo noticeable biodegradation in soil under environmentally relevant conditions Degradation of 1,4-dioxane was investigated in surface water according to OECD 309 TG, resulting in a calculated DT_{50} (SFO) ≥10,000 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 2917 km together with an overall persistence (P_{ov}) of 1771 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 draft 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 long range transport 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. 1,4-Dioxane was not removed from water. 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 compromises 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 men 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.

Due to the properties of 1,4-dioxane (persistency, mobility, long-range transport 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.

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 and humans 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.

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, keeping also in mind the classification as Carc. 1B. Long term effects of the substances at low levels are possible but unknown, yet.

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
- Decontamination of 1,4-dioxane from the environment and from drinking water resources is difficult and resource-intensive
- Potential for irreversible and increasing contamination of surface water and groundwater
- 1,4-Dioxane fulfils the criteria for classification as carcinogenic Carc. 1B
- 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
- Long-term effects are unknown

Conclusion

Although the carcinogenic properties of 1,4-dioxanealone would be 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 (men 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 long-range transport in water, difficulty of remediation and water purification. The observed probable serious effects for human health and the environment are carcinogenicity. Together, these elements lead to a very high potential for irreversible effects.

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Part II

7. Manufacture, import and export

7.1. Imports and exports of the substance into and from the EU

The substance is manufactured and/or imported in the European Economic Area in quantities of more than 1,000 tonnes per year. This volume does not take into account any exports into countries not being a member of the EEA.

These numbers do not include amounts of 1,4-dioxane that are constituents or impurities of other registered substances. 1,4-Dioxane is contained in at least 24 substances registered under REACH (as of 05-Aug-2019) with diverse uses, e.g. surfactants used in consumer products. The total amount of these substances placed on the European market is up to 1,000,000 tonnes per year and per individual registered substance.

8. Information on uses of the substance

8.1. Overview of uses

1,4-Dioxane is predominantly used as solvent in the synthesis of chemicals. It also can be generated as a by-product during chemical synthesis. As a result, 1,4-dioxane is found as constituent or impurity in other substances. The subsequent table provides a generalised overview for uses of 1,4-dioxane as such or products that contain 1,4-dioxane as constituent.

Table 14: General overview of uses according to public information at ECHA's dissemination site

	Use(s)
Uses as intermediate	Substance is used as an intermediate for the manufacture of another substance. Releases to the environment may occur as a result of regular plant operation, e.g. due to cleaning and maintenance processes.
Formulation	Substance is used for the formulation of mixtures. There is no specific information available in which chemical products the substance might be used. Release to the environment of this substance can occur from water-based formulation processes which include cleaning and maintenance operations during regular, batch-wise formulation events.
Uses at industrial sites	Substance is contained in laboratory chemicals, pH regulators and water treatment products. It is also used as a solvent for the manufacture of other chemicals. Release to the environment of this substance can occur from industrial use: in processing aids at industrial sites, of substances in closed systems with minimal release. Releases are also expected from cleaning and maintenance operations.
Uses by professional workers	The substance as such seems to be predominantly used as laboratory chemical. Other reported information at the ECHA dissemination site refer to uses of products where the substance is part of a mixture. This refers to

	products like, e.g. pH regulators, flocculants, precipitants, neutralisation agents. Other potential uses that are provided via ECHA's substance info card[6], in which the substance is expected to act as solvent in a mixture, e.g. varnishes, paint and printing inks etc. could not be confirmed from consultation processes with industry.
Consumer Uses	According to the ECHA dissemination site there are no consumer uses of 1,4-dioxane as such that are intended or supported by the registrants of the substance as such. Nevertheless, it cannot be excluded that there are uses of substances or related mixtures, where 1,4-dioxane is contained as constituent or impurity. Therefore, it is not clear whether and over which pathways the substance is emitted into the environment as a result of potentially occurring consumer applications of other substances.
Article service life	There is no article service life for 1,4-dioxane reported. There are no indications whether or into which articles the substances might have been processed. No data is currently available on the routes by which this substance might be released from articles into the environment.

Information on uses of substances which contain 1,4-dioxane according to other regulatory sources

1,4-Dioxane can also occur as an impurity, either as a residue or as a result of a chemical reaction. As described in Australia's Priority Existing Chemical Report on 1,4-dioxane, it may be present as a residue if used in the reaction medium during manufacture (e.g. of a flame retardant) or as a solvent during purification. 1,4-Dioxane may also be formed as a reaction by-product, particularly in chemicals which are produced by ethoxylation. These include alkyl ether sulphates (anionic surfactants) and other ethoxylated substances, such as alkyl, alkylphenol, and fatty amine ethoxylates; polyethylene glycols and their esters; and sorbitan ester ethoxylates. Uses of these chemicals include food, cosmetic, agricultural/veterinary, therapeutic, household and varied industrial applications (Australian Government, 1998).

Use of 1,4-dioxane in cosmetics:

According to Annex II of the EU Regulation (EC) No 1223/2009 on cosmetic products the use of 1,4-dioxane in cosmetic products is prohibited. However, it is allowed to use the substance as an auxiliary substance in the manufacture of those cosmetic products provided it is removed completely afterwards, respectively to such a large extent that the residual concentrations can be regarded as unavoidable and technically non-acting residues by technical means. In any case the residual concentration must not result in hazardous effects for human health. In a risk assessment by the Scientific Committee on Consumer Safety of the EU (SCCS) on residual levels of 1,4-dioxane in cosmetics, residual levels ≤10 ppm are considered safe (SCCS/1570/15)[7]. It can be assumed that these values for cosmetics and cosmetic detergents are complied with in practice.

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[6] https://echa.europa.eu/substance-information/-/substanceinfo/100.004.239; date of access: 25.01.2021

[7] https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_194.pdf; date of access: 10.08.2020

Uses of products containing 1,4-dioxane according to SPIN database[8]

For the latest reporting year (2017) the database on substances in preparations in Nordic countries (SPIN) reports the following data:

Table 15: Total uses of 1,4-dioxane (report year 2017)

Country	#prep	tonnes	Consumer preparations	Confidential
DK	349	15.7	-	-
SE	955	4.1	Yes	-
FI	0	-	-	Yes
NO	40	0.0	Yes	-

Table 16: Total uses of 1,4-dioxane (report year 2018)

Country	#prep	tonnes	Consumer preparations	Confidential
DK	176	7.5	-	-
SE	1184	10.4	Yes	-
FI	0	-	-	Yes
NO	28	0.1	Yes	-

The preparations for intended applications indicate that there might be a huge variety of products which might contain 1,4-dioxane. Besides expected industrial applications as such for manufacturing of chemicals, other relevant applications seem to be for example manufacture of paper and paper products, specialised construction activities together with services to buildings and landscape.

From the use categories to be reported for SPIN (use category description scheme UC 62), the highest amount of 1,4-dioxane is used as a solvent (total number of preparations reported: 5; 10.9 tons for reporting year 2017), followed by unspecified “other” uses (total number of preparations reported: 75; 3.4 tons for reporting year 2017).

In addition, a high number of preparations were reported to contain 1,4-dioxane, but with assumed negligible concentrations, based on the information displayed for the use categories. These are cleaning/washing agents (total reported: 270), surface-active agents (total reported: 208), non-agricultural pesticides (total reported: 189), paints, lacquers and varnishes (total reported: 139). There is also a wide variety of applications displayed in the SPIN database, where preparations are notified to contain 1,4-dioxane. It needs to be kept in mind, however, that the SPIN database not only refers to products where substances are intentionally added, but also deals with occurrence of substances as impurities.

Additionally, data from SPIN is not fully representative for the European Economic Region because products and frequency of application may differ between the different geographical regions in the EU.

Based on the data from the notifications, SPIN for 2017 concludes on an exposure potential

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[8] Source: www.spin2000.net; date of access: 10.08.2020

for 1,4-dioxane (note: no conclusions available for Finland, because reported information is confidential).

Table 17: Exposure potential of 1,4-dioxane from products, acc. to SPIN database (report year 2017)

Country	Quant. (max: 5)	Use index (UI, max: 5)						Range of use (RoU, max: 5)	Article index (AI, max: 3)
		surf. water	air	soil	waste water	Consumers	Occupational		
DK	1	5	5	3	5	5	5	4	3
NO	-	4	5	4	5	5	5	3	3
SE	3	5	5	5	5	5	5	5	3

Table 18: Exposure potential of 1,4-dioxane from products, acc. to SPIN database (report year 2018)

Country	Quant. (max: 5)	Use index (UI, max: 5)						Range of use (RoU, max: 5)	Article index (AI, max: 3)
		surf. water	air	soil	waste water	Consumers	Occupational		
DK	1	4	5	3	5	5	5	4	3
NO	-	5	5	4	5	5	5	4	3
SE	3	5	5	5	5	5	5	5	3

On the basis of this information there is a strong evidence that in principle all uses of the substance result in relevant releases into all environmental compartments.

Information on uses and occurrence of 1,4-dioxane according to Römpp encyclopedia on chemistry[9]*:*

1,4-Dioxane is used as a universal solvent for natural substances, resins, waxes, cellulose esters and cellulose ethers. It is used in the production of fats and colourants.

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[9] Source: https://roempp.thieme.de; date of access: 11.19.2019

Because of its good solubility and its cryoskopic constant it is used as a reference substance for the determination of the molecular mass of unknown substances.

Complexes of 1,4-dioxane with bromine or sulfur trioxide are used as bromination agents / sulfonation agents.

One of the most common uses of 1,4-dioxane was the application as stabiliser for chlorinated solvents, e.g. to prevent the chemical reaction of 1,1,1-trichloroethane (TCA) or trichloroethylene (TCE) with aluminium (see chapter 3.4). Use of TCA was phased out under the Montreal Protocol 1995 and the use of 1,4-dioxane as a solvent stabiliser was terminated (EU-RAR, 2002).

Information on uses from public RMOA consultation and open access information databases:

Environment:

1,4-Dioxane is used in industry as a process aid (solvent), as an intermediate for the production of other chemicals and as a component of heat transfer fluids. Except for sampling or maintenance work, all of these processes are expected to be carried out in closed systems. Therefore, only minor emissions into the environment are assumed from the intended uses of 1,4-dioxane in closed systems.

Workers:

1,4-Dioxane is used in industry as a process aid (solvent), as an intermediate for the production of other chemicals and as a component of heat transfer fluids. Except for sampling or maintenance work, these processes are carried out in closed systems.

There is a discrepancy in the description of the professional uses of 1,4-dioxane between ECHA's dissemination site, the SPIN database and ECHA’s substance info card. According to the latter one it appears that 1,4-dioxane is widely used in the professional sector. However, besides the general descriptors (here PROCs) for handling of substances, the dissemination site reports only one specific application description for the various professional uses of the substance, the use as laboratory reagent (PROC 15). It could be clarified, at least for the entries in ECHA´s substance info card regarding the professional uses described. The information about uses in the different sections in the substance info card are automatically generated from the use information in the registration dossiers that is not claimed as confidential. For example, the indication of ERC 8a to 8c in the registration dossier yields a generic phrase with examples for the substance info card, regardless of whether these examples fit the actual use.

A consultation with the German Paint and Printing Ink Industry e.V. as well as the German Industrial Association for Adhesives e.V. showed that 1,4-dioxane has no relevant use in paints, varnishes and adhesives neither as ingredient nor in production.

Moreover, the information provided by the registrants of 1,4-dioxane only has to cover their intended uses for the substance as such. There is no regulatory obligation, that uses of other registered substances which contain 1,4-dioxane as constituent or impurity need to be considered, too.

Consumers:

In the context of consumer uses of 1,4-dioxane it cannot be excluded that products for professional use applications, which contain the substance, are also sold to private customers even in case consumer uses are not supported by the registrants of 1,4-dioxane.

9. Release and exposure from uses

9.1. Exposure of humans

An evaluation of the direct exposure of workers or consumers resulting from manufacture and uses of 1,4-dioxane, or substances that contain 1,4-dioxane as constituent or impurity, was not undertaken for this SVHC proposal.

9.2. Releases to the Environment

9.2.1.1. Emissions from manufacture and uses of 1,4-dioxane

There are only a limited number of uses of 1,4-dioxane as such mentioned at ECHA's dissemination site. Predominant applications at industrial scale are the use as intermediate for the synthesis of other substances or as non-reactive processing aid (e.g. solvent) in the production of substances. Therefore, relevant releases into the environment from a limited number of industrial sites as point sources need to be expected. This evaluation includes the releases from the manufacture of 1,4-dioxane, too.

For professional applications only uses as laboratory chemical for scientific research & development and reagent in health services are declared. The releases into the environment will occur in a widespread manner. Nevertheless, the contribution of the professional uses of the substance as such to the overall releases of 1,4-dioxane to the environment are expected to be negligible.

9.2.1.2. Emissions of 1,4-dioxane as by-product

As explained in the subsequent paragraphs, 1,4-dioxane is a by-product occurring in the manufacture of polyethoxylates and polyesters. In the production process of polyethoxylates which act as surfactants, 1,4-dioxane is an unavoidable by-product in the synthesis. Purification processes are used to extract 1,4-dioxane from the polyethoxylate mixture, residual concentrations in those can be effectively controlled. Waste water from the extraction process is typically sent to industrial sewage treatment plants.

Data show, that one relevant concern for the environment arises from the residual content of 1,4-dioxane in polyethoxylate mixtures and their wide-spread use in cleaning products.

The amount of residual 1,4-dioxane in the ethoxylate mixture cannot be specified in general. It depends on whether in the area of application of the ethoxylates further regulatory requirements exist. For example, 1,4-dioxane is prohibited in cosmetic products according to Annex II of regulation (EC) No 1223/2009. The Scientific Committee on Consumer Safety (SCCS) concluded in their scientific opinion about an acceptable trace level in cosmetic products that residual concentrations of 1,4-dioxane below 10 ppm are considered as safe for consumers.

In contrast, ethoxylates used for general purpose cleaners for consumer use contain 1,4-dioxane in ranges >100 ppm, whereas industrial and professional cleaning products may even contain higher concentrations of 1,4-dioxane. Common to many special and general purpose cleaning products is that direct or indirect disposal down the drain with treatment in municipal waste water treatment plants is the follow-up of the use.

Even though 1,4-dioxane is only contained in relatively small concentrations in ethoxylates, the wide dispersive use and total usage amount of cleaning products containing ethoxylates result in relevant releases of 1,4-dioxane into the aquatic environment due to the large number of municipal sewage treatment plants.

1,4-Dioxane is also a by-product during esterification. Polyesters are a common type of base polymer manufactured in some large facilities in Europe. One of the most common is polyethylene terephthalate (PET), which is used in a wide range of applications. The most common ones are for example thin foil bags in supermarkets or single use plastic bottles for mineral water or beverages. Requirements for the tolerable content with regard to impurities or residual monomers in the packing material are set in the EU regulation on materials and articles intended to come into contact with food (Regulation (EC) No 1935/2004). To achieve the required residual content the polymer has to be purified to decrease the level of unacceptable constituents such as 1,4-dioxane below the regulatory thresholds. For the removal of 1,4-dioxane, extraction processes are applied. Similar to the production of ethoxylates, it is expected that extracted 1,4-dioxane is sent to industrial sewage treatment plants.

9.2.1.3. Release estimates

1,4-Dioxane is not a priority substance under other, environmental media orientated regulations such as Water Framework Directive (2000/60/EC) or Industrial Emissions Directive (2010/75/EU). Therefore, no general obligations for monitoring releases of the substance in the environment exist for industrial applicants of the substance or sewage treatment plants. In addition, available measuring data does not allow identification of the most relevant uses and sources of release respectively (in general). In conclusion, available measured data from single local sites will only allow an approximate estimation of releases of 1,4-dioxane on EU level.

Relevant point sources of 1,4-dioxane with 1,4-dioxane releases were identified recently (LANUV, 2019; Rüdel et al., 2020).

A detailed analysis of individual discharges is available for the river Rhine (LANUV, 2019), which is reflected in the following sections: The load of 1,4-dioxane in the river Rhine at the German-Dutch border near Kleve-Bimmen or Lobith was calculated from the data of the LANUV measurements resulting in an average rate of 200 - 250 kg/day or 73,000 – 91,250 kg/year as continuous outflowing quantity. For comparison: the Rhine enters the area of investigation upstream at the border of the German Federal State of North Rhine-Westphalia with an average load of 100 kg/d. Different sources of emissions were identified within the area of investigation and are presented hereinafter.

An industrial discharger was identified producing surface active substances for the manufacture of skin and hair care products, but also washing and cleaning products. Loads between 3 and 120 kg/d were detected for this industrial discharger.

At the mouth of the river Lippe into the river Rhine, loads of around 15 kg/d, with peaks of 50 kg/d, were determined.

The sewage treatment plant Düsseldorf-Süd was identified as a relevant discharger of 1,4-dioxane into the Rhine. Based on a weekly mixed sample, a load of 100 - 160 kg/d into the receiving water can be estimated. The sewage treatment plant receives waters from an industrial (indirect) discharger in Düsseldorf, who discharges the entire waste water from his site into the sewage system of the city of Düsseldorf. The load was estimated from a diversity of samples taken by LANUV at the outlet of the site operator's central wastewater protection system ranging from 8.6 to 144 kg/d. This is consistent with the above-mentioned data and the findings at the end of the sewage treatment plant Düsseldorf-Süd.

Emission rates into surface water between 6 and 24 kg 1,4-dioxane per day into the Rhine were determined in 2018 for another industrial discharger in Dormagen.

Taken together, individual dischargers, identified in the above summarised study (LANUV, 2019), contributed with emissions between 32.6 to 338 kg 1,4-dioxane per day and emissions up to 11,899 to 123,370 kg 1,4-dioxane per year respectively into the Rhine exclusively in the Federal State of North Rhine-Westphalia. Those dischargers were therefore identified as relevant point source for emissions of 1,4-dioxane to river Rhine.

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. Further, 1,4-dioxane concentrations of around 2.0 µg/L were measured in drinking water from that water supply. In Bavaria, polyester production facilities and facilities for the synthesis of detergents and precursors were identified as relevant point sources. Noteworthy, contaminations in the rivers Lech and Inn could be reduced to levels well below 1 µg/L. The reported reductions were mainly achieved due to separation of 1,4-dioxane-containing sewage and either advanced treatment or distillation and incineration. Further, technical grade hydrochloric acid from two technical processes was found to contain 1,4-dioxane as a contaminant and has been replaced (Rüdel et al., 2020).

10. Existing EU legislation

1,4-Dioxane is listed in Annex VI of the CLP regulation. ECHAs Risk Assessment Committee (RAC) adopted an opinion in March 2019 to classify 1,4-dioxane as Carc. 1B instead of the current classification as Carc. 2. The Carc. 1B-classification in the draft of the upcoming 17th ATP is considered to be included in Annex VI of the CLP regulation.

1,4-Dioxane is listed in Annex II of the Regulation (EC) No 1223/2009 on cosmetic products and therefore prohibited in cosmetic products. The Scientific Committee on Consumer Safety (SCCS) concluded in their scientific opinion about an acceptable trace level in cosmetic products that residual concentrations of 1,4-dioxane below 10 ppm are considered as safe for consumers.

11. Previous assessments by other authorities

For 1,4-dioxane a risk assessment was performed under Regulation EEC 793/93 – Existing Substances Regulation.

References for Part II

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