VERBAND DER CHEMISCHEN INDUSTRIE e.V.

REACH Praxisführer zur Expositionsbewertung und zur Kommunikation in den Lieferketten
Beispiele zu Teil II: Expositionsszenarien und Kommunikation in den Lieferketten

Beispiel 3: Stoffsicherheitsbericht HDDA

Dieses Beispiel veranschaulicht die Anwendung des iterativen 3-Stufen-Ansatzes zur Expositionsbewertung am Beispiel von HDDA (1,6-Hexandioldiacrylat)

Stand: November 2008

Version: 1

Wichtiger Hinweis für den Leser:

Dieses Beispiel eines Stoffsicherheitsberichtes ist von der Verfasserin in einer Arbeitsgruppe des VCI erstellt worden als Teil des gemeinsamen Projektes von Cefic/VCI zur Entwicklung von Instrumenten und Leitfäden – für die Stoffsicherheitsbeurteilung, den Stoffsicherheitsbericht und für Expositionsszenarien.

Das vorliegende Dokument gehört zum Teil II des „REACH Praxisführers zur Expositionsbewertung und zur Kommunikation in den Lieferketten“. Der Praxisführer besteht aus mehreren Teilen. Eine Übersicht finden Sie im Vorwort zu Teil I.

Eine Beschreibung der Inhalte und des Praxisführers steht auf der folgenden Internetseite zur Verfügung:

VCI: http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm

Alle zugehörigen Materialien (inklusive der Projektbeispiele zu Teil II und III) können von dieser Seite heruntergeladen werden. Sie finden hier zusätzlich Hinweise zu verwandten Themen und neuen Entwicklungen.

Die englischsprachigen Veröffentlichungen zum Praxisführer finden Sie auf der folgenden Internet-Seite:

CEFIC: http://cefic.org/templates/shwPublications.asp?HID=750

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Wenn bei der Ausarbeitung des Beispieles Schwerpunkte gesetzt worden sind, wird hierauf jeweils gesondert hingewiesen.

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CHEMICAL SAFETY REPORT

Substance Name: **1,6-hexandioldiacrylate**

EC Number: **235-921-9**

CAS Number: **13048-33-4**

Registrant's identity: **BASF SE**

Remarks:

This CSR war prepared as an example on behalf of the VCI Project. It is not complete neither with respect to the hazard part nor the information in the exposure part and can therefore not be used for any registration purposes

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1 SUMMARY OF RISK MANAGEMENT MEASURES

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Downstream use: Summary of conditions of use to ensure control of risk	
	General safety and hygiene measures: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is required additionally to the stated personal protection equipment. Containment and local exhaust ventilation related to workers: Containment plus good work practice required Local exhaust ventilation Spray application: Closed boxes Personal protective equipment: Respiratory protection: Not needed for intended / identified use. Hand protection: Chemical resistant protective gloves (EN 374) Suitable materials also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): nitrile rubber (NBR) - 0.4 mm coating thickness Supplementary note: The specifications are based on own tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the determined permeation time. Manufacturer's directions for use should be observed because of great diversity of types. Eye protection: Safety glasses with side-shields (frame goggles) (e.g. EN 166) Body protection: Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to DIN-EN 465).

2 DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

3 DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

PART B

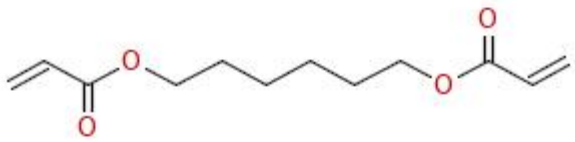
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	235-921-9
EC name:	hexamethylene diacrylate
CAS number (EC inventory):	13048-33-4
CAS number:	13048-33-4
CAS name:	2-Propenoic acid, 1,6-hexanediyl ester
IUPAC name:	hexane-1,6-diyl bisacrylate
Annex I index number	607-109-00-8
Molecular formula:	C12H18O4
Molecular weight range:	226.2689

Structural formula:



Remarks: -

1.2 Composition of the substance

Table 2: Constituents

Constituent	Typical concentration	Concentration range	Remarks
hexamethylene diacrylate 235-921-9	>= 90 % (w/w)		

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
Water 231-791-2	<= 0.1 % (w/w)		
acrylic acid 201-177-9	<= 0.1 % (w/w)		
cyclohexane 203-806-2	<= 0.2 % (w/w)		
not available	<= 10 % (w/w)		

Table 4: Additives

Constituent	Function	Typical concentration	Concentration range	Remarks
mequinol 205-769-8	stabilizer	<= 0.025 % (w/w)		

1.3 Physico-chemical properties

Table 5: Summary of physico- chemical properties

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	liquid	
Melting/freezing point	7.8 °C	
Boiling point	107 °C at 0.3 hPa (substance polymerizes before boiling)	
Relative density	1.01 g/cm3 at 20 °C	
Vapour pressure	<0.01 hPa at 20 °C	
Surface tension	based on chemical structure, no surface activity is predicted	
Water solubility	0.36 - 0.48 g/l at 20 °C	
Partition coefficient n-octanol/water (log value)	2.81 at 25 °C	
Flash point	>110 °C (cc)	
Flammability	non flammable The substance has no pyrophoric properties and does not liberate flammable gases on contact with water.	
Explosive properties	non explosive, because there are no chemical groups associated with explosive properties present in the molecule	
Self-ignition temperature	235 °C	
Oxidising properties	the substance is incapable of reacting exothermically with combustible materials based on chemical structure	
Granulometry	substance is marketed or used in a non solid form	
Stability in organic solvents and identity of relevant degradation products	stability of the substance is not considered as critcial	
Dissociation constant	substance does not contain any ionic structure	
Viscosity	ca. 2.5 mPa_s at 20 °C ca. 1.6 mPa_s at 40 °C	

Remarks: -

Testing proposal: -

2 MANUFACTURE AND USES

2.1 Manufacture

Methods of manufacture:
Origin of substance: Synthesis
Type of substance: Production

The acrylates can be prepared by a number of procedures. These include dehydration of corresponding hydroxyalkanoic acid, saponification of alkene nitrile, catalytic hydration of acetylene and carbon monoxide, or the reaction of acetone with hydrocyanic acid.

Methods of manufacture:
Origin of substance: Synthesis
Type of substance: Production

In ... propylene oxidation process acrolein is first formed by the catalytic oxidation of propylene vapor at high temp in the presence of steam. The acrolein is then oxidized to acrylic acid. ... The acrylic acid is esterified with alcohol to the ... acrylic ester in a separate process.

Methods of manufacture:
Origin of substance: Synthesis
Type of substance: Production

Esterification of 1,6-hexanediol with acrylic acid.

2.2 Identified uses

Table 6: Identified uses described by process category (PROC) and sector of use (SU)

	Sectors of Use (SU)					
	All SU	***SU 6***	***SU 7***	***SU 10***		
Process category (PROC)						
ALL PROCs	9.1					
PROC 5, 6, 7, 8, 9		9.2	9.2	9.2		

Table 7: Identified specific or individual uses described by preparation category (PC) processed into an article category (AC)

	Preparation category (PC)					
Article category (AC)						

Table 8: Identified uses described by sectors of uses and preparation category

	Preparation category (PC)				
	PC 9, 18, 26				
Sector of use (SU)					
SU 6, 7, 10	9.2				

2.3 Uses advised against

No.

3 CLASSIFICATION AND LABELLING

3.1 Classification in Annex I of Directive 67/548/EEC

Classification

Specific concentration limits

Concentration	**Classification**
C >= 20%	Xi; R 36/38-43
1% <= C < 20%	Xi; R43

3.2 Self classification(s)

Table 9: Classification according to Directive 67/548/EEC criteria

Endpoints	Classification	Reason for no classification	Justification for (non) classification can be found in section
Explosiveness		Classification criteria not met	6.1
Oxidising properties		Classification criteria not met	6.3
Flammability		Classification criteria not met	6.2
Thermal stability		Classification criteria not met	
Acute toxicity		Classification criteria not met	5.2.3
Acute toxicity- irreversible damage after single exposure		Classification criteria not met	5.2.3
Repeated dose toxicity		Classification criteria not met	5.6.3
Irritation / Corrosion	Xi; R36/38; Irritant; Irritating to eyes and skin.		5.3.4 and 5.4.3
Sensitisation	Xi; R43; Sensitising; May cause sensitisation by skin contact.		5.5.3
Carcinogenicity		Classification criteria not met	5.8.3
Mutagenicity - Genetic Toxicity		Classification criteria not met	5.7.3
Toxicity to reproduction- fertility		Classification criteria not met	5.9.3
Toxicity to reproduction- development		Classification criteria not met	5.9.3
Toxicity to reproduction – breastfed babies		Classification criteria not met	5.9.3
Environment		Classification criteria not met	7.6

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Abiotic degradation

4.1.1.1 Hydrolysis

Table 10: Overview of studies on hydrolysis

Method	Results	Remarks	Reference
HYDROWIN v1.67	Half-life (DT50): t1/2 (pH 8): 200d - 5yr	2 (reliable with restrictions) key study estimated by calculation	EPI Suite v.3.12

Data waiving *(if applicable)*

Discussion (screening testing)

4.1.1.2 Phototransformation/photolysis

4.1.1.2.1 Phototransformation in air

The studies on phototransformation in air are summarised in the following table:

Table 11: Overview of studies on phototransformation in air

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable.

Testing proposal

Not applicable.

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

4.1.1.2.2 Phototransformation in water

The studies on phototransformation in water are summarised in the following table:

Table 12: Overview of studies on phototransformation in water

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

Testing proposal

Not applicable.

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

4.1.1.2.3 Phototransformation in soil

The studies on phototransformation in soil are summarised in the following table:

Table 13: Overview of studies on phototransformation in soil

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

Reason: study scientifically unjustified

Justification: Substance is readily biodegradable

Testing proposal

Not applicable.

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

No information available, yet not expected to significantly contribute to the fate of HDDA in the environment.

4.1.2 Biodegradation

4.1.2.1 Biodegradation in water

Details on the studies on biodegradation in water are given in the following subsections.

4.1.2.1.1 Estimated data:

The estimated data for biodegradation in water are summarised in the following table:

Table 14: Estimated data for biodegradation in water

Estimation method	Results	Remarks	Reference
--	--	--	--

As reliable test data on the biodegradation of HDDA are available, no QSAR estimations were performed.

4.1.2.1.2 Screening tests

The test results are summarised in the following table:

Table 15: Screening tests for biodegradation in water

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable.

4.1.2.1.3 Simulation tests

Table 16: Simulation tests for biodegradation in water

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

Reason: study scientifically unjustified

Justification: Substance is readily biodegradable

4.1.2.1.4 Summary and discussion of biodegradation in water

Discussion (screening testing)

The following information is taken into account for any hazard / risk / persistency assessment:

Readily biodegradable (according to OECD criteria).

Discussion (simulation testing)

Not applicable.

4.1.2.2 Biodegradation in sediments

The test results are summarised in the following table

Table 17: Overview of simulation tests for biodegradation in sediments

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

Reason: study scientifically unjustified

Justification: Substance is readily biodegradable

Discussion

Not applicable.

4.1.2.3 Biodegradation in soil

The test results are summarised in the following table:

Table 18: Overview of studies on biodegradation in soil

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

Reason: study scientifically unjustified

Justification: Substance is readily biodegradable

Discussion

Not applicable.

4.1.2.4 Summary and discussion on biodegradation

Readily biodegradable (according to OECD criteria).

Testing proposal

Not applicable.

4.1.3 Summary and discussion on degradation

Abiotic degradation

In contact with water the substance will hydrolyse slowly.

After evaporation or exposure to the air, the product will be rapidly degraded by photochemical processes.

Biotic degradation

Readily biodegradable (according to OECD criteria).

Degradation rate in water	4.7 E-02 [d^{-1}][1]
Degradation rate in sediment	2.3E-03 [d^{-1}][2]
Degradation rate in soil	2.3E-02 [d^{-1}][3]
Degradation rate in air	1.2 [d^{-1}][4]

4.2 Environmental distribution

Adsorption to solid soil phase is not expected.
HDDA will not evaporate into the atmosphere from the water surface.
Over time, the substance will preferentially distribute into the air.

4.2.1 Adsorption/desorption

The studies on adsorption/desorption are summarised in the following table:

Table 19: Overview of studies on adsorption/desorption

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable.

Testing proposal

Not applicable.

Discussion

[1] According to the Technical Guidance Document on Risk Assessment [European Communities 2003], Part II: Environmental Risk Assessment, Table 7, page 54

[2] Calculated according to the Technical Guidance Document on Risk Assessment [European Communities 2003], Part II: Environmental Risk Assessment, equation (30), page 56

[3] Calculated according to the Technical Guidance Document on Risk Assessment [European Communities 2003], Part II: Environmental Risk Assessment, Table 8 and equation (29), page 57

[4] Calculated from atmosperic half-life estimated by AOPWIN v1.91 (see chapter 4.1.1.2.1)

The following information is taken into account for any hazard / risk / persistency assessment:

Adsorption to solid soil phase is not expected.

4.2.2 Volatilisation

The studies on volatilisation are summarised in the following table:

Table 20: Overview of studies on volatilisation

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable.

Testing proposal

Not applicable.

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

HDDA will not evaporate into the atmosphere from the water surface.

4.2.3 Distribution modelling

The data from distribution modelling studies are summarised in the following table:

Table 21: Overview of distribution modelling studies

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable.

Testing proposal

Not applicable.

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

The studies on aquatic bioaccumulation are summarised in the following table:

Table 22: Overview of studies on aquatic bioaccumulation

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Reason: study scientifically unjustified

Justification: logKow indicates no potential for bioaccumulation

4.3.2 Terrestrial bioaccumulation

The results of terrestrial bioaccumulation studies are summarised in the following table:

Table 23: Overview of studies on terrestrial bioaccumulation

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Reason: study scientifically unjustified

Justification: logKow indicates no potential for bioaccumulation

4.3.3 Summary and discussion of bioaccumulation

Aquatic bioaccumulation

Terrestrial bioaccumulation

The following information is taken into account for any hazard / risk / persistency assessment:

Significant accumulation in organisms is not to be expected.

Testing proposal

Not applicable.

4.4 Secondary poisoning

As HDDA is not suspicious to accumulate via the food chain, secondary poisoning is of no concern with regard to HDDA.

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1 Non-human information

5.1.2 Human information

5.1.3 Summary and discussion on toxicokinetics

5.2 Acute toxicity

5.2.1 Non-human information

5.2.1.1 Acute toxicity: oral

5.2.1.2 Acute toxicity: inhalation

Acute inhalation study	LC50 > 0.9 mg/l (6 h, 14 days)

5.2.1.3 Acute toxicity: dermal

Acute Dermal Toxicity in Rats:	LD50 > 2000 mg/kg bw,

5.2.1.4 Acute toxicity: other routes

5.2.2 Human information

5.2.3 Summary and discussion of acute toxicity

5.3 Irritation

5.3.1 Skin

5.3.1.1 Non-human information

Skin Irritation in Rabbits (OECD 404): irritant

[Well defined to severe erythema (OECD-PII >2)]

5.3.1.2 Human information

5.3.2 Eye

5.3.2.1 Non-human information

Eye Irritation in Rabbits (OECD 405): irritant

[Serious corneal opacity, considerable redness and oedema]

5.3.2.2 Human information

5.3.3 Respiratory tract

5.3.3.1 Non-human information

5.3.3.2 Human information

5.3.4 Summary and discussion of irritation

5.4 Corrosivity

5.4.1 Non-human information

Not corrosive.

5.4.2 Human information

5.4.3 Summary and discussion of corrosion

5.5 Sensitisation

5.5.1 Skin

This section exemplifies what data fields will be automatically retrieved by the IUCLID 5 plug-in once available.

5.5.1.1 Non-human information

Maximisation test: positive

Table 24: Summary of experimental studies on skin sensitisation

Method	Results	Remarks	Reference

The results of estimated data on skin sensitisation are summarised in the following table:

Table 25: Summary of estimated data ((Q)SAR) on skin sensitisation

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

5.5.1.2 Human information

The exposure-related observations in humans are summarised in the following table:

Table 26: Summary of exposure-related observations in humans

Subjects / Study type	Results	Remarks	Reference

5.5.2 Respiratory system

5.5.2.1 Non-human information

The results of experimental studies on respiratory sensitisation are summarised in the following table:

Table 27: Summary of experimental studies on respiratory sensitisation

Method	Results	Remarks	Reference

The results of estimated data on respiratory sensitisation are summarised in the following table

Table 28: Summary of estimated data ((Q)SAR) on respiratory sensitisation

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

5.5.2.2 Human information

The exposure-related observations in humans are summarised in the following table:

Table 29: Summary of exposure-related observations in humans

Subjects / Study type	Results	Remarks	Reference

5.5.3 Summary and discussion of sensitisation

Skin sensitisation

Respiratory sensitisation

Justification for classification or non classification

5.6 Repeated dose toxicity

5.6.1 Non-human information

5.6.1.1 Repeated dose toxicity: oral

5.6.1.2 Repeated dose toxicity: inhalation

5.6.1.3 Repeated dose toxicity: dermal

5.6.1.4 Repeated dose toxicity: other routes

5.6.2 Human information

5.6.3 Summary and discussion of repeated dose toxicity:

Testing proposal *(when relevant)*

5.7 Mutagenicity

5.7.1 Non-human information

5.7.1.1 In vitro data

AMES test (OECD#471): negative.

[not mutagenic]

5.7.1.2 In vivo data

5.7.2 Human information

5.7.3 Summary and discussion of mutagenicity

Testing proposal *(when relevant)*

5.8 Carcinogenicity

5.8.1 Non-human data

5.8.1.1 Carcinogenicity: oral

5.8.1.2 Carcinogenicity: inhalation

5.8.1.3 Carcinogenicity: dermal

5.8.2 Human data

5.8.3 Summary and discussion of carcinogenicity

Testing proposal *(when relevant)*

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.1.1 Non-human data

5.9.1.2 Human data

5.9.2 Developmental toxicity

5.9.2.1 Non-human data

5.9.2.2 Human data

5.9.3 Summary and discussion of reproductive toxicity

Testing proposal *(when relevant)*

5.10 Other effects

5.10.1 Non-human data

5.10.2 Human data

5.10.3 Summary and discussion

5.11 Derivation of DNEL(s) /DMELs

a. Relevant Toxicology Data

b. Selection of the appropriate Tier

c. Application of the individual Assessment Factors (AF)

Determination of Assessment Factor (AF) = Uncertainty Factor = Safety Factor:

Oral route

2 Interspecies (RIP 3.2, Sect 1.3.4.2)

6 subacute to chronic (RIP 3.2, Sect 1.3.4.2)

10 intake route

10 individual susceptibility

The default of AF = 1200 is used for systemic effects caused by HDDA

An approach may be suggested based on the observation that acrylates generally show no systemic toxicity in long term studies (ethyl acrylate, NTP TR259, Ghanayem BI, 1985). In this approach, the NOAEL for systemic toxicity may be the high dose, which is acknowledged to show only local toxicity effects. Therefore, in the HDDA 28-day subacute toxicity/reproductive screen, the systemic NOAEL is predicted to be 750 mg/kg/d. Using the default AF of 1200, the DNEL would be:

750 mg/kg/d / 1200 AF = 0.625 mg/kg/d or 625 ug/kg/d.

Using specifically-chosen AF factors for a Tier 1 Risk Assessment from TGD Table 1-9, we may select:

4 for interspecies effects, based on allometric scaling (A. Renwick). (Delete the 2.5 “extra interspecies” factor-what is this specifically?)

10 Intra species (individual susceptibility)

1 duration/study length (no systemic effects seen in chronic studies on acrylates, (category effect, ethyl acrylate, NTP).

1 Dose-Response.

Specific AF factor for local effects caused by HDDA might be: 40.

250 mg/kg/day / 40 = 6.25 mg/kg/d.

Inhalation:

USA (ACGIH) OEL: 1mg/m³

UK OEL data: 3mg/m³

DNEL : 0.318 ppm[5]

Workers

Study Type	**Point of departure**	**AF**	**DNEL**
OECD 422	*NOAEL oral, systemic* *750 mg/kg/day*	*1200*	DNEL oral, chronic, systemic 0.63 mg/kg/d
	NOAEL oral, local *250 mg/kg/day*	*40*	DNEL oral, chronic, local 6.25 mg/kg/d
Default OEL	*OEL (UK)* *3 mg/m³*		DNEL inhalation 3 mg/m³ (0.318 ppm)

General population

No free HDDA on the final poster

5.11.1 Overview of typical dose descriptors for all endpoints

[5] DNEL (inhalation) is a very conservative estimation from USA OEL value,

Table 30: Available dose-descriptor(s) per endpoint for a certain substance as a result of its hazard assessment.

Endpoint		**Quantitative dose descriptor[6] (appropriate unit) or qualitative assessment**		**Associated relevant effect[7]**	**Remarks on study[8]**
		Local[9]	Systemic[10]		
Acute toxicity[11]	oral				
	dermal				
	inhalation				
Irritation/Corrosivity	skin		NA[12]		
	eye		NA		
	resp. tract		NA		
Sensitisation	skin		NA		
	resp. tract		NA		
Repeated dose toxicity sub-acute/ sub-chronic/ chronic	oral				
	dermal				
	inhalation				
Mutagenicity	in vitro				
	in vivo				
Carcinogenicity	oral				
	dermal				
	inhalation				
Reproductive toxicity[13] fertility impairment	oral	NA			
	dermal	NA			
	inhalation	NA			
Reproductive toxicity developmental tox	oral	NA			
	dermal	NA			
	inhalation	NA			

6 NOAEL (NOAEC), LOAEL , T25, BMD(L)10 or any other dose descriptor; indicate whether this concerns a no or lowest observed effect level etc
7 In this column the relevant effect for which the dose descriptor is determined is provided
8 This column is for indicating whether data were available, whether the substance is classified for this endpoint, for shortly describing specifics of the study (e.g. 28-d gavage rat, 5 d/wk or 2-gen diet rat, 7 d/wk), and for indicating (additional) uncertainty in available data
9 Local exposure: units are mg/m3 for inhalation, and mg/cm2 or ppm for dermal exposure
10 Systemic: units are mg/m3 for inhalation, and mg/kg bw/day for oral and dermal exposure
11 In general, sublethal toxicity is a more rational starting point for acute toxicity than mortality data; information on acute toxicity may also be derived from e.g. repeated dose toxicity studies or reproductive toxicity studies
12 Not Applicable
13 These repeated exposure studies may also show relevant acute effects of the test substance; these should be accounted for under the endpoint acute toxicity

5.11.2 Correction of dose descriptors if needed (for example route-to-route extrapolation), application of assessment factors and derivation of the endpoint specific DN(M)EL

Table 31: Corrected dose descriptor(s) per endpoint and endpoint-specific DNEL(s)/DMEL(s) for the relevant exposure pattern[14]

Endpoint		**Most relevant quantitative dose descriptor[15] (appropriate unit)**		**Corrected dose descriptor (appropriate unit)**		**Overall AF applied**	**Endpoint-specific DNEL/DMEL (appropriate unit)**	
		Local[16]	Systemic[17]	Local[3]	Systemic[4]		Local[3]	Systemic[4]
Acute toxicity	oral							
	dermal							
	inhalation							
Irritation/Corrosivity	skin		NA[18]		NA			NA
	eye		NA		NA			NA
	resp. tract		NA		NA			NA
Sensitisation	skin		NA		NA			NA
	resp. tract		NA		NA			NA
Repeated dose toxicity sub-acute/ sub-chronic/ chronic	oral							
	dermal							
	inhalation							
Mutagenicity	in vitro							
	in vivo							
Carcinogenicity	oral							
	dermal							
	inhalation							

[14] Repeat as appropriate for the different populations (workers/general population and eventually specific sensitive population)

[15] NOAEL (NOAEC), LOAEL , T25, BMD10 etc or any other dose descriptor; indicate whether this concerns a no or lowest observed effect level etc

[16] Local exposure: units are mg/m^3 for inhalation, and mg/cm^2 or ppm for dermal exposure

[17] Systemic: units are mg/m^3 for inhalation, and mg/kg bw/day for oral and dermal exposure

[18] Not Applicable

Endpoint		**Most relevant quantitative dose descriptor[15] (appropriate unit)**		**Corrected dose descriptor (appropriate unit)**		**Overall AF applied**	**Endpoint-specific DNEL/DMEL (appropriate unit)**	
		Local[16]	Systemic[17]	Local[3]	Systemic[4]		Local[3]	Systemic[4]
Reproductive toxicity fertility impairment	oral	NA		NA			NA	
	dermal	NA		NA			NA	
	inhalation	NA		NA			NA	
Reproductive toxicity developmental tox	oral	NA		NA			NA	
	dermal	NA		NA			NA	
	inhalation	NA		NA			NA	

.

5.11.3 Selection of the critical DNEL(s)/DMELs and/or qualitative/semi-quantitative descriptor for critical health effects

Table 32: DN(M)ELs for workers

Exposure pattern	Route	Descriptors	DNEL/DMEL (appropriate unit)	Most sensitive endpoint
Acute - systemic effects	dermal (mg/kg bw /day)	19		
	Inhalation (mg/m^3)			
Acute - local effects	Dermal (mg/cm^2)			
	Inhalation (mg/m^3)			
Long-term - systemic effects	Dermal (mg/kg bw /day)			
	Inhalation (mg/m^3)			
Long-term – local effects	Dermal (mg/cm^2)			
	Inhalation (mg/m^3)			

Discussion

Table 33: DN(M)ELs for the general population[20]

Exposure pattern	Route	Descriptors	DNEL/DMEL (appropriate unit)	Most sensitive endpoint
Acute - systemic effects	Dermal (mg/kg bw /day)			
	Inhalation (mg/m^3)			
	Oral (mg/kg bw /day)			
Acute - local effects	Dermal (mg/cm^2)			
	Inhalation (mg/m^3)			
Long-term - systemic effects	dermal(mg/kg bw /day)			
	Inhalation (mg/m^3)			
	oral(mg/kg bw /day)			
Long-term – local effects	Dermal (mg/cm^2)			
	Inhalation (mg/m^3)			

Discussion

[19] Values in IUCLID 5 are DNEL/DMEL/ not quantifiable

[20] General population includes consumers and humans via the environment. In rare cases it may also be relevant to derive a DNEL for specific subpopulations, such as children. In this case the table need to be repeated.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

6.1 Explosivity

The substance has no explosive properties. There are no chemical groups associated with explosive properties present in the molecule.

6.2 Flammability

The substance is non flammable. The substance has no pyrophoric properties and does not liberate flammable gases on contact with water.

6.3 Oxidising potential

The substance has no oxidizing properties. The substance is incapable of reacting exothermically with combustible materials based on chemical structure.

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

Acute tests on all three trophic levels were performed to examine the aquatic toxicity of HDDA.

7.1.1 Toxicity data

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

The results are summarised in the following table:

Table 34: Overview of short-term effects on fish

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

The substance is acutely toxic for aquatic organisms.

7.1.1.1.2 Long-term toxicity to fish

The results are summarised in the following table:

Table 35: Overview of long-term effects on fish

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IU5 (followed by transfer to CSR using the PlugIn-tool) !!

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

7.1.1.2 Aquatic invertebrates

7.1.1.2.1 Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 36: Overview of short-term effects on aquatic invertebrates

Species	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable

Discussion

To determine the toxicity of HDDA to aquatic invertebrates, a non-GLP study following the method laid down in Directive 79/831/EEC using Daphnia magna was performed. The calculated EC50 (48h) value in this study was 2.6 mg/L [BASF SE 1989].

The following information is taken into account for any hazard / risk / persistency assessment:

The substance is acutely toxic for aquatic organisms.

7.1.1.2.2 Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 37: Summary of long-term effects on invertebrates

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IU5 (followed by transfer to CSR using the PlugIn-tool) !!

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

7.1.1.3 Algae and aquatic plants

The results are summarised in the following table:

Table 38: Overview of effects on algae and aquatic plants

Method	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable

Discussion

Effects on algae / cyanobacteria

The following information is taken into account for any hazard / risk / persistency assessment:

The substance is acutely toxic for aquatic organisms.

Effects on aquatic plants other than algae

No information available.

The following information is taken into account for any hazard / risk / persistency assessment:

--

7.1.1.4 Sediment organisms

The results are summarised in the following table:

Table 39: Overview of effects on sediment organisms

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver !! (to be inserted later…)

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

7.1.1.5 Other aquatic organisms

The results are summarised in the following table:

Table 40: Overview of effects on other aquatic organisms

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver !! (to be inserted later…)

Discussion

The following information is taken into account for any hazard / risk / persistency assessment:

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

Table 41: PNEC aquatic

	Value	Assessment factor	Remarks/Justification

	Value	Assessment factor	Remarks/Justification

7.1.2.2 PNEC sediment

Table 42: PNEC sediment

	Value	Assessment factor	Remarks/Justification

7.2 Terrestrial compartment

7.2.1 Toxicity data

!! Draft waiver !! (to be inserted later…)

7.2.1.1 Toxicity to soil macro organisms

The results are summarised in the following table:

Table 43: Overview of effects on soil macro-organisms

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IU5 (followed by transfer to CSR using the PlugIn-tool) !!

Discussion of effects on soil macro-organisms except arthropods

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC::

Discussion of effects on soil arthropods

No information available.

The following information is taken into account for effects on soil arthropods for the derivation of PNEC:

--

7.2.1.2 Toxicity to terrestrial plants

The results are summarised in the following table:

Table 44: Overview of effects on terrestrial plants

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IUS (followed by transfer to CSR using the PlugIn-tool) !!

Discussion

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

7.2.1.3 Toxicity to soil micro-organisms

The results are summarised in the following table:

Table 45: Overview of effects on soil micro-organisms

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IU5 (followed by transfer to CSR using the PlugIn-tool) !!

Discussion

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

7.2.1.4 Toxicity to other terrestrial organisms

The results are summarised in the following table:

Table 46: Overview of effects on terrestrial arthropods other than soil macro-organisms

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IU5 (followed by transfer to CSR using the PlugIn-tool) !!

Discussion

The following information is taken into account for any hazard / risk assessment::

7.2.2 Calculation of Predicted No Effect Concentration (PNEC_soil)

Table 47: PNEC soil

	Value	Assessment factor	Remarks/Justification

7.3 Atmospheric compartment

No information available.

7.4 Microbiological activity in sewage treatment systems

7.4.1 Toxicity to aquatic micro-organisms

The results are summarised in the following table:

Table 48: Overview of effects on terrestrial arthropods other than soil macro-organisms

Species	Results	Remarks	Reference

Data waiving *(if applicable)*

Not applicable

Testing proposal *(if applicable)*

Not applicable

Discussion

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

Depending on local conditions and existing concentrations, disturbances in the biodegradation process of activated sludge are possible.

7.4.2 PNEC for sewage treatment plant

Table 49: PNEC sewage treatment plant

	Value	Assessment factor	Remarks/Justification

7.5 Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1 Toxicity to birds

The results are summarised in the following table:

Table 50: Overview of effects on birds

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Testing proposal *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

!! Testing proposal to be laid down in IU5 (followed by transfer to CSR using the PlugIn-tool) !!

Discussion

The following information is taken into account for effects on birds for the derivation of PNEC:

7.5.2 Toxicity to mammals

The results are summarised in the following table:

Table 51: Overview of effects on mammals

Method	Results	Remarks	Reference
--	--	--	--

Data waiving *(if applicable)*

!! Draft waiver or propose testing !! (to be inserted later…)

Discussion

The following information is taken into account for effects on mammals for the derivation of PNEC:

7.5.3 Calculation of PNECoral (secondary poisoning)

Table 52: PNEC oral

	Value	Assessment factor	Remarks/Justification
PNEC oral (mg/kg food)	--	--	--

7.6 Conclusion on the environmental classification and labelling

The hazard assessment of HDDA reveals no need to classify the substance as dangerous to the environment.

8 PBT AND VPVB ASSESSMENT

8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

8.1.1 Persistence Assessment

HDDA is readily biodegradable. Therefore, it is not a P and not a vP substance, respectively.

8.1.2 Bioaccumulation Assessment

The measured logKow for HDDA is 2.81, thus well below 4.5. Therefore, the substance is not a B and not a vB substance, respectively.

8.1.3 Toxicity Assessment

When compared to the screening criteria for (T), data available for HDDA from short-term aquatic toxicity studies – with EC50 or LC50 values well above 0.1 mg/L for all three trophic levels – indicate that the substance does presumably not fulfil the (T) criterion.

Declaredly, the toxicity criterion (T) for PBT assessment cannot definitely be decided on the basis of acute studies alone. However, given the fact that HDDA is clearly not fulfilling the (P) and (B) criteria, no further assessment of the (T) criterion is necessary.

8.1.4 Summary and overall Conclusions on PBT or vPvB Properties

HDDA is neither a PBT nor a vPvB substance.

8.2 Emission Characterisation

HDDA is not classified as dangerous for the environment, therefore no emission characterisation and no environmental exposure assessment has been carried out.

9 EXPOSURE ASSESSMENT

9.1 Exposure Scenarios

9.1.1 Basic Exposure Scenarios by ECETOC TRA

All possible categories (PROCs) considered in ECETOC TRA have been estimated for the substance. In case the results indicate the further assessment is required, follow the link to the refinement in the branch-specific scenario and the additional risk management measures provided in the following chapter. DNEL used as calculated in chapter 5.11, PNEC as calculated in chapter 7.

Description of ECETOC TRA details can be found in the Technical Report 93 (2004) or at https://www.ecetoc-tra.org/

Table 53: Overview on workplace exposure scenarios by ECETOC TRA

process cate-gories [PROC]	Use Scenarios	Duration of activity [hours]	LEV (Y/N)	Estimated Exposition [ppm]	MoE [DNEL/ est expo]	Further assessment required
PROC 1	Use in a closed process with no likelihood of exposure	> 4 hours	Yes	0,01	31,8	No
PROC 2	Use in closed process with occasional controlled exposures e.g. during sampling	> 4 hours	Yes	0,5	0,636	Yes **no refinement done – if needed, please contact manufacturer**
PROC 3	Use in a closed batch process i.e. where only limited opportunity for breaching arises e.g. sampling	> 4 hours	Yes	0,1	3,18	No
PROC 4	Use in a batch or other process (including related process stages e.g. filtration, drying) where opportunities for exposure arise e.g. sampling, dis/charging of materials	> 4 hours	Yes	1	0,318	Yes **no refinement done – if needed, please contact manufacturer**
PROC 5	Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendaring of liquid and solid-based products	> 4 hours	Yes	1	0,318	Yes **for refinement see chapter 9.2**
PROC 6	Spraying of the substance or preparations containing the substance in industrial applications e.g. coatings	1 - 4 hours	Yes	12	0,026	Yes **for refinement see chapter 9.2**
PROC 7	Dis/charging the substance (or preparations containing the substance) to/from vessels	1 - 4 hours	No	6	0,053	Yes **for refinement see chapter 9.2**
PROC 8	Filling containers with the substance or its preparations (including weighing)	1 - 4 hours	No	6	0,053	Yes **for refinement see chapter 9.2**
PROC 9	Roller application or brushing of adhesives and other surface coatings	1 - 4 hours	No	300	0,001	Yes **for refinement see chapter 9.2**
PROC 10	Use as a blowing agent in the manufacture of foams, etc.	> 4 hours	Yes	0,5	0,636	Yes **no relevant**

						PROC
PROC 11	Use for coating/treatment of articles, etc. (including cleaning) by dipping or pouring	> 4 hours	Yes	3	0,106	Yes **for refinement see chapter 9.2**
PROC 12	Production of products or articles from substance by compression, tabletting, extrusion or pelletisation	> 4 hours	Yes	3	0,106	Yes **no refinement done – if needed, please contact manufacturer**
PROC 13	Use as a laboratory reagent	1 - 4 hours	Yes	0,06	5,3	No
PROC 14	Use as a fuel	< 15 mins	No	0,1	3,18	No
PROC 15	Use as a lubricant (including metal working fluids)	> 4 hours	Yes	50	0,006	Yes **no refinement done – if needed, please contact manufacturer**

After UV curing, HDDA becomes part of a solid matrix and does not exist as a single molecule anymore. Therefore, wide dispersive use is not considered relevant for this substance. For the same reason, consumer exposure of HDDA is excluded.

As HDDA does not need to be classified as dangerous to the environment, a respective exposure assessment is not carried out.

9.1.2 Basic Exposure Scenarios by other sources

(optional)

9.2 Generic / Sector group- / branch-specific Exposure Scenarios

Table 54: Sector-specific scenarios by CEFICs UV/EB acrylate resins sector group, Sectors of Use 6, 7, 10 (SU 6, 7, 10) and NACE C 20.3.

Type	Scenario Title	Duration of activity (hours)	additional OC / RMM	Est. Exposition [ppm] (refined)	Margin of Exposure [DNEL/ est expo]	Further assessment required
SU 7, 10 UV/EB 1	FORMULATION (covering PROC 5)	< 4 hours	• Ambient temperature (< 30°C) • Room ventilation rate > 6 / h • Chemical resistant protective gloves (EN 374), nitrile rubber (NBR) - 0.4 mm coating thickness • Safety glasses with side-shields (frame goggles) (e.g. EN 166)	0.016 (PROC 5)	19.9 (PROC 5)	No* (PROC 5)
SU 7, 10 UV/EB 2	MAINTENANCE (covering PROC 7 and PROC 8)	< 1 hours	• Ambient temperature (< 30°C) • Room ventilation rate > 6 / h • Chemical resistant protective gloves (EN 374), nitrile rubber (NBR) - 0.4 mm coating thickness • Safety glasses with side-shields (frame goggles) (e.g. EN 166)	0.024 (PROC 7) 0.024 (PROC 8)	13.25 (PROC 7) 13.25 (PROC 8)	No** (PROC 7) No** (PROC 8)
SU 6, 7 PC 9, PC 18, PC 26 UV/EB 3	APPLICATION (covering PROC 6, PROC 9 and PROC 11)	> 4 hours	• Ambient temperature (< 30°C) • Room ventilation rate > 6 / h • Chemical resistant protective gloves (EN 374), nitrile rubber (NBR) - 0.4 mm coating thickness • Safety glasses with side-shields (frame goggles) (e.g. EN 166) • HDDA used in the preparation at max. 30% [w/w] • Spray booth	0.000576 (PROC 6) 0.0144 (PROC 9) 0.000144 (PROC 11)	541.7 (PROC 6) 20.8 (PROC 9) 2208.3 (PROC 11)	No*** (PROC 6) No*** (PROC 9) No*** (PROC 11)

The description of RMMs will be more standardized. Here some more details have been given at this chapter (duplicating from A 1) for transparency.

Effectiveness of RMM in general:

Use of adequate gloves (as specified): 90 % recovery (= factor 0.1)

Use of adequate breathing protection (as specified): 95 % recovery (= factor 0.05)

Use of adequate spray booth (technical standard): 99 % recovery (= factor 0.01)

Following calculation is shown for transparency in this example only - but it would not be given in a normal CSR :

*Exposition (Table 54) = Exposition (Table 53)*1/6 (ventilation rate)*0.1(gloves)
0.016 = 1*0.16*0.1
[how to quantify change in duration of activity from >4 to <4??]
Margin of exposure (Table 54) = Exposition (Table 53)/Exposition (Table 54)* Margin of exposure (Table 53)
19.875 = 1/0.016*0,318

**Exposition (Table 54) = Exposition (Table 53)*0.25 (duration)* 1/6 (ventilation rate)*0.1(gloves)
0.024 = 6*0.25*0.16*0.1
Margin of exposure (Table 54) = Exposition (Table 53)/Exposition (Table 54)* Margin of exposure (Table 53)
13.25 = 6/0.024*0,053

***Exposition (Table 54) = Exposition (Table 53)*1/6 (ventilation rate)*0.1 (gloves)*0.3 (concentration)*0.01 (spray booth)
0.000576 = 12*0.16*0.1*0.3*0.01
0.0144 = 300*0.16*0.1*0.3*0.01
0.000144 = 3*0.16*0.1*0.3*0.01
Margin of exposure (Table 54) = Exposition (Table 53)/Exposition (Table 54)* Margin of exposure (Table 53)
541.7 = 12/0.000576*0,026
20.8 = 300/0.0144*0,001
2208.3 = 3/0.000144*0,106

According to the conditions of the sector-specific scenario. Parameter values (use frequency, duration, relevant exposure pathways etc.) for input into this sector-specific model have been collected for sector group specific product applications, following the model of the UV/EB sector group table of habits and practices.

Please contact UV/EB sector group for all necessary information. (Link is not workable yet!)

9.3 Individual Exposure Scenarios / individual Use Conditions

Not performed, because use have been evaluated as safe in step 2.

Table 55: Overview on exposure scenarios and coverage of substance life cycle

Number and title (*copy from tables in section 2.2.)*	**Manufacture**	**Preparation making**	**Industrial and/or wide disperse use**	**Consumer use**	**Article service life**	**Waste stage**

9.3.1 Individual exposure scenario 1 (iES 1)

9.3.1.1 Short title of individual exposure scenario 1

9.3.1.2 Description of activities and processes covered in iES 1

9.3.1.3 Operational conditions related to frequency, duration and amount of use

Table 56: Duration, frequency and amounts related to exposure of workers

Information type	**Data field**	**Explanation**
Use amount per worker [workplace] per day	kg/d	
Duration per day at workplace [for one worker]	h/day	
Frequency at workplace [for one worker]	Times per …..	
Other determinants related to duration, frequency and amount of use		

Remarks or additional information:

Table 57: Duration, frequency and amount related to consumer uses

Information type	**Data field**	**Explanation**
Number of uses/applications per day/year by one consumer [in one flat]	Times per day or year	
Amount of product per application	kg	
Duration of use per day or per year	h/day; days/year	
Fraction of amount available for exposure via air (migration fractions, release fraction)[1]	%	
Fraction of amount available for exposure via skin (migration fractions, release fraction)[1]		

Information type	Data field	Explanation
Fraction of amount available for exposure via ingestion (migration fractions, release fraction)[1]		
Other determinants related to duration, frequency and amount		

1) see Guidance Table D.5.3 and section R.15.4

Remarks or additional information:

Table 58: Duration, frequency and amounts related to emissions from industrial sites

Information type	Data field	Explanation
Annual amount used per site	Kg/y	
Emission days per site	d/y	
Other determinants related to duration, frequency and amount		

Remarks or additional information:

Table 59: Duration, frequency and amounts related to emissions from wide disperse use

Information type	Data field	Explanation
Annual amount used in a preparation category (ies) selected in 9.1.1.1	kg/y	
Emission days per year related to that preparation category	d/y	
Other determinants related to duration, frequency and amount		

Remarks or additional information:

Table 60: Duration, frequency and amounts related to emissions from article service life

Information type	Data field	Explanation
annual amount processed into an article category (ies) selected in 9.1.1.1	kg/y	
Fraction of amount available for releases to the environment (migration fractions, release fraction)[1]	%	
Emission days per year related to that article category	d/y	
Other determinants related to duration, frequency and amount		

[1)] See Guidance Chapter R.17 on releases from articles

Remarks or additional information:

9.3.1.4 Operational conditions related to product characteristics

Table 61: Product Characteristic

Information type	Data field	Explanation
Type of product the information relates to	Substance as such, preparation, article	
Physical state of product	gas, liquid, solids	
For solids: Categorisation of dust grades see table Guidance R.14-8	Low, medium, high	
Concentration of substance in product	%	
Concentration after dilution for use (if relevant)	%	
Surface-mass ratio of the article	Cm^2/kg	
Service life span of the article	Y	
Condition of use promoting release from article (*see environmental release category (ERC) 10a to 11b in table R.16-22)*	y/n: loss over life time	

Remarks or additional information:

9.3.1.5 Other operational conditions of use

Table 62: Respiration volume and skin contact under conditions of worker uses

Information type	Data field	Explanation
Respiration volume under conditions of use	m^3/d	
Skin contact area with the substance under conditions of use	cm^2	
Other determinants related to respiration and skin contact		

Table 63: Respiration volume, skin contact and ingestion under condition of consumer uses

Information type	Data field	Explanation
Skin/mouth contact area	Cm^2	
Inhalation rate under conditions of use		
Body weight of	Kg	
Other determinants related to …		

Remarks or additional information:

Table 64: Conditions leading to dilution of initial release related to human health

Information type	Data field	Explanation
Room size and ventilation rate	m^3; exchange per hour	

Information type	Data field	Explanation
Other determinants related to dilution		

Remarks or additional information:

Table 65: Conditions leading to dilution of initial release related to environment

Information type	Data field	Explanation
Discharge volume of sewage treatment plant	m^3/d	
Available river water volume to receive the emissions from a site	m^3/d	
Other determinants related to dilution		

Remarks or additional information:

Table 66: Process condition

Table 67: Technical fate of substance and losses from process to waste, waste water and air

Information type	Data field	Explanation
Fraction of applied amount lost from process to waste gas,	kg/kg	Short description
Fraction of applied amount lost from process to waste water (after internal recycling of substance, if any)	kg/kg	
Fraction of applied amount lost from process to waste (after internal recycling of substance, if any)	kg/kg	
Fraction of applied amount leaving the site with products	kg/kg	Short description
Fraction consumed in process	kg/kg	Short description

Remarks or additional information:

9.3.1.6 Risk management measures

9.3.1.6.1 Risk management measures related to workers

	General safety and hygiene measures: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is required additionally to the stated personal protection equipment. Containment and local exhaust ventilation related to workers:

	Containment plus good work practice required Local exhaust ventilation Spray application: Closed boxes Personal protective equipment Respiratory protection: Suitable respiratory protection for higher concentrations or long-term effect: Gas filter for gases/vapours of organic compounds (boiling point >65 °C, e. g. EN 14387 Type A) Hand protection: Chemical resistant protective gloves (EN 374) Suitable materials also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): nitrile rubber (NBR) - 0.4 mm coating thickness Supplementary note: The specifications are based on own tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the determined permeation time. Manufacturer's directions for use should be observed because of great diversity of types. Eye protection: Safety glasses with side-shields (frame goggles) (e.g. EN 166) Body protection: Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to DIN-EN 465).

Table 68: Measures related to the design of product (other than concentration) related to workers

Table 69: Containment and local exhaust ventilation related to workers

Information type	**Data field**	**Explanation**
Containment plus good work practice required	Effectiveness in terms of residual exposure	Short description on the technical type and level of containment
Local exhaust ventilation required plus good work practise	Effectiveness in terms of reduction factor against	short description

Information type	Data field	Explanation
	situation without LEV or residual exposure	

Remarks or additional information:

Table 70 : Personal protection equipment (PPE) required under regular working conditions

Table 71 : Other risk management measures related to workers

9.3.1.6.2 Risk management measures related to consumers

Not relevant, no consumer exposure

Table 72: Measures related to the design of product (other than concentration) related to consumers

Table 73: Instructions addressed to consumers

Table 74: PPE required under regular conditions of consumer use

9.3.1.6.3 Risk management measures related to environment

Production processes are continuously environmentally monitored. And waste water is treated in a waste water treatment plants so that no direct discharge of the substance into surface water occurs.

Table 75 : Measures related to the design of products (other than concentration)

Table 76: Risk management measures related to environmental emissions from sites

Information type	Data field	Explanation
Onsite pre-treatment of waste water	Effectiveness [fraction in waste water related fraction emitted to sewage]	Short description of technique
Resulting fraction of applied amount in waste water released from site	Kg/kg	
Air emission abatement	Effectiveness [fraction in waste air	Short description of

Information type	Data field	Explanation
	compared to fraction emitted]	technique
Resulting fraction of applied amount in waste gas released to environment	kg/kg	
Fraction of substance in waste treated onsite aiming at final disposal (with or without recovery of heat.)	kg/kg	
Fraction of applied amount sent to external waste treatment (sum of direct losses from processes and residues from waste water and waste gas treatment)	kg/kg	Short description of technique
Municipal or other type of external waste water treatment	Effectiveness of substance removal [fraction of substance in treated waste water compared to fraction emitted into sewer]	Short description of technique
Recovery of sludge for agriculture or horticulture	Yes/no	
Other risk management measures		

Remarks or additional information:

Table 77: Risk management measures related to emissions to the environment from wide disperse use

Information type	Data field	Explanation
Municipal waste water treatment	Yes/no	Short description of technique including sludge disposal
Other risk management measures		

Remarks or additional information:

Table 78: Other RMM

9.3.1.7 Waste related measures

Table 79: Waste management measures

Information type	Data field	Explanation
Amount of substances in waste resulting from the activities/processes covered in the exposure scenario	kg/y	
Amount of substances in waste resulting from service life of articles	kg/y	
Type of waste, suitable waste codes		
Type of external treatment aiming at recycling or recovery of substances	Type of treatment according to Appendix R.18-1	
Fraction of the amount of substance in waste stream recovered.	kg/kg	

Information type	Data field	Explanation
Type of external treatment aiming at final disposal of the waste	Type of treatment according to Appendix R.18-1	
Fraction of substance released into the environment via air (after abatement)	kg/kg	
Fraction of substance released into the environment via waste water (after abatement)	kg/kg	
Fraction of substance released into the environment via air (after abatement)	kg/kg	
Fraction of substance released into the environment via waste water (after abatement)	kg/kg	
Fraction of substance disposed of as secondary waste	kg/kg	
Other waste management measures		

Remarks or additional information:

Table 80: Other waste management measures

9.3.2 Exposure estimation

9.3.2.1 Workers exposure

9.3.2.1.1 Acute/Short term exposure

Table 81: Acute exposure concentrations to workers

Routes of exposure	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	Value	unit	
Dermal exposure					
Inhalation exposure					

Summary of the short-term exposure values.

Table 82: Summary of acute exposure concentrations to workers

Routes of exposure	Concentrations	Justification
Dermal exposure (in mg/cm^2)		

Routes of exposure	Concentrations	Justification
Inhalation exposure (in mg/m^3)		

9.3.2.1.2 Long-term exposure

Table 83: Long-term exposure concentrations to workers

Routes of exposure	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	Value	unit	
Dermal exposure					
Inhalation exposure					

Summary of the long-term exposure values.

Table 84: Summary of long-term exposure concentration to workers

Routes of exposure	Concentrations	Justification
Dermal exposure (in mg/cm^2)		
Inhalation exposure (in mg/m^3)		

9.3.2.2 Consumer exposure

9.3.2.2.1 Acute/Short term exposure

When several life cycle steps are relevant for the exposure scenario, then exposure at these different stages should be taken into account (e.g. service life of article)

Table 85: Acute exposure concentrations to consumers

Routes of exposure	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	Value	unit	
Oral exposure					
Dermal exposure					
Inhalation exposure					

Summary of the short-term exposure values.

Table 86: Summary of acute exposure concentrations to consumers

Routes of exposure	Concentrations	Justification
Oral exposure (in mg/kg bw/d)		
Dermal exposure (in mg/cm^2)		
Inhalation exposure (in mg/m^3)		

9.3.2.2.2 Long-term exposure

Table 87: Long term exposure concentrations to consumers

Routes of exposure	Estimated Exposure Concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
Oral exposure					
Dermal exposure					
Inhalation exposure					

Summary of the long-term exposure values.

Table 88: Summary of long term exposure concentrations to consumers

Routes of exposure	Concentrations	Justification
Oral exposure (in mg/kg bw/d)		
Dermal exposure (in mg/cm^2)		
Inhalation exposure (in mg/m^3)		

9.3.2.3 Indirect exposure of humans via the environment (oral)

Table 89: Concentration for oral exposure of humans via the environment

	Estimated exposure concentrations	Measured exposure concentrations	Explanation / source of measured data

	value	unit	value	unit	
Wet fish					
Drinking water					
Meat					
Milk					
Other					

Summary of the exposure concentration in to be used for the risk characterisation of indirect exposure of man via the environment

Table 90: Total daily dose for oral exposure of humans via the environment

Total daily dose for oral exposure via the environment (mg/kg bw/d)		**Justification**
Exposed via local concentration	**Exposed via local and regional concentration**	

9.3.2.4 Environmental exposure

In case the exposure scenario is covering several life stages, the section below has to be repeated to cover those different life stages within this section.

9.3.2.4.1 Environmental releases

Table 91: Releases to the environment from point source

compartments	**Predicted releases (kg/d)**	**Measured release (kg/d)**	**Explanation / source of measured data**
Aquatic (without WWTP)	[21]		*These data correspond to release to waste water*
Aquatic (after WWTP)			*These correspond to release to natural waters after the waste water treatment plant.*
Air (direct + WWTP)			
Soil (direct only)			

[21] The predicted release are estimated from the "annual amount used" and the "number emission days" (cf Table 58) and the "fraction of applied amount lost from process to waste water" (cf Table 67)

Table 92: Releases to the environment from dispersive use

compartments	Predicted releases (kg/d)	Measured release (kg/d)	Explanation / source of measured data
Aquatic (without WWTP)	22		*These data correspond to release to waste water*
Aquatic (after WWTP)			*These correspond to release to natural waters after the waste water treatment plant.*
Air (direct + WWTP)			
Soil (direct only)			

Summary of the releases taken into account for the exposure estimation.

Table 93: Summary of the releases to the environment

Compartments	Release from point source (kg/d) (local exposure estimation)	Total release for regional exposure estimation (kg/d)	Justification
Aquatic (without WWTP)			
Aquatic (after WWTP)			
Air (direct + WWTP)			
Soil (direct releases only)			

9.3.2.4.2 Exposure concentration in waste water treatment plants (WWTP)

Table 94: Concentrations in waste water

Compartments	Estimated exposure concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
Waste water					
Waste water sludge					

22 The predicted release are estimated from the “annual amount used” and the “number emission days” (cf Table 59 and/or Table 60) and the “fraction of applied amount lost from process to waste water” (cf Table 67)

Compartments	Estimated exposure concentrations		Measured exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	

Summary of the exposure concentration in waste water treatment plants taken into account for further exposure estimation (water and soil concentrations) or risk characterisation for micro organisms in the WWTP

	Value	Justification
Concentration in wastewater (PECstp)(in mg/l)		
Concentration in waste water sludge (in mg/kg d.w.)		

9.3.2.4.3 Exposure concentration in aquatic pelagic compartment

Table 95: Local concentrations in water

Compartments	Estimated exposure concentrations		Measured local exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
Freshwater					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…
Marine water					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…
Intermittent releases to water					

Summary of the Predicted Exposure Concentrations (PEC) in the aquatic pelagic compartment taken into account for risk characterisation

Table 96: Predicted Exposure Concentrations (PEC) in aquatic compartment

Compartments	Local concentration	PEC aquatic (local+regional)	Justification

Freshwater (in mg/l)			
Marine water (in mg/l)			
Intermittent releases to water (in mg/l)			

9.3.2.4.4 Exposure concentration in sediments

Table 97: Local concentrations in sediment

Compartments	**Estimated exposure concentrations**		**Measured local exposure concentrations**		**Explanation** *(including if equilibrium method partitioning has been used, report the partitioning coefficient)* / **source of measured data**
	value	**unit**	**value**	**unit**	
Freshwater sediments					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…
Marine water sediments					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…

.

Summary of the exposure concentration in aquatic sediments taken into account for risk characterisation

Table 98: Predicted Exposure Concentrations (PEC) in sediments

Compartments	**Local concentration**	**PEC sediment (local+regional)**	**Justification**
Freshwater sediments (in mg/kg d.w)			
Marine water sediments (in mg/kg d.w.)			

9.3.2.4.5 Exposure concentrations in soil and groundwater

Table 99: Local concentrations in soil

Compartments	**Estimated exposure concentrations**	**Measured local exposure concentrations**	**Explanation** *(including number of days for averaging)* / **source of measured data**

	value	unit	value	unit	
Agricultural soil averaged					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…
Grassland averaged					
Groundwater					

Summary of the Predicted Exposure Concentration (PEC) in soil taken into account for risk characterisation

Table 100: Predicted Exposure Concentrations (PEC) in soil and groundwater

	Local concentration	PEC soil/groundwater (local+regional)	Justification
Agricultural soil averaged (mg/kg ww)			
Grassland averaged (mg/kg ww)			
Groundwater(mg/l)			

9.3.2.4.6 Atmospheric compartment

Table 101: Local concentrations in air

	Estimated exposure concentrations		Measured local exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
During emission					
annual average					
Annual total deposition					

Summary of the Predicted Exposure Concentration in soil taken into account for risk characterisation

Table 102: Predicted Exposure Concentration (PEC) in air

	Local concentration	PEC air (local+regional)	Justification
During emission (µg/m3)			
annual average (µg/m3)			
Annual deposition (µg/m²/d)			

9.3.2.4.7 Exposure concentration relevant for the food chain (Secondary poisoning)

Table 103: Local concentration relevant for secondary poisoning

	Predicted exposure concentrations		Measured local exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
Concentration in food of fish eating predator					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…
Concentration in food of fish eating top-predator (marine)					*Estimated local exposure concentration based on…*
					Estimated predicted exposure concentration (PEC) = estimated local exposure concentration + regional concentration (from Table 105)
					Measured concentration in…
Concentration in earthworm					

.

Summary of the Predicted Exposure Concentration in food for secondary poisoning taken into account for risk characterisation

Table 104: Predicted Exposure Concentration in food (PECoral) for secondary poisoning

	Local concentration	PEC oral (local+regional)	Justification
PECoral predator (in mg/kg w.w)			
PECoral top predator (in mg/kg w.w.)			
Concentration in earthworm (in mg/kg w.w.)			

9.3.3 Individual exposure scenario 2 (iES 1)

9.3.3.1 Short title of individual exposure scenario 2

9.3.3.2 Description of activities and processes covered in iES 2

9.3.3.3 Operational conditions related to frequency, duration and amount of use

…

9.4 Regional exposure concentrations

Table 105: Regional concentrations in the environment

	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	value	unit	value	unit	
Freshwater					
Marine water					
Freshwater sediments					
Marine sediments					
Agricultural soil					
Grassland					
Air					

Table 106: Regional concentrations in food and drinking water

	Predicted regional Exposure Concentrations		Measured regional exposure concentrations		Explanation / source of measured data
	value	unit	value	Unit	
Wet fish					
Drinking water					
Meat					
Milk					

10 RISK CHARACTERISATION

10.1 Generic Risk Characterisation (ECETOC TRA)

See 9.1

10.2 Sector group- / branch-specific Risk Characterisation

See 9.2

10.3 Individual Risk Characterisation

10.3.1 (Title of individual exposure scenario 1)

10.3.2 Human health

10.3.2.1 Workers

Table 107: (Semi) Quantitative risk characterisation for workers

Route		iES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	DN(M)EL[23]	Risk characterisation ratio[24]
Dermal- local	**Acute**	In mg/cm^2			
	Long term	In mg/cm2			
Dermal- systemic	**Acute**	in mg/kg bw/d			
	Long term	in mg/kg bw/d			
Inhalation - local	**Acute**	in mg/m3			
	Long term	in mg/m3			
Inhalation - systemic	**Acute**	= Inhalation-local in mg/m3			
	Long term				
Combined routes	**Acute**				RCR Inhalation-systemic + RCR Dermal- systemic
	Long term				

[23] *The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in* Table 32.

[24] *Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)*

Table 108: Qualitative risk characterisation for workers

Route		iES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	Qualitative risk characterisation
Dermal- local	**Acute**	In mg/cm^2		
	Long term	In mg/cm2		
Dermal- systemic	**Acute**	in mg/kg bw/d		
	Long term	in mg/kg bw/d		
Inhalation - local	**Acute**	in mg/m3		
	Long term	in mg/m3		
Inhalation - systemic	**Acute**	= Inhalation-local in mg/m3		
	Long term			
Combined routes	**Acute**			
	Long term			

10.3.2.2 Consumers

Table 109: (Semi) Quantitative risk characterisation for consumers

Route		iES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	DN(M)EL[25]	Risk characterisation ratio [26]
Dermal- local	**Acute**	In mg/cm^2			
	Long term	In mg/cm2			
Dermal- systemic	**Acute**	in mg/kg bw/d			
	Long term	in mg/kg bw/d			
Inhalation - local	**Acute**	in mg/m3			
	Long term	in mg/m3			
Inhalation - systemic	**Acute**	= Inhalation-local in mg/m3			
	Long term				
Oral (systemic)	**Acute**	in mg/kg bw/d			
	Long term	in mg/kg bw/d			
Combined routes	**Acute**				RCR Inhalation-systemic + RCR Dermal- systemic
	Long term				

[25] The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in Table 32

[26] Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)

Table 110: Qualitative risk characterisation for consumers

Route		iES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	Qualitative risk characterisation
Dermal- local	**Acute**	In mg/cm^2		
	Long term	In mg/cm2		
Dermal- systemic	**Acute**	in mg/kg bw/d		
	Long term	in mg/kg bw/d		
Inhalation - local	**Acute**	in mg/m3		
	Long term	in mg/m3		
Inhalation - systemic	**Acute**	= Inhalation-local in mg/m3		
	Long term			
Oral systemic	**Acute**	in mg/kg bw/d		
	Long term	in mg/kg bw/d		
Combined routes	**Acute**			
	Long term			

10.3.2.3 Indirect exposure of humans via the environment

Table 111: (Semi) Quantitative risk characterisation for humans exposed via the environment

Route	iES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	DN(M)EL[27]	Risk characterisation ratio[28]
Dermal- systemic[29] (acute or long term)	in mg/kg bw/d			
Inhalation- systemic (long term)	in mg/m3 (from Table 102)			
Oral- systemic (long term)	in mg/kg bw/d (from Table 90)			
Combined routes				RCR Inhalation-systemic + RCR Oral-systemic

27 The 8 D(M)NELs relevant here can be extracted from IUCLID 5 and are already reported in Table 32

28 Equal to the ratio of the relevant EC (reported in column 3) to the relevant D(M)NEL (reported in column 5)

29 Dermal exposure is rarely relevant for exposure of man via the environment (bathing waters)

Table 112: Qualitative risk characterisation for humans exposed via the environment

Route	iES 1- exposure concentrations (EC)	Leading toxic end point / Critical effect	Qualitative risk characterisation
Dermal- systemic[30] (acute or long term)	in mg/kg bw/d		
Inhalation- systemic (long term)	in mg/m3 (from Table 102)		
Oral- systemic (long term)	in mg/kg bw/d (from Table 90)		
Combined routes			RCR Inhalation- systemic + RCR Oral-systemic

10.3.3 Environment

10.3.3.1 Aquatic compartment (including sediment and secondary poisoning)

Table 113: Risk characterisation for the aquatic compartment

Compartments	PEC	PNEC	PEC/PNEC	Discussion
Freshwater	*in mg/l (from Table 96)*	*in mg/l (from Table 41)*		
Marine water	*idem*	*idem*		
Sediment	*in mg/kg (from Table 98)*	*in mg/kg (from Table 42)*		
Aquatic freshwater food chain	*in mg/kg (from Table 104)*	*in mg/kg food (from Table 52)*		
Aquatic marine water food chain	*idem*	*idem*		

10.3.3.2 Terrestrial compartment (including secondary poisoning)

Table 114: Risk characterisation for the terrestrial compartment

Compartments	PEC	PNEC	PEC/PNEC	Discussion
Agricultural soil	*in mg/kg (from Table 100)*	*in mg/kg (from Table 47)*		
Grassland	*idem*	*idem*		

[30] Dermal exposure is rarely relevant for exposure of man via the environment (bathing waters)

Terrestrial food chain	*in mg/kg (from Table 104)*	*in mg/kg food (from Table 52)*		

10.3.3.3 Atmospheric compartment

10.3.3.4 Microbiological activity in sewage treatment systems

Compartments	PEC	PNEC	PEC/PNEC	Discussion
STP	*in mg/l (from Table 96)*	*in mg/l (from Table 49)*		

10.4 (Title of individual exposure scenario 2)

…..

10.5 Overall exposure (combined for all relevant emission/release sources)

10.5.1 Human health (combined for all exposure routes)

Table 115: Identification of relevant combination of exposure scenarios

Exposure scenarios	Combination 1	Combination 2		
ES 1				
ES 2				

Table 116: Risk characterisation for combined relevant emission

Relevant combination of exposure scenario	Risk characterisation ratio
Combination 1	
Combination 2	

10.5.2 Environment (combined for all emission sources)

REFERENCES

It should be clarify whether all the references should be put at the end of the documents or not (might be tricky for the development of the IUCLID 5 plug-in!)

ANNEX

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