

EU의 신화학물질 관리정책(REACH) 법령집

2004. 1

EU의 신화학물질 관리정책(REACH) 법령집

Proposal for a Regulation of the
European Parliament and of the
Council Concerning REACH

2004. 1



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3. (article) / ,
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(b) 가 가 50% .

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8. (import) Community .

9. (importer) Community

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11. (downstream user) _____,

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12. (use) 가 , , , , , , , .

13. (distributor), 3, Community

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24. (registrant of own use)

25. (identified use)

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28. (per year) , .

29. (restriction) ,
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 - Council Directive 89/107/EEC 가
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- polymer

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2) 가(Human health hazard assessment)

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3) 가(Environmental hazard assessment)

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1 4 가

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 - (2) Acute effects (acute toxicity, irritation corrosivity)
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vivo

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(.

,

(route of administration))

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(organism)

(effect values)(: LC50

NOEC)

factor)

. 가 (assessment

(species)

PNEC

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가(Exposure Estimation) 가 .
(1) 가(emission estimation)
(2) (chemical fate and pathway)
(3) 가(estimation of exposure levels)

5.2.2. 가
가
.

5.2.3. (degradation), (transformation)
(reaction process) (characterization)
(environmental distribution and fate) 가가 .

5.2.4. 가 (, ,)
)
 (environmental sphere)
 . (, ,)
)가 가 (pattern)
 (variation) . , 가
 .
 -
 - 가
 - /
 -
 -
 -
 - /
 - 가
 - , , / (Section 3 Step 1)

5.2.5. 가 가 , 가
 .
 가 . , , (pattern)
 가 .

6. (Risk Characterization)

- 6.1. ,
.
- 6.2. Section (Risk Management Measure) 가 , (, ,)
(environmental sphere) . ,
(emission)/ (release)
.
- 6.3. .
- Derived No - Effect Levels ,
 - PNECs (concentration) ,
 - (event) 가
가
- 6.4 , ,
- Section 1 3 , Section 6.2 가
(estimate) DNEL PNEC ,
 - Section 2 (event)
가 ,
.

6.5. DNEL PNEC 가 가 가

(qualitative assessment)가 .

PBT vPvB ,

(site) Section 5, Step 2 ,

(downstream user) ,

 .

7. (Chemical Safety Report Format)

CHEMICAL SAFETY REPORT FORMAT

PART A

1. SUMMARY OF RISK MANAGEMENT MEASURES
2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED
3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

PART B

1. IDENTIFICATION OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES
2. CLASSIFICATION AND LABELLING
3. ENVIRONMENTAL FATE PROPERTIES
 - 3.1. Degradation
 - 3.2. Environmental distribution
 - 3.3. Bioaccumulation

PART C

1. HUMAN HEALTH HAZARD ASSESSMENT
 - 1.1. Toxicokinetics metabolism and distribution
 - 1.2. Acute toxicity
 - 1.3. Irritation
 - 1.3.1. Skin
 - 1.3.2. Eye
 - 1.3.3. Respiratory Tract
 - 1.4. Corrosivity
 - 1.5. Sensitisation
 - 1.5.1. Skin
 - 1.5.2. Respiratory system
 - 1.6. Repeated dose toxicity
 - 1.7. Mutagenicity
 - 1.8. Carcinogenicity
 - 1.9. Toxicity for reproduction
 - 1.9.1. Effects on fertility
 - 1.9.2. Developmental Toxicity
 - 1.10. Other effects
-

2. HUMAN HEALTH ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

- 2.1. Explosivity
- 2.2. Flammability
- 2.3. Oxidising potential

3. ENVIRONMENTAL HAZARD ASSESSMENT

- 3.1. Aquatic Compartment (including sediment)
- 3.2. Terrestrial Compartment
- 3.3. Atmospheric Compartment
- 3.4. Microbiological Activity in Sewage Treatment Systems

4. PBT AND vPvB ASSESSMENT

5. EXPOSURE ASSESSMENT

- 5.1. [Title of Exposure Scenario 1]
 - 5.2.1. Exposure Scenario
 - 5.2.2. Exposure Assessment
- 5.2. [Title of Exposure Scenario 2]
 - 5.3.1. Exposure Scenario
 - 5.3.2. Exposure Assessment
- [etc.]

6. RISK CHARACTERISATION

- 6.1. [Title of Exposure Scenario 1]
 - 6.1.1. Human Health
 - 6.1.1.1. Workers
 - 6.1.1.2. Consumers
 - 6.1.1.3. Humans liable to indirect exposure via the environment
 - 6.1.2. Environment
 - 6.1.2.1. Aquatic Compartment (incl. Sediment)
 - 6.1.2.2. Terrestrial Compartment
 - 6.1.2.3. Atmospheric Compartment
 - 6.1.2.4. Microbiological Activity in Sewage Treatment Systems
 - 6.2. [Title of Exposure Scenario 2]
 - 6.2.1. Human Health
 - 6.2.1.1. Workers
 - 6.2.1.2. Consumers
 - 6.2.1.3. Humans liable to indirect exposure via the environment
-
-

6.2.1. Human Health

6.2.1.1. Workers

6.2.1.2. Consumers

6.2.1.3. Humans liable to indirect exposure via the environment

6.2.2. Environment

6.2.2.1. Aquatic Compartment (incl. Sediment)

6.2.2.2. Terrestrial Compartment

6.2.2.3. Atmospheric Compartment

6.2.2.4. Microbiological Activity in Sewage Treatment Systems
[etc.]

6.x. Overall exposure (combined for all relevant emission/release sources)

6.x.1 Human health (combined for all exposure routes)

6.x.1.1

6.x.2 Environment (combined for all emission sources)

6.x.2.1

ANNEX II

Article 4(2)(a)

ANNEX II

Article 4(2)(a)

EINECS no	Name/Group	CAS no
200-061-5	D-glucitol C ₆ H ₁₄ O ₆	50-70-4
200-066-2	Ascorbic acid C ₆ H ₈ O ₆	50-81-7
200-075-1	Glucose C ₆ H ₁₂ O ₆	50-99-7
200-294-2	L-lysine C ₆ H ₁₄ N ₂ O ₂	56-87-1
200-312-9	Palmitic acid, pure C ₁₆ H ₃₂ O ₂	57-10-3
200-313-4	Stearic acid, pure C ₁₈ H ₃₆ O ₂	57-11-4
200-334-9	Sucrose, pure C ₁₂ H ₂₂ O ₁₁	57-50-1
200-432-1	DL-methionine C ₅ H ₁₁ NO ₂ S	59-51-8
200-711-8	D-mannitol C ₆ H ₁₄ O ₆	69-65-8
201-771-8	1-sorbose C ₆ H ₁₂ O ₆	87-79-6
204-007-1	Oleic acid, pure C ₁₈ H ₃₄ O ₂	112-80-1
204-664-4	Glycerol stearate, pure C ₂₁ H ₄₂ O ₄	123-94-4
204-696-9	Carbon dioxide CO ₂	124-38-9
205-278-9	Calcium pantothenate, D-form C ₉ H ₁₇ NO ₅ .1/2Ca	137-08-6
205-582-1	Lauric acid, pure C ₁₂ H ₂₄ O ₂	143-07-7
205-590-5	Potassium oleate C ₁₈ H ₃₄ O ₂ K	143-18-0
205-756-7	DL-phenylalanine C ₉ H ₁₁ NO ₂	150-30-1
208-407-7	Sodium gluconate C ₆ H ₁₂ O ₇ .Na	27-07-1
212-490-5	Sodium stearate, pure C ₁₈ H ₃₆ O ₂ .Na	822-16-2
215-279-6	Limestone A noncombustible solid characteristic of sedimentary rock. It consists primarily of calcium carbonate	1317-65-3

215-665-4	Sorbitan oleate C ₂₄ H ₄₄ O ₆ Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids erucic, linoleic and oleic (<i>Brassica napus</i> , Crucifera).	1338-43-8
216-472-8	Calcium distearate, pure C ₁₈ H ₃₆ O ₂ .1/2Ca	1592-23-0
231-147-0	Argon Ar	7440-37-1
231-153-3	Carbon C	7440-44-0
231-783-9	Nitrogen N ₂	7727-37-9
231-791-2	Water, distilled, conductivity or of similar purity H ₂ O	7732-18-5
231-955-3	Graphite C	7782-42-5
232-273-9	Sunflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, and oleic. (<i>Helianthus annuus</i> , Compositae).	8001-21-6
232-274-4	Soybean oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic (<i>Soja hispida</i> , eguminosae).	8001-22-7
232-276-5	Safflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid linoleic (<i>Carthamus tinctorius</i> , Compositae).	8001-23-8
232-278-6	Linseed oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, linolenic and oleic (<i>Linum usitatissimum</i> , Linaceae).	8001-26-1
232-281-2	Corn oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic. (<i>Zea mays</i> , Gramineae).	8001-30-7

232-293-8	Castor Oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid ricinoleic (<i>Ricinus communis</i> , Euphorbiaceae).	8001-79-4
232-299-0	Rape oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids erucic, linoleic and oleic (<i>Brassica napus</i> , Cruciferae).	8002-13-9
232-307-2	Lecithins The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid.	8002-43-5
232-436-4	Syrups, hydrolyzed starch A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins.	8029-43-4
232-442-7	Tallow, hydrogenated	8030-12-4
232-675-4	Dextrin	9004-53-9
232-679-6	Starch High-polymeric carbohydrate material usually derived from cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water.	9005-25-8
232-940-4	Maltodextrin	9050-36-6
234-328-2	Vitamin A	11103-57-4
238-976-7	Sodium D-gluconate C ₆ H ₁₂ O ₇ .xNa	14906-97-9
248-027-9	D-glucitol monostearate C ₂₄ H ₄₈ O ₇	26836-47-5
262-988-1	Fatty acids, coco, Me esters	61788-59-8
262-989-7	Fatty acids, tallow, Me esters	61788-61-2

263-060-9	Fatty acids, castor-oil	61789-44-4
263-129-3	Fatty acids, tallow	61790-37-2
266-925-9	Fatty acids, C12-18 This substance is identified by SDA Substance Name: C12-C18 alkyl carboxylic acid and SDA Reporting Number: 16-005-00.	67701-01-3
266-928-5	Fatty acids C16-18 This substance is identified by SDA Substance Name: C16-C18 alkyl carboxylic acid and SDA Reporting Number: 19-005-00.	67701-03-5
266-929-0	Fatty acids, C8-18 and C18-unsatd. This substance is identified by SDA Substance Name: C8-C18 and C18 unsaturated alkyl carboxylic acid and SDA Reporting Number: 01-005-00.	67701-05-7
266-930-6	Fatty acids, C14-18 and C16-18-unsatd. This substance is identified by SDA Substance Name: C14-C18 and C16-C18 unsaturated alkyl carboxylic acid and SDA Reporting Number: 04-005-00	67701-06-8
266-932-7	Fatty acids, C16-C18 and C18-unsatd. This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated alkyl carboxylic acid and SDA Reporting Number: 11-005-00	67701-08-0
266-948-4	Glycerides, C16-18 and C18-unsatd. This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated trialkyl glyceride and SDA Reporting Number: 11-001-00.	67701-30-8
267-007-0	Fatty acids, C14-18 and C16-18-unsatd., Me esters This substance is identified by SDA Substance Name: C14-C18 and C16-C18 unsaturated alkyl carboxylic acid methyl ester and SDA Reporting Number: 04-010-00.	67762-26-9

267-013-3	Fatty acids, C6-12 This substance is identified by SDA Substance Name: C6-C12 alkyl carboxylic acid and SDA Reporting Number: 13-005-00.	67762-36-1
268-099-5	Fatty acids, C14-22 and C16-22 unsatd. This substance is identified by SDA Substance Name: C14-C22 and C16-C22 unsaturated alkyl carboxylic acid and SDA Reporting Number: 07-005-00	68002-85-7
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-657-0	Fatty acids, soya	68308-53-2
269-658-6	Glycerides, tallow mono-, di- and tri-, hydrogenated	68308-54-3
270-298-7	Fatty acids, C14-22	68424-37-3
270-304-8	Fatty acids, linseed-oil	68424-45-3
270-312-1	Glycerides, C16-18 and C18-unsatd. mono-and di- This substance is identified by SDA Substance Name: C16-C18 and C18 unsaturated alkyl and C16-C18 and C18 unsaturated dialkyl glyceride and SDA Reporting Number: 11-002-00.	68424-61-3
288-123-8	Glycerides, C10-18	85665-33-4
292-771-7	Fatty acids, C12-14	90990-10-6
292-776-4	Fatty acids, C12-18 and C18-unsatd.	90990-15-1
296-916-5	Fatty acids, rape-oil, erucic acid-low	93165-31-2

ANNEX III

Article 4(2)(b)

ANNEX III

Article 4(2)(b)

1. .
2. , ,
(article) .
3. ,
4. ,
 ,
5. :
() , , (flavouring agent), , (filler), ,
(carrier), , 가 , (antifoamer, defomer),
, , (binder), (emulsifier),
(de-emulsifier), , (agglomerating agent), , flow
modifier, pH , , sequestrant, (coagulant),
(flocculant), , (chelating agent),
()
6. 가 , (by - products)
7. ,
 .
8. (modify) , ,
 . , Directive 67/548
9. 가 , ,

ANNEX IV

Article 9

ANNEX IV

Article 9

Annex IV IX

Annex IV IX Article 9, 11, 12, 39, 40 44 가
(evaluation) . (tonnage
level) , (the standard requirements) Annex V ,
가 , Annex 가 .
, , , .
Annex , 가 .

Step 1. (Gather And Share Existing Information)

가 .
가 , (registrations) Article 10 17
(consortia) . 가 ,
, .
가 .
,
(: from QSARs, read-cross from other substances, in-vitro
testing, epidemiological data) . , Article 9 and Annex V
, .
, 가 가 .

Step 2. (Consider Information Needs)

가
Annex Annexes Annexe
(variation) Annex IX
.
.
.

Step 3. (Identify Information Gaps)

가 가 가
가 가 가
.
.

Step 4. / (Generate New Data/Propose Testing strategy)

가
(gap) , (Annex V and VI),
(Annex VII and VIII).
가
.
.
, Annex V IX (rules)
가 .

Notes

Note 1: 가 , , .

Note 2: 가
 , Article 115 ,
 , .

Information referred to in Article 9(1) (A)(I) to (V)

1. General Registrant Information

1.1.

1.1.1. , , , ,

1.1.2.

1.1.3.

1.2. Joint submission of data by consortia: other consortia members

Article 10 17

가 .
 , 가
 .

- , , ,

-

Annex IV, V, VI, VII or VIII ()

가
 .

- , , ,
- () ()
- Annex IV, V, VI, VII or VIII ()

2. Identity of the substance

, Section
가 ,
 ,

2.1 Name or other identification of each substance

2.1.1. IUPAC

2.1.2. (usual name, ,)

2.1.3. EINECS EIINCS (가)

2.1.4. CAS CAS (가)

2.1.5. (가)

2.2. Information related to molecular and structural formula of each substance

2.2.1. (including SMILES notation, if available)

2.2.2. (가)

2.2.3.

2.3. Composition of each substance

2.3.1. (%)

2.3.2.

2.3.3. (%)

2.3.4. 가 (,) (ppm,%)

2.3.5. (spectral data)(, ,)

2.3.6. HPLC, GC

2.3.7. , , 가

3. Information on manufacture and use(s) of the substance(s)

3.1. / :

3.1.1. ()

3.2. :

3.3. ()

3.4. ((substance), (preparation)

3.5. ()

3.6. ()

3.7. (6 .)

가 , (,
non-statutory recommendations by supplier).

4. CLASSIFICATION AND LABELLING

4.1. Directive 67/548/EEC Article 4 6

가 , , end-point 가
.(, 가 ,)

4.2. Directive 67/548/EEC Article 23 25

4.3. Directive 67/548/EEC Article 4(4) Directive 1999/45/EC Article 4 7 , 가 , .

5. GUIDANCE ON SAFE USE CONCERNING:

Article 29 .

5.1 (4)

5.2. , (5)

5.3. (6)

5.4. (7)

5.5. (14) 가 , 가 가 .

5.6. (8)

5.7. (10)

5.8.

5.8.1. (13)

5.8.2.

5.8.3. (public)

4.8. (14)

ANNEX V

10

ANNEX V

10

Annex Column 1 Point 13(1) (a) 1

. Annex Column 2

,

,

. Annex column 2

(registration dossier)

.

, Annex IX Annex

column 1

column 2 Annex IX 7

.

Annex (properties)

, 가 , (historical

data), (valid) (Q)SARSs , (read - across

approach) 가 .

endpoints , 가 Annex column 2 Annex IX

,

5.

Column 1	Column 2
5.1. 20 101.3kpa	
5.2. /	5.2 0 , 가 .
5.3.	5.3 가 : - - 360 , 가 , ; - (: , , (degradation), (decompositon))
5.4.	5.4. 가 : - , 가 . , 가 ; - . (Ideal Gas Laws) 가
5.5.	5.5. 가 .: - (transtion)가 ((state) (change) (decomposition)) : (transition) 가 , 10 20 (가 가) ; - 300 200 300 ,

5.6.	5.6. 가 . - 가 20 1mg/l ; - "micelles"
5.7.	5.7. 가 .: - 가 (12 -) ; - . " " , (limit test) .
5.8. n - /	5.8. 가 . 가 (: (surface activity) , , ,), log P .
5.9.	5.9. , 가 . - . ; - 100 가 , ; - 200 - .
5.10.	5.10. , 가 . - 가 . .; - , 가 , , .; -

5.11.	5.11. , 가 : - - , 가 200 - , 가 500J/g , 가 500 - (UN Division 5.1), 가 : * UN Packaging (high hazard) (high hazard) , 15 wt% , * UN Packaging III , 30 wt% : 가 800J/g , .
5.12. (self-ignition temperature)	5.12. , 가 : - (spontaneously) - , 200 - 가 - 160 가 400 self-heating

5.13. (Oxidising properties)	5.13 . , 가 : - - - - , 가 (combustible) , ((elements) . .) 가 , (full test) . 가(evaluation) (oxidising potential) 가 .
5.14. (Granulometry)	5.14 . 가 .

6.

(in vivo)

/

Column 1	Column 2
6.1. endpoint 가	6.1. 3 4 , 가 :
(1)	- - (pH <2.0) (pH> 11.5)
(2) 가	-
(3) (in vitro)	-
(4) (in vitro)	- (2000mg/kg buffalo weight)
6.2. endpoint 가	6.2. 3 , 가 :
(1)	- - (pH <2.0) (pH> 11.5)
(2) 가	-
(3) (in vitro)	- , 가
6.3. endpoint 가	6.3. 2 , 가 .
(1)	- , ; , (pH <2.0) (pH> 11.5)
(2) 가 (Murin Local Lymph Node Assay (LLNA))	- 가 . 가 가 , , LLNA가 , GPMT(Guinea Pig Maximization Test)가 .
6.4. 6.4.1. (in vitro)	6.4 가 , 가

7.

Column 1		Column 2	
		Column 1	
7.1.	(Aquatic toxicity)		
7.1.1.	(Daphina) -	7.1.1.	, 가
		∴	
-	-	-	(< 10µg/l)
		-	(biological membrane)
			(MW >800 >15);
		-	가 가
		()	
			(aquatic organism)
		가	가
		,	(Annex VII,
		7.1.5)가	.
			(
		<1mg /l),	(Annex VII,
		7.1.5)가	.

8.

,

가

,

.

ANNEX VI

10

가

ANNEX VI

10

가

Annex Column 1 Article 11(1) (b) 10

Annex

Column 1 Annex V Column 1

가 . Annex Column 2 ,
 ,
 . Annex column 2가
 (registration dossier)

column1 , Annex IX Annex
 .

column 2 Annex IX

Annex (properties)
 , 가 , ,
 (Q)SARs , (read-across approach)
 가 .

endpoints , 가 Annex column 2 Annex IX

6.

/

Column 1	Column 2
Column 1	Column 1
6.1. 6.1.1. (in vivo)	6.1.1. 가 . - - (pH < 2.0) (pH > 11.5) - - (toxic) - (2000mg/kg buffalo weight) - Annex V, Section 6.1 가 가 .
6.2. 6.2.1. (in vivo)	6.2.1. 가 : - - (pH < 2.0) (pH > 11.5) - - , 가 - Annex V, Section 6.2 가 가 .

6.4. 6.4.2. (in vitro) cytogenicity 6.4.3. (in vitro) Annex V, 6.4.1. 6.4.2. (negative result)	6.4.2. 가 . (in vivo) cytogenicity 1 2 6.4.3. (in vivo) 가 가 , 가 . 6.4. Annex V VI , (in vivo)
6.5. (10 - 2Pa , 20) , .(6.5.2). 6.5.1 6.5.3 가 가()	6.5. 가 . - - - 가() :

6.6. 6.6.1. - (28), 가 , , 가 , .	6.6.1. - (28) 가 . - 가 , - (90) 가 가 - , 가 - . (1) / ; (2) (3) - - / - (in vitro) - . (MW>800 >15) , (log Kow < -1 > 4) 가 , .
--	---

(1)

(2)

- 20 10 - 2

;

- (MMAD) 100 μm 1
wt%

가 (MMAD
 $<100\mu\text{m}$ 1 wt%)
 (aerosols), (particles)
 (droplets) 가 ,
 가 .

- (90) (Annex VII, 6.6.2)
 가 .

- 가

- 가 가
 가

- (toxicokinetic
 studies)

, (tissue)
 (organ)

, Article 39,40 44
 가 가

, 가 가
 가 .

202

6.7.1. / (Screening for developmental toxicity) (OECD 421), 가 in vitro (Q)SAR 가가	6.7.1. screening , 가 , . (Annex VI, 6.7.2).
6.7.2. , (AnnexX B. 31 OECD414)	6.7.2. . . - (Annex VII, 6.7.3) (90) 가 (histopathological effects on the gonads) 가 가 .
6.8 (Toxicokinetics) 6.8.1. 가 가	

7. (Ecotoxicological information)

Column 1	Column 2
7.1. (Aquatic toxicity)	7.1.2. 가 :
7.1.2. (algae)	- (< 10 µg /l)
	- (biological membrane) (MW >800 >15);
	- 가 가
7.1.3. (fish)	7.1.3. 가 :
:	- (< 10 µg /l)
	- (biological membrane) (MW >800 >15);
	- 가 가
	(Annex VII,
	7.1.6) ()
	(aquatic organism) , 가
	가 , Article 39,40
	44 가
	, 가
	.
	(
	<1mg /l),
	(Annex VII, 7.1.6)

7.1.4. (Activated sludge respiration inhibition testing) (emission)가	7.1.4. 가 : - (< 10µg/l) - (), 가 가 , nitrification inhibition test
7.2. (Degradation) 7.2.1. (Biotic) 7.2.1.1 7.2.2. (Abiotic) 7.2.2.1. pH 가	7.2. (Annex VII, 7.2.1.2 7.2.1.4) Annex I 가가 가 가 , Article 39,40 44 가 , 가 가 7.2.1.1. 가 7.2.2.1 가 : - 가 10µg/l
7.3. (Fate and behaviour in the environment) 7.3.1. / (Adesorption/desorption screening study)	7.3.1. 가 , - 가 (adsorption) 가 가 (:) /). - (decompose)

ANNEX VII

100

가

ANNEX VII

100 가

Article 11 (1) (c) ANNEX

ANNEX Column 1 Article 11 (1) (c) 100
ANNEX Column 1 가
ANNEX Column 2 가
ANNEX Column 2
ANNEX
ANNEX Column 1 가
ANNEX 가
ANNEX Column 2

5.

Column 1	Column 2
5.18.	5.18 .
5.19.	5.19 . - 가 (가 12) -
5.20.	
5.21.	

6.

/

Column 1	Column 2
	6.4. ANNEX 가 , . 가 가 , .

6.6. 6.6.1. (28), 1 , . 가 6.6.2 ANNEX ANNEX section 3	
6.6.2. (90), 1 , 가	6.6.2. (90) : - (28) R48 , NOAEL - 28 , NOAEL - 90 - 가 - , - , -28 가 가 : :

	(1) / 가 ; (2) ; (3) : - ; - 가 / ; - 가 : , > 800 > 15 (log Kow < -1 >4) 가 , ∴ (1) ; (2) : - 20 10 - 2Pa; - w/w , 100 μm MMAD 가 , 1% ; - , (MMAD <100 μm 가 w/w >1%). , 가 . 가 , point 35 38 가 :
--	--

	- (NOAEL) 가 , 90 NOAEL - (, /); - 가 / ; , (, ,) ; - (,)
6.7. 6.7.1. , ANNEX (ANNEX B.31 OECD 414) , 2 , 가 6.7.3. 2 , 28 90 , 가 , , 1	6.7. 가 : - , 가 ; - , 가 .

7.

Column 1	Column 2
Column 1	Column 1
7.1.	7.1. ANNEX가
	가 ,
	.
7.1.5. Daphina (ANNEX)	7.1.5. 가 : - (> 800, > 15); - 가 .
7.1.6. (ANNEX)	7.1.6. 가 : - (> 800, > 15); - 가 .
7.1.6.1, 7.1.6.2 7.1.6.3.	
7.1.6.1 (FELS)(OECD 210)	7.1.6.1. 가 , FELS point 35
7.1.6.2. sac-fry stages (ANNEX C. 15 OECD 212)	38 가
7.1.6.3. , (ANNEX C. 14 OECD215)	.

7.2.	7.2. ANNEX 가 가 , 가 .
7.2.1. 7.2.1.3 7.2.1.4 38 가 35 .	
7.2.1.2.	7.2.1.2. 가 : - 가 10 µg/ l ; - .
7.2.1.3. (가)	7.2.1.3. 가 : - ; - 가
7.2.1.4. (가)	7.2.1.4. 가 : - ; - 가
7.2.3.	7.2.3. ANNEX 가 가 , 가 .

7.3. 7.3.2. (1) , 가 , 7.3.3. / ANNEX	7.3.2. 가 : - 가 (, log Kow < 3) 7.3.3 가 : - , 가 (, 가) -
7.4. 7.4.1. 7.4.2. 7.4.3.	7.4. 가 , 가 . 가 , Equilibrium partitioning method 가 . .

9.

.

,

가

ANNEX VIII

1000

가

ANNEX VIII

1000 가

Article 11 (1) (d) ANNEX

ANNEX Column 1 Article 11 (1) (d) 1000
Column 1 ANNEX V, VI VII Column 1
가 ANNEX Column 2 가
ANNEX Column 2
ANNEX
ANNEX Column 1
가
ANNEX
가
ANNEX Column 2

Column 1	Column 2
	Column
	6.4.가
	,
	.
	6.6.3. , (≥ 12
	) , point 35 38 가
	:
	- ,
	;
	-
	가 가
	28 90
	;
	- 28 90
	가 ;
	- 90
	가
	6.6. , , point 35
	38 가
	:
	- (, /
	);
	- 가 /
	;
	,
	(, ,)
	;
	- (,
	)

6.7. 6.7.4. 2 , ANNEX , 가 , 1	6.7.4. : - 가 ; - 가 , - 가 ; - 가 (), - 가 .
	6.9. 38 , point 35 가 : - 가 ; - 3 , - / 가 .

7.

Column 1	Column 2
	Column 1
7.2.	7.2. ANNEX 가 가 , . 가 .
7.2.1. 7.2.1.5. (, ,)) (/)	
7.3.	7.3. ANNEX 가 가 , . 가 .
7.3.4 .	
7.4.	7.4 . 가 , . .
7.4.4 . ANNEX ,	
7.4.5 . , ANNEX	

7.4.6. , ANNEX	
7.5. (sediment)	7.5. 가 , 가 .
7.6.	7.6. 가 , 가 .

9.

가 . ,

ANNEX IX

Annex V VIII

ANNEX IX

Annex V VIII

Annex V VIII

- Article 11 (1) (a) 1
- Article 11 (1) (b) 10
- Article 11 (1) (c) 100
- Article 11 (1) (d) 1000

Annex V VIII Column 2 (rules) ,

Annex, Section 1

. 가(evaluation) , (Member states) 가
가(assess) .

1. Testing does not appear scientifically necessary

1.1. Use of existing data

1.1.1. GLP or Annex X

가 , Annex X

(1) (classification), (labeling) 가(Risk Assessment)

(2) 가

1.1.2. GLP or Annex X

가 , Annex X

(1) (classification), (labeling) 가(Risk Assessment)

(2) Annex X

(3) , Annex X

(4) 가

1.1.3. Historical human data

Historical human data가

(specific health effect)
(strength) (analysis type), (parameters),
(magnitude) (specificity)

가

(1) (group) (characterization)

(2) (characterization)

(3) (length)

(4)

(5) (bias) (confounding factors)

(6)

가

1.2. Weight of evidence

(source) 가 (notion) 가 (source)

가 , 가

가 .

Annex X , 가 가

가 .

가 ,

- 가 .

- 가 .

가 .

1.3. Structure - Activity Relationship (SAR)

- ((Q)SARs: Qualitative or Quantitative Structure - Activity Relationship Models)

(Q)SARs , .

- 가 (Q)SAR

- 가 (classification), (labeling), 가(risk assessment)

- 가 .

1.4. In vitro methods

in vitro
 . , ' ' (:
 ECVAM criteria for the entry of a test into the prevalidation process)
 . , (tonnage
 level) Annex V VI
 , Annex VII VIII
 .
 in vitro 가 ,
 Annex IX Annex V VIII
 ,
 .
 ,
 (1) 가 validation study
 in vitro
 (2) 가 (classification), (labeling), 가(risk assessment)
 (3) 가 .

1.5. Grouping of substances and read-across approach

, (ecotoxicological)
 가 (group)
 (category) (as they are under the ICCA HPV initiative).
 ,
 (interpolation)
 (read-across

approach). endpoint .

- (1) .
- (2) , / ,
가
- (3) , .
가 .

2. Testing technically not possible

, ,
,
가 가 ,
, 가 , endpoint

3. Substance-Tailored exposure-driven testing

(Chemical Safety Report)
, Annex VII VIII .
, (justification) 가 .