

## ORDINANCE ON NOTIFICATION OF NEW CHEMICAL SUBSTANCES

*Adopted by Council of Ministers' Decree No 327/2004, published in the State Gazette issue No. 110 from 17 December 2004, in force from 1 January 2005*

### Section One

#### **General provisions**

##### **Article 1**

This Ordinance shall regulate:

1. the terms and conditions for notification of new chemical substances intended for placing on the market separately or as part of preparations;
2. the terms and conditions for notification of intermediates;
3. the obligations of the notifier after the issuance of registration certificate for a notified chemical substance;
4. the content of the public register of notified substances.

##### **Article 2**

The new chemical substances intended for placing on the market separately or as part of preparations are subject to notification.

##### **Article 3**

The registration certificate shall be issued for notified chemical substances by the Minister of Environment and Water or, by an authorised by him functionary.

### Section Two

#### **Conditions and procedure for the notification of new chemical substances**

##### **Article 4**

(1) For the purpose of notifying new chemical substances or intermediates, the notifier shall submit to the Minister of Environment and Water documents, specified in Article 10 of the Law on Protection against the Harmful Impact of Chemical Substances and Preparations (LPHICSP).

(2) Depending on the quantity of the new chemical substance or intermediate, the technical dossier under Article 10, point 1 of LPHICSP shall be prepared in accordance with:

1. Annex № 1 – for quantities below 100 kg per year per manufacturer;
2. Annex № 2 - for quantities of 100 kg per year per manufacturer or before the total quantity placed on the market reaches 1 tonne per manufacturer;
3. Annex № 3 - for quantities of 1 tonne per year per manufacturer or before the total quantity placed on the market reaches 5 tonne per manufacturer.

(3) The Protocols of analyses carried out shall be attached to the documents set out in Paragraph 1.

##### **Article 5**

(1) With a purpose of notifying polymers, which contain in combined form 2 % or more of a new chemical substance, the notifier shall submit to the Minister Environment and Water documents specified in Article 10 of LPHICSP.

(2) Depending on the quantity of the polymer, the technical dossier under Article 10, point 1 of LPHICSP shall be prepared in accordance with:

1. Annex № 1 and additional information as required under Annex № 4, part “A” - for quantities below 100 kg per manufacturer per year;

2. Annex № 2 and additional information as required under Annex № 4, part “B” - for quantities of 100 kg per manufacturer per year or before the total quantity placed on the market reaches 1 tonne per manufacturer;

3. Annex № 3 and additional information as required under Annex № 4, part “B” - for quantities of 1 tonne per year per manufacturer or before the total quantity placed on the market reaches 5 tonne per manufacturer.

(3) The Protocols of analyses carried out shall be attached to the documents set out in Paragraph 1.

### **Article 6**

(1) For applying reduced test package under Article 8, Paragraph 2 of LPHICSP, for new substances which are intermediates, the notifier shall submit to the Minister of Environment and Water an application, accompanied by:

1. information in accordance with Annex No 5;

2. declarations from the notifier and from the two customers under Article 8, Paragraph 3, point 1 of LPHICSP, in accordance with Article 8, Paragraph 3 of LPHICSP.

(2) The Minister of Environment and Water shall issue an authorisation for application of reduced test package envisaged in Paragraph 1 within a period of 20 days from the date of submission of the documents under Paragraph 1, when the conditions set out in Article 8, Paragraph 3 of LPHICSP, and criteria laid down in Annex No 8 are fulfilled.

(3) The Minister of Environment and Water shall inform the notifier about errors and/or incompleteness within 10 days from the date of submission of the documents under Paragraph 1.

(4) When incompliance with the criteria laid down in Annex No 6 has been found, the Minister of Environment and Water shall require from the notifier to submit monitoring data and/or reliable model calculations.

(5) In the cases under Paragraphs 3 and 4, the time-limit for the issuance shall start from the date of receiving corrected and completed documents.

### **Article 7**

(1) After having obtained an authorisation under Article 6, Paragraph 2 of LPHICSP, the notifier shall submit to the Minister of Environment and Water the documents under Article 10, point 2 - 7 of LPHICSP and Technical dossier under Annex No 7, for the issuance of registration certificate for a notified chemical substance.

(2) The Protocols of analyses carried out shall be attached to the documents set out in Paragraph 1.

## **Article 8**

(1) The Minister of Environment and Water shall issue a registration certificate in accordance with Annex No 8 within the following time limits:

1. Thirty days following the submission of documents under Article 4, Paragraph 2, points 1 and 2, and Article 5, Paragraph 2, points 1 and 2, and Article 7;
2. Sixty days following the submission of documents under Article 4, Paragraph 2, point 3 and Article 5, Paragraph 2, point 3.

(2) The Minister of Environment and Water shall inform the notifier about errors and/or incompleteness within 10 days from the date of submission of the documents under Articles 4, 5 and 7.

(3) In the cases under Paragraph 2, the time-limits shall start from the date of receiving corrected and completed documents.

(4) If the notifier has not received a notice that the dossier contains errors and/or is incomplete within the time-limit set out in Paragraph 2, the substance may be placed on the market no sooner than 15 days after the submission of the documents.

## **Article 9**

(1) The producers of a new chemical substances, which is not subject to notification in accordance with Article 8, Paragraph 8 of LPHICSP, must package and provisionally label the new chemical substance in accordance with Chapter two of LPHICSP and the label should bear the warning "Caution - substance not yet fully tested!".

(2) The producer or importer of a new chemical substance, which is not subject to notification in accordance with Article 8, Paragraph 8 of LPHICSP, and which is labelled as very toxic, toxic, carcinogenic, toxic for reproduction and/or mutagenic, must transmit to the Minister of Environment and Water any appropriate information as regards Annex No 9, points 2.4-2.6.

(3) In the cases set out in Article 8, Paragraph 8, point 3 of LPHICSP, the producer or importer of a new chemical substance, which is not subject to notification, shall submit to the Minister of Environment and Water information in accordance with Annex No 9.

(4) In the cases set out in Article 8, Paragraph 8, point 5 of LPHICSP, the producer or importer of a new chemical substance, which is not subject to notification, shall submit to the Minister of Environment and Water a Technical dossier in accordance with Annex № 10.

## **SECTION III**

### **OBLIGATIONS OF THE NOTIFIER AFTER THE ISSUANCE OF REGISTRATION CERTIFICATE FOR A NOTIFIED CHEMICAL SUBSTANCE OR INTERMEDIATE**

## **Article 10**

(1) The notifier shall package and label the notified chemical substances in accordance with Article 4, Paragraph 2, point 3 and Article 5, Paragraph 2, point 3 under the Chapter two of LPHICSP.

(2) Where the substances have been notified in accordance with Article 4, Paragraph 2, point 1 and 2, Article 5, Paragraph 2, point 1 and 2 and Article 7, these must be packaged and provisionally labelled in accordance with Chapter two of LPHICSP and the label should bear the warning "Caution - substance not yet fully tested!".

(3) If the notifier has received new data concerning the notified substance, he is obliged to re-classify, re-label and re-package the substance till the quantities under Article 4, Paragraph 2, point 3 and Article 5, Paragraph 2, point 3, are reached.

### **Article 11**

(1) Before the quantity of the substance notified under Article 4, Paragraph 2, point 1 and Article 5, Paragraph 2, point 1 reaches 100 kg per manufacturer per year or before the total quantity placed on the market reaches 500 kg per manufacturer, the notifier shall submit to the Minister of Environment and Water:

1. A technical dossier in accordance with Article 4, Paragraph 2, point 2;
2. A technical dossier in accordance with Article 5, Paragraph 2, point 2 and Additional information in accordance with Annex № 4, part "B".

(2) Before the quantity of the substance notified under Article 4, Paragraph 2, point 2 and Article 5, Paragraph 2, point 2 reaches 1 tonne per manufacturer per year or before the total quantity placed on the market reaches 5 tonnes per manufacturer, the notifier shall submit to the Minister of Environment and Water:

1. A technical dossier in accordance with Article 4, Paragraph 2, point 3;
2. A technical dossier in accordance with Article 5, Paragraph 2, point 3 and Additional information in accordance with Annex № 4, part "C".

(3) The Protocols of analyses carried out shall be attached to the documents set out in Paragraphs 1 and 2.

(4) The notifier may not provide the information required in the technical dossiers under Paragraphs 1 and 2, with the exception of points 1 and 2 thereof, if the data have originally been submitted at least 10 years prior to the last notification of this substance.

### **Article 12**

- (1) Every notifier shall inform the Minister of Environment and Water in cases of:
1. changes in the annual or total quantities placed on the market;
  2. new knowledge of the effects of the substance on man and/or the environment;
  3. new uses of the substance;
  4. any change in the composition of the substances as given in Section 1.3, and Annex No 1, 3, 7 and 10;
  5. any change in the status of the notifier.

(2) Any importer of a substance produced outside the territory of the Republic of Bulgaria shall provide the sole representative with up-to-date information concerning the quantities of the substance introduced by him to the market.

### **Article 13**

(1) Where the quantity of a notified chemical substance placed on the market reaches 10 tonnes per manufacturer per year or where the total quantity placed on the market reaches 50 tonnes per manufacturer, the notifier shall submit to the Minister of Environment and Water a declaration of reaching this quantity.

(2) The Minister of Environment and Water may require from the notifier to carry out all or some of the Additional tests in accordance with Annex No 11, level 1 in a defined time-limit and to submit the results.

### **Article 14**

(1) Where the quantity of the notified under Article 7 intermediate reaches 10 tonnes per manufacturer per year or where the total quantity reaches 50 tonnes per manufacturer, the notifier shall submit to the Minister of Environment and Water a declaration of reaching this quantity and the results from the tests carried out in accordance with Annex No 12.

(2) The Minister of Environment and Water shall require from the notifier to carry out all or some of the Additional tests on water organisms in accordance with Annex No 11, level 1 in a defined time-limit and to submit the results.

### **Article 15**

(1) Where the quantity of a notified chemical substance placed on the market reaches 100 tonnes per manufacturer per year or where the total quantity placed on the market reaches 500 tonnes per manufacturer, the notifier shall submit to the Minister of Environment and Water a declaration of reaching this quantity.

(2) The Minister of Environment and Water shall require from the notifier to carry out all or some of the Additional tests in accordance with Annex No 11, level 1 in a defined time-limit and to submit them, except for the cases when the notifier submits justified proves that these tests are not appropriate or other test would be more appropriate.

### **Article 16**

(1) Where the quantity of the notified under Article 7 intermediate reaches 100 tonnes per manufacturer per year or where the total quantity reaches 500 tonnes per manufacturer, the notifier shall submit to the Minister of Environment and Water a declaration of reaching this quantity.

(2) The Minister of Environment and Water shall require from the notifier to carry out all or some of the Additional tests for reproductive toxicity in accordance with Annex No 11, level 1 in a defined time-limit and to submit the results.

### **Article 17**

(1) Where the quantity of a notified chemical substance placed on the market reaches 1000 tonnes per manufacturer per year or where the total quantity placed on the market reaches 5000 tonnes per

manufacturer, the notifier shall submit to the Minister of Environment and Water a declaration of reaching this quantity.

(2) The Minister of Environment and Water shall draw up a programme of tests/studies according to Annex No 11, level 2 and shall require to be carried out by the notifier within a defined time-limit and to present the results.

#### **Article 18**

(1) Where the quantity of the notified under Article 7 intermediate reaches 1000 tonnes per manufacturer per year or where the total quantity placed on the market reaches 5000 tonnes per manufacturer, the notifier shall submit to the Minister of Environment and Water a declaration of reaching this quantity.

(2) The Minister of Environment and Water can require from the notifier to carry out all or some of the Additional tests for reproductive toxicity in accordance with Annex No 11, level 2 in a defined time-limit and to submit the results.

#### **Article 19**

If the notifier has carried out additional tests in accordance with Annex No 11, he shall submit to the Minister of Environment and Water the Protocols of these analyses.

#### **Article 20**

(1) Data from the tests carried out in accordance with the methods set out in Annex No 3 to the Ordinance on the classification, packaging and labelling of chemical substances and preparations, adopted by Council of Minister's Decree No 316 from 2002 (State Gazette No 5 from 2003, amended No 66 from 2004), shall be included in Annexes № 1 - 4, 7, 10 – 12.

(2) The Protocols of analyses carried out shall be attached to the data set out in Paragraph 1.

(3) The tests under Paragraph 1 shall be carried out in accordance with the principles of Good Laboratory Practice as defined in the Ordinance on principles, inspection and verification of Good Laboratory Practice, adopted by Council of Minister's Decree No 207 from 2004 (State Gazette No 74 from 2004) and following the requirements of the Ordinance No 25 on the protection and humane treatment of testing animals (State Gazette No 59 form 2003).

#### **Article 21**

(1) If the test is not technically possible or data resulting from the scientific experience exist, the notifier may not give certain information stating clearly in written the reasons for this.

(2) Where the Minister of Environment and Water finds the stated reasons not justified, he shall inform the notifier thereof and shall require the submission of the data under Paragraph 1.

#### **Article 22**

When the notifier has additional information on the harmful effect of the substance, he shall submit this information to the Minister of Environment and Water even in cases when the Minister has not required it.

### **Article 23**

The first notifier of a notified substance can submit a justified request to the Minister of Environment and Water temporary not to disclose, for a period no longer than one year, to a subsequent notifier of the same substance the results from the tests of the notified substance.

### **Article 24**

(1) A subsequent notifier can submit to the Minister of Environment and Water a request for information whether the substance, which he intends to notify, has already been notified.

(2) Following information shall be attached to the request under Paragraph 1:

1. data from the analyses providing evidence of the identity of the substance, including the degree of purity and the impurities;
2. a declaration for the quantity of the substance intended for placing on the market;
3. a request for information about the name and address of the first notifier.

(3) In the case of a substance identical to already notified substance and in the absence of a submitted request under Article 23, the Minister of Environment and Water shall, within 15 days, inform:

1. the subsequent notifier - about the name and address of the first notifier;
2. the first notifier - about the name and address of the subsequent notifier.

(4) Where the substance is not identical to the already notified substance or a request under Article 23 has been submitted, the Minister of Environment and Water shall, within 15 days, inform the subsequent notifier that he cannot refer to these data for a period no longer than one year from the date of issuance of the registration certificate under Article 8, Paragraph 1.

### **Article 25**

(1) With a view to avoiding the duplication of testing on vertebrate animals:

1. the notifier and the subsequent notifier shall reach an agreement on sharing the testing results of this substance, and
2. the first notifier shall declare that he grants the subsequent notifier the right to use the results from physico-chemical, toxicological, and/or ecotoxicological properties testing of the notified substance.

(2) In the cases under Paragraph 1, the Minister of Environment and Water shall permit the subsequent notifier to refer to the testing results of already notified substance.

### **Article 26**

(1) The Minister of Environment and Water shall keep a public register of notified substances containing information in accordance with Annex № 13.

(2) The public register under Paragraph 1 shall contain the following information:

1. Identity of the notified chemical substance;
2. Information on the notified chemical substance;
3. Physical and chemical properties of the new notified chemical substance;
4. Summary of toxicological studies;
5. Summary of ecotoxicological studies;
  
6. Possibility of rendering the new notified chemical substance harmless.

### **Additional provision**

**§ 1.** Within the meaning of this Ordinance:

1. "Highly effective exhaust ventilation" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that chemical agents remain within the catchment area, e.g. the occurrence of chemical agents in the workplace atmosphere can practically be excluded.

2. "Other exhaust ventilation system" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the occurrence of chemical agents in the workplace atmosphere cannot be excluded.

3. "Emission" is the release of a substance from a system to the workplace and/or the environment from organised or non-organised sources within the system.

4. "Effective exhaust ventilation system" is an exhaust ventilation system of open and semi-open type which is dimensioned in such a way that the chemical agents remain within the catchment area, i.e. the occurrence of chemical agents in the workplace atmosphere can be largely excluded or proof of adherence to the limit value is furnished.

5. "Integrated exhaust ventilation system" is an exhaust ventilation system of closed type which is used in combination with locks, enclosures, housings, containers, etc., in order to restrict the chemical agents to the inner part of the closed functional unit.

6. "Monomer" is a simple molecule capable of polymerising.

7. "Low-emission forms of use" are:

a) expendable packaging, i.e. the hazardous substance is enclosed in appropriate packaging and, without opening the packaging, is introduced into a reaction system;

b) change in consistency, i.e. the substance is used, for example, in the form of a paste or a granulate instead of in powder form;

c) master batch, where the hazardous substance is surrounded by a plastic matrix which prevents direct contact with the hazardous substance. Abrasion of the plastic matrix and, therefore, the release of the hazardous substance, total or partial, is possible.

8. "Emission-free form of use" is, for example, a master batch without abrasion, i.e. the plastic matrix is so resistant to abrasion that no hazardous substance can be released.

9. "Family of polymers" is a group of polymers (homopolymers and co-polymers) with different average molecular weights or with different content as a result from the different proportion of the monomer units.

10. "Co-polymer" is a polymer whose macromolecule is formed by two or more monomer units of different types.

11. "Technical dossier" is a documentation comprising of technical and scientific data on certain chemical substance, on the basis of which the hazards for human health and the environment are evaluated, as well as the description of the analyses carried out, methods used and bibliographic references.

12. "Technically leakproof" are the systems, sub-systems and functional elements where the rate of leakage is below  $0,00001 \text{ mbar} \cdot \text{l} \cdot \text{s}^{-1}$ .

13. "Highly degradable polymer" is a polymer which is complying with the following criteria: a) high average molecular weight ( $M_n$ ) - over 1000;

b) low water extraction without extraction additives and impurities – below 10 mg/l;

c) the content of low molecular compounds is low – monomers and their derivatives without including additives and impurities, with a molecular weight ( $M$ ) below 1000 – less than 1%.

14. "Homopolymer" is a polymer whose macromolecule is formed by one and the same monomer units.

### **Final provisions**

§ 2. The Ordinance is adopted on the grounds of Article 11 of the Law on the Protection against Harmful Impact of the Chemical Substances and Preparations.

§ 3. The Ordinance shall enter into force on 1 January 2005.

### **Annex № 5 to Article 6, Paragraph 1, point 1**

#### **Information on an intermediate, produced or imported in a quantity of 1 tonne per year for applying reduced test package under Article 8, Paragraph 2**

Name of the intermediate. ....

Manufacturer: .....

Manufacturer's address: .....

Notifier: .....

Notifier's address: .....

First customer: .....

Customer's address: .....

Second customer: .....

Customer's address .....

## 1. Identity of the intermediate

### 1.1. Name

#### 1.1.1. Names in the IUPAC nomenclature

#### 1.1.2. Other names (trivial name, commercial name, synonyms)

#### 1.1.3. CAS (registration) number and CAS (registration) name

### 1.2. Empirical (molecular) and structural formula

### 1.3. Composition of the intermediate

## 2. Information on the intermediate

2.1. Description of the closed system, where intermediate is moving during the life cycle of the substance (description of the technical measures ensuring the rigorous containment of the life cycle of the substance).

#### 2.1.1. Description of sampling procedures.

#### 2.1.2. Description of charging procedures

#### 2.1.3. Description of transportation procedures

#### 2.1.4. Description of cleaning procedures

#### 2.1.5. Description of means by which the closure of the production system is reached.

Process-related openings must be as small as possible. The power of extraction and the air ducting must be designed so that there is sufficient under pressure within the extraction unit to ensure that all of the gases, vapours and/or dusts that occur are fully captured and carried away. Back-flow of the extracted hazardous substances into the working area must be prevented. This means that hazardous substances are prevented from escaping from the closed functional unit into the working area.

#### 2.1.6. Construction type and technical specifications of each of the functional units

### 2.2. Detailed description of production processes of each site

#### 2.2.1. Detailed description of cleaning and maintenance procedures

2.2.2. Treatment of production wastes – whether and where:

2.2.2.1. production and/or processing wastes are discharged to waste-water

2.2.2.2. liquid or solid waste is incinerated

2.3. Detailed assessment of the possible emissions and possible exposure to man and the environment during the whole life cycle,

2.3.1. ways in which emission levels are decreased and controlled

To guarantee a maximum level of protection for workers and the environment minimisation of emission a rigorous containment of the process must therefore be undertaken.

Taking into account the possibility to preview the emission release and precautionary principle, and because not all of physico-chemical, toxicological and ecotoxicological properties of the intermediate are established, it is therefore assumed that the intermediate can present a specific hazard. Therefore, appropriate control techniques for rigorous control over the exposure must be applied.

2.3.2. Chemical reactions related to residues and their treatment

2.4. Changes which might lead to exposure on humans and/or the environment (changes in the functional units of the site, new sites or users)

#### **Annex № 6 to Article 6, Paragraphs 2 and 4**

Criteria for the assessment of closed systems during the handling of chemical substances

##### *1. Application of assessment criteria*

An assessment index is used in order to assess whether certain system is closed. The assessment index classifies the handling of the substance and the resultant process-related exposure potential. In order to determine the assessment index, the plant and/or plant unit related to the production or handling of the intermediate is examined. Each individual functional element must be assessed individually.

Systems are regarded as closed if the assessment of all of the available functional elements corresponds to the assessment index 0,5 and if only functional elements are involved which are of closed type with assured leakproofness and/or equipped with integrated exhaust ventilation. In addition, direct skin contact must be excluded.

In the examples given in the Table, relevant functional elements are assessed by assessment index 0,5, 1, 2 or 4. .

Functional elements of closed type with leakproofness assured are indicated by the assessment index 0,5.

Functional elements of closed type where leakproofness is not assured or partially open type with effective exhaust ventilation are indicated by the assessment index 1.

Functional elements of partially open type with opening as intended with simple exhaust ventilation or open with simple exhaust ventilation are indicated by the assessment index 2.

Functional elements of open type or partially open type, or with natural ventilation are indicated by the assessment index 4.

A system with functional elements of partially open type with highly effective exhaust ventilation which, also indicated by the assessment index 0,5, is not regarded as closed if all the functional elements are not of closed type with leakproofness assured.

Functional elements 1, 2 and 4 can change their index after applying additional measures. These measures and the explanations for each of the functional elements are given in columns 6 and 7.

The set of examples in the Table facilitates the classification of the functional elements. Functional elements which are not included in the collection of examples can be classified by means of conclusions drawn by analogy. The plant or plant unit is then classified using the index value of the functional element which has received the highest assessment index.

## *2. Checking*

The checking of the closed system shall be performed by assessing the adherence to the process parameters, as well as the fulfilment of the additional measures (where such have been laid down).

### **Examples of assessment of functional elements**

Table

Number	Functional element	Constructional type	Examples of constructional type	Assessment index		Explanations
				Without additional measures	With additional measures	
1	2	3	4	5	6	7
1.	Static seals					
1.1.	Static seals	Inseparable connections	Welded	0,5		
			Soldered	0,5		
1.2.	Static seals	Separable connections	Welded lip seal	0,5		Reduce connections to number required
			Cutting ring and clamping ring connection ≤ DN 32	0,5		Open connections as little as possible

			- NPT thread $\leq$ DN 50, $\Delta t \leq 100$ °C	0,5		Leak tests prior to resumption of operation
			Cutting ring and clamping ring connection $>$ DN 32	1	0,5 assurance of leakproofness by means of monitoring and repair (*)	Use new seals in case of resumption of operation involving separated connections
			NPT thread $>$ DN 50, $\Delta t > 100$ °C	1	0,5 assurance of leakproofness by means of monitoring and repair (*)	Where possible, flanges to be opened for operational reasons should not be equipped with tongue and groove (danger of misalignment)
			Flange with tongue and groove with suitable seal	1	0,5 assurance of leakproofness by means of monitoring and repair (*)	
			Flange with projection and recess with suitable seal	1	0,5 assurance of leakproofness by means of monitoring and repair (*)	

			Flange with V-groove and suitable V-groove seal	1	0,5 assurance of leakproofness by means of monitoring and repair (*)	
			flange with smooth seal rail and suitable seals	1	0,5 assurance of leakproofness by means of monitoring and repair (*)	
1.3.	Quasi-static seals					
1.3.1.	Fittings	Shafts and spindle seals of fittings e.g. ball valves, Stopcocks, valves, butterfly valves, slide valves	Stuffing box seals	2	1 - in the case of regular monitoring and repair	
			Stuffing box seals with self-adjustment (spring-loaded)	1	0,5 - technically leakproof	

			Double stuffing box with barrier seal	1	0,5 - with monitoring of the barrier pressure system	By means of regular visual checks or process control technology equipment
			O-ring seal	1	0,5 - technically leakproof	
			Stopcock liner seal	1	0,5 - assurance that technically leakproof by means of monitoring and repair	
			Piston seal	1	0,5 - technically leakproof	
			Bellows seal	0,5		
			Diaphragm seal	0,5		

			Magnetic clutch	0,5		
1.3.2.	Others	Control rods	stuffing box seals	2	1 - in the case of regular monitoring and repair	
			Stuffing box seals with self-adjustment (spring-loaded)	1	0,5 - technically leakproof	
			Double stuffing box with barrier seal	1	0,5 - with monitoring of the barrier pressure system	By means of regular visual checks or process control technology equipment
			O-ring seal	1		
			Piston seal	1		
			Bellows seal	0,5		

			Diaphragm seal	0,5		
2.	Dynamic seals					
2.1.	Seals with revolving parts	hermetically sealed	Canned motor	0,5		
			Magnetic clutches	0,5		
		Seals which are not contactless	Single-axial face seal	1		
			Double-axial face seal	1		
			Double-axial face seal with barrier fluid	1	0,5 - with monitoring of the barrier pressure system by means of regular checking, as a rule, once a day (for example process control technology equipment with alarm)	

			Stuffing box seal	2	1 - in the case of regular monitoring and repair	
			Stuffing box seal with self-adjustment (spring-loaded)	2	0,5 - technically leakproof	
		Contactless seals	Contactless seals	2		
			Gas-lubricated seal	1	0,5 - with monitoring of the gas flow	
2.2.	Seals for oscillating parts	Bellows seal	Bellows valves	0,5		
			Reciprocating pumps with bellows seal	0,5		
		Diaphragm seals	Diaphragm pumps	0,5		

			Conical diaphragm valves	0,5		
		Cups	Reciprocating pumps	1		
			Scraper rings	1		
3.	Substance transfer and filling points					
3.1.	For solid substances					
3.1.1.	Sacks					
3.1.1.1.	Sacks (emptying)	Open manhole, open container	Manual emptying	4	2 - with other exhaust ventilation equipment	If a hazardous substance is present in the container due account must be taken of this
					1 - with effective exhaust ventilation equipment	

					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	
		Sack-slitting and emptying machine			0,5 - emission-free form of use (e.g. master batch without abrasion)	
		Encapsulated sack-slitting and emptying Machine with integrated exhaust ventilation equipment		1	0,5 - compression and packing of the empty sacks within the encapsulated area, assurance of leakproofness by means of monitoring and repair	

3.1.1.2.	Sacks (filling)	Manual filling, open sack filling	Manual filling	4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	
					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	
		Sack-filling equipment	Valve-sack filling machine, e.g. pneumatic packer, spiral packer, net filling scales	4	2 - with other exhaust ventilation equipment	

					1 - with effective exhaust ventilation equipment	
					0,5 - with highly effective exhaust ventilation equipment	
			Vacuum packer	2	1 - with effective exhaust ventilation equipment	
					0,5 - with highly effective exhaust ventilation equipment	
			Completely encapsulated filling machine with integrated Exhaust ventilation equipment	1	0,5 - assurance of leakproofness by means of monitoring and repair (*)	
			Bag forming, filling and sealing machine	1	0,5 - assurance of leakproofness by means of monitoring and repair (*)	
3.1.2.	Big bags, intermediate					

	bulk containers					
3.1.2.1.	Big bags, intermediate bulk containers (emptying)	open manhole	manual emptying	4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	
					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	

		Big bag emptying equipment		4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	
					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	
3.1.2.2.	Big bags, intermediate bulk containers (filling)	Filling of open large sacks	Manual filling	4	2 - with other exhaust ventilation equipment	

					1 - with effective exhaust ventilation equipment	
					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	
		Big bag filling equipment	Open filling	4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	

					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	
		Big-bag filling equipment	Completely encapsulated filling machine with integrated exhaust ventilation equipment	1	0,5 - with special filling heads (e.g. laterally sealing) dust-free closing technology; late trickling from the filling head is prevented, assurance of leakproofness by means of monitoring and repair	
			Large sack scales	4	2 - with other exhaust ventilation equipment	

					1 - with effective exhaust ventilation equipment	
					1 - low emission form of use, no further hazardous substance present	
					0,5 - with highly effective exhaust ventilation equipment	
					0,5 - emission-free form of use (e.g. master batch without abrasion)	
3.1.3.	Containers					

3.1.3.1.	Containers (emptying)	With closed emptying equipment		1	0,5 - if leakproofness is assured by means of special measures (e.g. monitored self-locking connection) and integrated exhaust ventilation equipment is present, assurance of leakproofness by means of monitoring and repair (*)	The container's cover seal must meet the demands of 1.2.
					0,5 if leakproofness is assured by means of special measures (e.g. monitored self-locking connection) and highly effective exhaust ventilation equipment is present, assurance of leakproofness by means of monitoring and repair	
		Open container		4	2 - with other exhaust ventilation equipment	

					1 - with effective exhaust ventilation equipment	
					0,5 - with highly effective exhaust ventilation equipment	
3.1.3.2.	Container (filling)	With special filling equipment		1	0,5 - if leakproofness is assured by means of special measures (e.g. monitored self-locking connection), assurance of leakproofness by means of monitoring and repair (*)	
		Open filling		4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	

					0,5 - with highly effective exhaust ventilation equipment, assurance of leakproofness by means of monitoring and repair (*)	
3.1.4.	Drums	With emptying equipment	closed	1	0,5 - if leakproofness is assured by means of special measures (e.g. monitored self-locking connection) and integrated exhaust ventilation equipment is present	
3.1.4.1.	Drums (emptying)		Mechanical conveyance, e.g. by spiral conveyor	4	0,5 - if leakproofness is assured by means of special measures (e.g. monitored self-locking connection) and exhaust ventilation equipment or highly effective exhaust ventilation equipment is present	

			Pneumatic conveyance, e.g. air-blaster	4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	
					0,5 - with highly effective exhaust ventilation equipment	
					2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	
					0,5 - with highly effective exhaust ventilation equipment	

		Open container	Mechanical conveyance, e.g. by spiral conveyor	4	2 - with other exhaust ventilation equipment			
					1 - with effective exhaust ventilation equipment			
					0,5 - with highly effective exhaust ventilation equipment			
					Pneumatic conveyance, e.g. air-blaster		2 - with other exhaust ventilation equipment	
							1 - with effective exhaust ventilation equipment	
						4	0,5 - with highly effective exhaust ventilation equipment	

3.1.4.2.	Drums (filling)	With special filling equipment		1	0,5 - if leakproofness is assured by means of special measures (e.g. monitored self-locking connection) and integrated exhaust ventilation equipment is present	
		Open filling		4	0,5 - if leakproofness is assured by means of special measures (e.g. monitored self-locking connection) and highly effective exhaust ventilation equipment is present	
					2 - other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	

					0,5 - with highly effective exhaust ventilation equipment	
3.1.5.	Silo vehicles					
3.1.5.1.	Silo vehicles (emptying)	Fixed pipework, articulated arm		1	0,5 - assurance of leakproofness by means of monitoring and repair (*); complete capture of residual quantities during decoupling and coupling processes	
		Hose connection	Fixed use (connecting hoses and couplings are provided by the company)	1	0,5 - assurance of leakproofness by means of monitoring and repair (*); complete capture of residual quantities during decoupling and coupling processes	

			Other use (connecting hoses and couplings are not provided by the company)	2	1 - complete capture of the residual quantities	
3.1.5.2.	Silo vehicles (filling)	Fixed pipework, articulated arm		1	0,5 - assurance of leakproofness by means of monitoring and repair (*); complete capture of residual quantities during decoupling and coupling processes	
		Hose connection	Fixed use (connecting hoses and couplings are provided by the company)	1	0,5 - assurance of leakproofness by means of monitoring and repair (*); complete capture of residual quantities during decoupling and coupling processes	

			Other use (connecting hoses and couplings are not provided by the company)	2	1 - Complete capture of the residual quantities	
3.1.6.	Inlet and outlet fittings	For silos, filling equipment, bulk-material containers	Butterfly valves	1	0,5 - assurance of leakproofness by means of monitoring and repair (*): regular cleaning	
			Cocks and stopcocks	1	0,5 - assurance of leakproofness by means of monitoring and repair (*): regular cleaning	
			Flat slide valves	1	0,5 - assurance of leakproofness by means of monitoring and repair (*): regular cleaning	
			Slide valve plate	1	0,5 - assurance of leakproofness by means of monitoring and repair (*): regular cleaning	

			Pinch valve with soft seal	1		
			Iris diaphragm valve	1		
			Hose valve	1		
3.2.	Substance transfer points for liquids					
3.2.1.	Small containers and drums					
3.2.1.1.	Small containers and drums (emptying)	Fixed connections (pipework, hose connections, articulated arm)	With gas-displacement or gas offtake at a safe point or transfer to a treatment or incineration plant	1	0,5 - assurance of leakproofness by means of monitoring and repair (*); leak test after establishing the connection, complete capture of the residual quantities	With regard to connection elements see 1.

			Without gas-displacement and without gas offtake at a safe point	4		
		Open packing drums	With drum pump or hose	4	1 - in the case of a construction which is free from leaks and drip quantities as well as being equipped with highly effective exhaust ventilation equipment	Regular checking of the exhaust ventilation equipment; the small container or drum must be closed immediately after the filling process
		Emptying in closed units	Encapsulation	1	0,5 - with integrated exhaust ventilation equipment and opening and closing of the packing drums in the closed unit	Regular checking of the exhaust ventilation equipment.

3.2.1.2.	Small containers and drums (filling)	Fixed connections (pipework, hose connections, articulated arm)	With gas-displacement or gas offtake at a safe point or transfer to a treatment or incineration plant	1	0,5 - assurance of leakproofness by means of monitoring and repair (*); leak test after establishing the connection, complete capture of the residual quantities	With regard to connection elements see 1.
			Without gas-displacement and without gas offtake	4	1 - in the case of a construction which is free from leaks and drip quantities as well as being equipped with effective exhaust ventilation equipment	
		Open packing drums	With filling hose	4	0,5 - in the case of a construction which is free from leaks and drip quantities as well as being equipped with highly effective exhaust ventilation equipment	

			Encapsulation	1	0,5 - with integrated exhaust ventilation equipment and closing of the packing drums in the closed unit	Regular checking of the exhaust ventilation equipment.
3.2.2.	Tanker, tank wagon, large containers					
3.2.2.1.	Tanker, tank wagon, large containers	Fixed connection. e.g. fixed pipework, hose connections, steel	With gas displacement or gas offtake at a safe point or transfer to a treatment or incineration plant	1	0,5 - Assurance of leakproofness by means of monitoring and repair (*); leak test after establishing the connection, complete capture of the residual quantities	With regard to connection elements see 1.
			Without gas displacement and without gas offtake	4		
		Other hose connections		2	1 - complete capture of the residual quantities	

3.2.2.2.	Tankers/tank wagons, large containers (filling)	Fixed pipework, hose connections, steel loading arms	With gas displacement or gas offtake at a safe point or transfer to a treatment or incineration plant	1	0,5 - assurance of leakproofness by means of monitoring and repair, leak test after establishing the connection, complete capture of residual quantities	The containers must be closed immediately after filling
			Without gas displacement and without gas offtake	4		
		open filling	filling pipe	4	1 - with highly effective exhaust ventilation, complete capture of the residual quantities	The containers must be closed immediately after filling
3.3.	Substance transfer points gases					with regard to the functional elements see 1
3.3.1.	Gases (filling and emptying)			1	0,5 - Assurance of leakproofness by means of monitoring and repair (*); leak test after establishing the	Closed plant systems, parts of units and functional elements must be operated, monitored and

					connection; gas displacement or offtake of residual gas at a safe point or transfer to a treatment or incineration plant	maintained in such a way that they remain technically leakproof in the case of the mechanical, chemical and thermal stresses that can be expected for the envisaged type of operation.
4.	Sampling points					
4.1.	Open sampling		Valve, stopcock	4	2 - with other exhaust ventilation equipment	
4.2.	Closed sampling			1	0,5 - assurance of leakproofness by means of monitoring and repair (*)	Sampling must be done by a closed sampling system avoiding uncontrolled escape of product. Uncontrolled escape of product is understood as: . the splashing of liquid during sampling from pressurised plant

						<p>parts</p> <ul style="list-style-type: none"> <li>- after-run of liquid from pipe connection</li> <li>pieces of tubes which are mounted on the sampling unit .</li> <li>escape of product vapours</li> <li>- overflow from overfilled sampling vessels.</li> </ul>
5.	Storage in packing drums					
5.1.	Solid substances, with the exception of certain explosives	Transport packaging according to ADR - requirements	Drums, containers	0,5		With sufficient ventilation (min. twofold change of air)
			Bags; plastic, textile, paper and multi-layered sacks	0,5		With sufficient ventilation (min. twofold change of air)

5.2.	Solid substances, certain explosives (containing nitro-glycerine)	Transport packaging according to ADR - requirements		4	2 - with other exhaust ventilation equipment	
					1 - with effective exhaust ventilation equipment	
					0,5 - with highly effective exhaust ventilation equipment	
5.3.	Liquids	Transport packaging according to ADR - requirements	Containers, metal drums, sheet iron cans, plastic drums, tubes, cans, containers	0,5		With sufficient ventilation (min. twofold change of air)
5.4.	Gaseous substances	Transport packaging according to ADR - requirements	Compressed gas cylinders	1	0,5 - assurance of leakproofness by means of monitoring and repair	With sufficient ventilation (min. twofold change of air)

			Compressed gas containers			With regard to functional elements see 1; closed plant systems, parts of units and functional elements must be operated, monitored and maintained in such a way that they remain technically leakproof in the case of the mechanical, chemical and thermal stresses that can be expected for the envisaged type of operation.
			Compressed gas drums			

**Annex № 7 to Article 7, Paragraph 1, Article 12, Paragraph 1, point 4 and Article 20, Paragraph 1**

**Technical dossier of an intermediate produced or imported in a quantity exceeding 1 tonne per year per manufacturer or before the overall quantity placed on the market reaches 5 tonnes**

Name of intermediate: .....

Manufacturer: .....

Manufacturer's address: .....

Production site address: .....

Notifier: .....

Notifier's address: .....

First customer: .....

Customer's address: .....

Second customer: .....

Customer's address:.....

*1. Identity of the intermediate*

1.1. Name

1.1.4. Names in the IUPAC nomenclature

1.1.5. Other names (usual name, trade name, synonyms )

1.1.6. CAS (registration) number and CAS (registration) name

1.4. Empirical (molecular) and structural formula

1.5. Composition of the chemical substance

1.3.1. Degree of purity (%)

1.3.2. Impurities, including isomers and by-products

1.3.3. Percentage of main impurities

1.3.3. Percentage of main impurities

1.3.4. Contents of a stabilising agent or an inhibitor, or other additives, listed in order of magnitude: name, nature, absolute amount and relative content: ..... kg, ..... %

1.3.5. Spectral data (ultraviolet, infra red, nuclear magnetic resonance or mass spectrum)

1.3.6. High pressure liquid chromatography (HPLC) and gas chromatography (GS)

1.4. Methods of detection and determination

A full description of methods used or appropriate bibliographical references thereto. Apart from those, information shall be given on analytical methods known to notifier for the detection and identification of the intermediate and its transformation products in the environment, as well as for the determination of human exposure.

*2. Information on the intermediate*

2.1. Production

The information must be sufficient to allow an approximate, but realistic determination of human and environmental exposure associated with production processes. Full details of the production process are required.

2.1.1. Technological processes used in production

2.1.2. Exposure estimate related to production:

a) working environment

b) environment

2.2. Proposed field of application

Information given under this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the intermediate, as associated with proposed/anticipated uses.

2.2.1. Area of application: description of intended types of use

2.2.1.1. Technological processes related to the use of the substance (where known)

2.2.1.2. Exposure estimate(s) related to the use of the substance (where known):

a) working environment

b) environment

2.2.1.3. Form under which the intermediate is marketed: chemical substance, preparation

2.2.1.4. Concentration of intermediate in marketed preparations

2.2.2. Fields of application with approximate breakdown:

a) industries

b) agriculture and farming

c) mass use

2.2.3. Identity of recipients of substance (where known)

2.2.4. Waste quantities and composition of waste resulting from the use of intermediate (where known)

2.3. Estimated amounts of intermediate produced or imported for each of the anticipated fields of application

2.3.1. Overall amount produced and/or imported intermediate in tonnes per year:

a) over the first calendar year

b) over the following calendar years

2.3.2. Amount produced or imported intermediate in accordance with 2.2.1 and 2.2.2, expressed in percentage:

a) over the first calendar year

b) over the following calendar years

2.4. Recommended methods and precautions concerning:

2.4.1. Application and usage

2.4.2. Storage

2.4.3. Transport

2.4.4. Fire (nature of gasses and products evoked, most effective means of extinguishing)

2.4.5. Other dangers, particularly chemical reactions with water

2.5. Emergency measures in the case of contamination or spillage (accidents)

2.6. Emergency measures in the case of injury to persons (poisoning)

2.7. Packaging (type, size)

3. *Physical and chemical properties of the intermediate*

3.1. Physical condition of substance at 20 °C and 101,3 kPa

3.2. Melting point

3.3. Boiling point

3.5. Vapour pressure

3.6. Surface tension

3.8. Partition coefficient n-octanol/water

3.9. Flash point

3.10. Flammability

- 3.11. Explosive properties
- 3.12. Self-ignition temperature
- 3.13. Oxidising properties
- 3.15. Granulometry (Dispersion analysis)

#### 4. *Toxicological studies*

##### 4.1. Acute toxicity

Only one route of administration shall be used for testing the acute toxicity (points 4.1.1. - 4.1.2.). All intermediates, other than gasses shall be examined via one route of administration - the oral route. Gasses should be tested by the inhalation route of administration.

##### 4.1.1. Acute oral toxicity

##### 4.1.2. Acute inhalation toxicity

##### 4.1.5. Skin irritation

##### 4.1.6. Eye irritation

##### 4.1.7. Skin sensitisation

##### 4.3. Other effects

##### 4.3.1. Mutagenicity

The intermediate shall be examined by bacteriological method, with and without metabolic activation. (reverse mutation test).

#### 5. *Ecotoxicological studies*

##### 5.1. Effects on organisms

##### 5.1.1. Acute toxicity for fish

##### 5.2. Degradation: biotic (microbial)

6. Additional information on substances structurally close to the notified intermediates (if the notifier has such an information) – data from physico-chemical, toxicological and ecotoxicological studies of the substances.

The numbering in this Annex is not serial and follows the numbering of the electronic carrier (electronic technical dossiers).

## Annex № 9 to Article 9, Paragraphs 2 and 3

### Information

#### on a new chemical substance which is not subject to notification under the provisions of Article 8, Paragraph 8, point 3 of LPHICSP

Name of the chemical substance: .....

Manufacturer: .....

Manufacturer's address: .....

Production site address: .....

Importer: .....

Importer's address: .....

Quantity: .....

#### 1. Identity of the chemical substance

##### 1.1. Name

1.1.1. Names in the IUPAC nomenclature

1.1.2. Other names (usual name, trade name, synonyms)

1.1.3. CAS (registration) number and CAS (registration) name

1.2. Empirical (molecular) and structural formula

1.3. Composition of the chemical substance

1.3.1. Degree of purity (%)

1.3.2. Impurities, including isomers and by-products

1.3.3. Percentage of main impurities

1.3.4. Contents of a stabilising agent or an inhibitor, or other additives, listed in order of magnitude: name, nature, absolute amount and relative contents: ..... kg, ..... %

1.3.5. Spectral data (ultraviolet, infra red, nuclear magnetic resonance or mass spectrum)

1.3.6. High pressure liquid chromatography (HPLC) and gas chromatography (GS)

1.4. Methods of detection and determination

A full description of methods used or appropriate bibliographical references thereto. Apart from those, information shall be given on analytical methods known to notifier for the detection and identification of the chemical substance and its transformation products in the environment, as well as in cases of human exposure.

#### 2. Information on the chemical substance

2.1. Exposure estimate related to production:

a) working environment

b) environment

The information must be sufficient to allow an approximate, but realistic determination of human and environmental exposure associated with production processes. Precise description is not required.

#### 2.2. Proposed field of application

Information given under this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, as associated with proposed/anticipated uses.

2.2.1. Areas of application: description of intended types of use

- 2.2.1.1. Technological processes related to the use of the substance
- 2.2.1.2. Exposure estimate related to the use of the substance (where known):
  - a) working environment
  - b) environment
- 2.2.1.3. Form under which the substance is marketed: chemical substance, preparation
- 2.2.1.4. Concentration of substance in marketed preparations
- 2.2.2. Approximate breakdown of quantities per fields of application:
  - a) industries
  - b) agriculture and farming
  - c) mass use
- 2.2.3. Identification of recipients
- 2.2.4. Waste quantities and composition of waste resulting from the use of chemical substance (where known)
- 2.3. Estimate of the amounts of chemical substance produced or imported in each of the anticipated fields of application
- 2.4. Recommended methods and precautions concerning:
  - 2.4.1. Application and usage
  - 2.4.2. Storage
  - 2.4.3. Transport
  - 2.4.4. Fire (nature of gasses and products evoked, most effective means of extinguishing)
  - 2.4.5. Other dangers, particularly chemical reactions with water
  - 2.4.6. Information concerning the susceptibility of substance to cause explosion when presented in the form of a dust
- 2.5. Emergency measures in the case of contamination or spillage
- 2.6. Emergency measures in the case of injury or poisoning of persons
- 2.7. Packaging (type, size)
- 2.8. Data on labelling

**Annex № 10 to Article 9, Paragraph 4, Article 12, Paragraph 1, point 4, Article 16, Paragraph 2 and Article 20, Paragraph 1**

**Technical dossier of a new chemical substance which is not subject to notification under the provisions of Article 8, Paragraph 8, point 3 of LPHICSP**

Name of the chemical substance: .....

Manufacturer: .....

Manufacturer's address: .....

Production site address: .....

Importer: .....

Importer's address: .....

Quantity: .....

*1. Identity of the chemical substance\*\**

1.1. Name

1.1.4. Names in the IUPAC nomenclature

1.1.5. Other names (usual name, trade name, synonyms)

1.1.6. CAS (registration) number and CAS (registration) name

- 1.4. Empirical (molecular) and structural formula
- 1.5. Composition of the chemical substance
- 1.3.7. Degree of purity (%)
- 1.3.8. Impurities, including isomers and by-products
- 1.3.9. Percentage of main impurities
- 1.3.10. Contents of a stabilising agent or an inhibitor, or other additives, listed in order of magnitude: name, nature, absolute amount and relative contents: ..... kg, ..... %
- 1.3.11. Spectral data (ultraviolet, infra red, nuclear magnetic resonance or mass spectrum)
- 1.3.12. High pressure liquid chromatography (HPLC) and gas chromatography (GS)
- 1.5. Methods of detection and determination

A full description of methods used or appropriate bibliographical references thereto. Apart from those, information shall be given on analytical methods known to notifier for the detection and identification of the chemical substance and its transformation products in the environment, as well as in cases of human exposure.

## *2. Information on the chemical substance*

### 2.1. Exposure estimate related to production:

a) working environment

b) environment

The information must be sufficient to allow an approximate, but realistic determination of human and environmental exposure associated with production processes. Precise description is not required.

### 2.2. Proposed field of application

Information given under this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, as associated with proposed/anticipated uses.

#### 2.2.1. Areas of application: description of intended types of uses

##### 2.2.1.1. Technological processes related to the use of the substance

##### 2.2.1.2. Exposure estimate related to the use of the substance (where known):

a) working environment

b) environment

##### 2.2.1.3. Form under which the substance is marketed: chemical substance, preparation

##### 2.2.1.4. Concentration of substance in marketed preparations

#### 2.2.2. Approximate breakdown of quantities per fields of application:

a) industries

b) agriculture and farming

c) mass use

#### 2.2.3. Identification of recipients

#### 2.2.4. Waste quantities and composition of waste resulting from the use of chemical substance (where known)

### 2.3. Estimate of the amounts of chemical substance produced or imported in each of the anticipated fields of application

### 2.4. Recommended methods and precautions concerning:

#### 2.4.1. Application and usage

#### 2.4.2. Storage

#### 2.4.3. Transport

#### 2.4.4. Fire (nature of gasses and products evoked, most effective means of extinguishing)

#### 2.4.5. Other dangers, particularly chemical reactions with water

#### 2.4.6. Information concerning the susceptibility of substance to cause explosion when presented in the form of a dust

- 2.5. Emergency measures in the case of contamination or spillage
- 2.6. Emergency measures in the case of injury or poisoning of persons
- 2.7. Packaging (type, size)

2.8. Data on labelling

*3. List of customers*

*4. Justification of the quantity of the new chemical substance*

*5. Programme for process-oriented researches*

The numbering in this Annex is not serial and follows the numbering of the electronic carrier (electronic technical dossiers).

## **Annex № 12 to Article 14, Paragraph 2 and Article 20, Paragraph 1**

### **Additional tests to the technical dossier of a notified under Article 7 intermediate, placed on the market in quantities exceeding 10 tonnes per manufacturer per year or before the overall quantity placed on the market reaches 50 tonnes**

Name of the intermediate: .....

Manufacturer: .....

Manufacturer's address: .....

Production site address: .....

Notifier: .....

Notifier's address: .....

First customer: .....

Customer's address: .....

Second customer: .....

Customer's address: .....

#### *1. Identity of the intermediate*

##### 1.1. Name

##### 1.1.7. Names in the IUPAC nomenclature

##### 1.1.8. Other names (usual name, trade name, synonyms)

##### 1.1.9. CAS (registration) number and CAS (registration) name

#### *3. Physical and chemical properties of the intermediate*

##### 3.4. Relative density

##### 3.7. Water solubility

#### *4. Toxicological studies*

##### 4.1. Acute toxicity

All intermediates, other than gasses shall be examined via at least two routes of administration, one of which is the oral route. The choice of the second route will depend on the nature (type, essence, physico-chemical properties and characteristics) and the likely route of human exposure (via the skin or via inhalation). Gasses and volatile liquids should be tested by the inhalation route of administration.

##### 4.1.3. Acute transcutaneous toxicity

##### 4.2. Repeated dose toxicity

The choice of the route of administration should be determined having regard to the likely route of human exposure to the intermediate. In the absence of counter-indications, the oral route shall be preferred.

- 4.2.1. Repeated dose toxicity (28 days)
- 4.3. Other effects
- 4.3.2. Reproductive toxicity on the first offspring
- 4.3.3. Toxic kinetic behaviour (base set information)

#### 5. *Ecotoxicological studies*

- 5.1. Effects on organisms
- 5.1.2. Acute toxicity for fish
- 5.1.3. Growth-inhibitor test on algae
- 5.1.6. Bacterial inhibition

In those cases where biodegradation may be affected by the inhibitory effect of the chemical substance on bacteria, a test to determine the impact of the substance on the bacteria, involved in its biodegradation shall be carried out.

#### 5.2. Abiotic degradation (without microbial participation)

If the substance is not readily biodegradable, a test on the hydrolysis as a function of pH needs to be carried out.

#### 5.3. Absorption/desorption data

### 6. *Possibility of rendering the substance harmless*

#### 6.1. For industrial processes:

- 6.1.1. Possibility of recycling
- 6.1.2. Possibility of neutralising the adverse effects
- 6.1.3. Possibility of destruction:
  - a) controlled discharge
  - b) incineration
  - c) water treatment plants
  - d) others

#### 6.2. For the public at large

- 6.2.1. Possibility of recycling
- 6.2.2. Possibility for elimination of adverse effects
- 6.2.3. Possibility of destruction:
  - a) controlled discharge
  - b) incineration
  - c) water treatment plants
  - d) others