

Annex VII. A INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 7 (1)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned. For intermediates with limited exposure the provisions under point 7 apply.

0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.

1. IDENTITY OF THE SUBSTANCE

1.1. Name

1.1.1. Names in the IUPAC nomenclature

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

1.1.3. CAS number and CAS name (if available)

1.2. Molecular and structural formula

1.3. Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including isomers and by-products

1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ppm, %

1.3.5. Spectral data (UV, IR, NMR or mass spectrum)

1.3.6. HPLC, GC

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allows detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production

2.0.2. Exposure estimates related to production:

- working environment

- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

- 2.1.1.1. Technological process(es) related to the use of the substance (where known)
 - 2.1.1.2. Exposure estimate(s) related to use (where known):
 - working environment
 - environment
 - 2.1.1.3. Form under which the substance is marketed: substance, preparation, product
 - 2.1.1.4. Concentration of the substance in marketing preparations and products (where known)
 - 2.1.2. Fields of application with approximate breakdown:
 - industries
 - farmers and skilled trades
 - use by the public at large
 - 2.1.3. Where known and where appropriate, the identity of the recipients of the substance
 - 2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)
 - 2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
 - 2.2.1. Overall production and/or imports in tonnes per year:
 - the first calendar year
 - the following calendar years
- For the substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.
- 2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:
 - the first calendar year
 - the following calendar years
- 2.3. Recommended methods and precautions concerning:
 - 2.3.1. Handling
 - 2.3.2. Storage
 - 2.3.3. Transport
 - 2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
 - 2.3.5. Other dangers, particularly chemical reaction with water
 - 2.3.6. If relevant, information concerning the susceptibility of the substance to explode when presented in the form of a dust
 - 2.4. Emergency measures in the case of accidental spillage
 - 2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
 - 2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

- 3.0. State of the substance at 20 oC and 101,3 kPA
 - 3.1. Melting-point
 - 3.2. Boiling-point
 - 3.3. Relative density
 - 3.4. Vapour pressure
 - 3.5. Surface tension
 - 3.6. Water solubility
 - 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. Oxidizing properties

3.15. Granulometry:

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalatory route, a test should be conducted to determine the particle size distribution of the substance as it will be marketed.

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

For tests 4.1.1 to 4.1.3, substances other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route will depend on the nature of the substance and the likely route of human exposure. Gases and volatile liquids should be administered by the inhalation route.

4.1.1. Administered orally

4.1.2. Administered by inhalation

4.1.3. Administered cutaneously

4.1.5. Skin irritation

4.1.6. Eye irritation

4.1.7. Skin sensitization

4.2. Repeated dose

The route of administration should be the most appropriate having regard to the likely route of human exposure, the acute toxicity and the nature of the substance. In the absence of contra-indications the oral route is usually the preferred one.

4.2.1. Repeated dose toxicity (28 days)

4.3. Other effects

4.3.1. Mutagenicity

The substance shall be examined in two tests. One shall be a bacteriological (reverse mutation) test, with and without metabolic activation. The second shall be a non-bacteriological test to detect chromosome aberrations or damage. In the absence of contra-indications, this test should normally be conducted in vitro, both with and without metabolic activation. In the event of a positive result in either test, further testing according to the strategy described in Annex V should be carried out.

4.3.2. Screening for toxicity related to reproduction (for the record)

4.3.3. Assessment of the toxicokinetic behaviour of a substance to the extent that can be derived from base set data and other relevant information

5. ECOTOXICOLOGICAL STUDIES

5.1. Effects on organisms

5.1.1. Acute toxicity for fish

5.1.2. Acute toxicity for daphnia

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 a substance on the bacteria, a test for bacterial inhibition should be carried out prior to undertaking the biodegradation.

5.2. Degradation

- biotic

- antibiotic:

If the substance is not readily biodegradable then consideration should be given to the need to carry out the following tests: hydrolysis as a function of pH.

5.3. Absorption/desorption screening test

6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

6.1. For industry/skilled trades

6.1.1. Possibility of recycling

6.1.2. Possibility of neutralization of unfavourable effects

6.1.3. Possibility of destruction:

- controlled discharge
- incineration
- water purification station
- others

6.2. For the public at large

6.2.1. Possibility of recycling

6.2.2. Possibility of neutralization of unfavourable effects

6.2.3. Possibility of destruction:

- controlled discharge
- incineration
- water purification station
- others

7. REDUCED TEST PACKAGE FOR INTERMEDIATES AT QUANTITIES =1 TONNE / ANNUM

1. Without prejudice to other Community legislation, the following definitions apply:

- "Intermediate" is a chemical substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another chemical substance(s).

- "Emission" concerns the release of a substance from a system, for example when a system is breached. To guarantee a maximum level of protection for workers and the environment minimisation of emission through rigorous containment of the process must therefore be the primary aim.

- "Exposure" is concerned with what happens to a substance after it has been emitted, whether this is into the wider environment or whether the substance can be potentially inhaled or come in contact with the skin of a member of the workforce. If emissions can be anticipated to occur, rigorous exposure control must be achieved by appropriate techniques, noting the need to adopt the precautionary principle in that physicochemical, toxicological and ecotoxicological properties which had not been tested shall be assumed as being hazardous.

- "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. 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 underpressure 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.

- "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. This means that the occurrence of chemical agents in the workplace atmosphere can practically be **excluded**.

- "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.

- "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**.

- "Low-emission forms of use" are, for example:

- expendable packaging, i.e. the hazardous substance is enclosed in appropriate packaging and, without opening the packaging, is introduced into a reaction system together with this packaging.

- 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.

- master batch; this means that the hazardous substance is surrounded by a plastic matrix which prevents direct contact with the hazardous substance. The plastic matrix itself is not a hazardous substance. Abrasion of the plastic matrix and therefore of the hazardous substance, is, however, possible.

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

- "Technically leakproof" is applied to a sub unit if a leak is not discernible during testing, monitoring or checking for leakproofness, e.g. using foaming agents or leak searching / indicating equipment performed for the particular use. Systems, sub systems and functional elements are technically leakproof, if the Rate of leakage is $< 0.00001 \text{ mbar} \cdot \text{l} \cdot \text{s}^{-1}$.

2. For intermediates, the notifier may request the competent authority to grant permission to apply a reduced test package (RTP). This RTP represents a minimum data set designed to produce a first preliminary risk assessment for any chemical intermediate to be placed on the market. Any additional test result might be required, in accordance with Article 16(1), based on the outcome of the risk assessment.

3. Conditions for a application of a reduced test package

The notifier must demonstrate to the satisfaction of the competent authority where the substance is notified that the following conditions are fulfilled.

a) The substance is solely manufactured for and consumed in or used for chemical processing. Monomers are excluded. When processed the substance is transformed into chemically different molecules, not being polymers.

b) The substance is restricted to a maximum number of 2 users' sites. For example, it may be manufactured by one company and then transported to 1 or 2 others for processing. Note that if supply is intended to progress to more than 2 users' sites, the conditions for a RTP are no longer met and the dossier must be upgraded to the appropriate level.

c) The supply to the enterprise which uses the intermediate for further processing must be directly from the notifier and not through an intermediate supplier.

d) The substance must be rigorously contained by technical means during its whole lifecycle. This includes production, transportation, purification, cleaning and maintenance, sampling, analysis, loading and unloading of equipment/vessels, waste disposal/purification and storage. In general, an appropriate process would have all functional elements of the plant such as filling ports, emptying equipment etc. either of a closed construction type with assured leakproofness or of a closed construction type with integrated exhaust ventilation.

e) Where there is the potential for exposure, procedural and control technologies must be used which minimise emission and the resulting exposure.

f) In case of cleaning and maintenance works special procedures such as purging and washing must be applied before the system is opened or entered.

g) Transport operations will be in compliance with the requirements of Council Directive 94/55/EC as amended from time to time.

- h) In case of accident and where waste is generated following purification or cleaning and maintenance procedures, environmental exposure may occur. In either case, procedural and/or control technologies are used which minimise emissions and the resulting exposures.
- i) A management system must exist which identifies the roles of the individuals in the organisation.
- j) The packaging of the substance will be labelled according to Annex VI of 67/548/EEC and additionally with the following sentence: “Caution - substance not yet fully tested“.
- k) The notifier must operate a system of product stewardship and must monitor the users (a maximum of 2) to ensure compliance with the conditions listed above.

4. Technical dossier to be supplied for a reduced test package

A notifier requesting an RTP for a substance must supply the following technical dossier to the competent authority for all production and user sites:

- a) A statement that the notifier and each user accepts the conditions listed in 3 above.
- b) A description of the technical measures by which rigorous containment of the substance is achieved¹, including procedures for charging, sampling, transfer and cleaning. It is not necessary to provide details of the integrity of every seal or efficiency of integrated exhaust ventilation. However, whatever means are used to achieve rigorous containment of the process it is important that the information is available, if needed, to verify that the assertions made for achievement of control are true.
- c) If the criteria for the assessment of closed systems during handling of chemical agents detailed in section 5 below are not fulfilled, the notifier must submit exposure data based on representative monitoring data and/or reliable model calculations to enable the competent authority to make a decision whether to accept an RTP-request or not.
- d) A detailed description of the processes at all sites involved in production and use. In particular, it must be stated whether production and/or processing wastes are discharged to waste-water, liquid or solid waste is incinerated, and how the cleaning and maintenance of all equipment is made.
- e) A detailed assessment of the possible emissions and possible exposure to man and the environment during the whole life cycle, including details of the various chemical reactions involved in the process and the ways in which residues are dealt with.
Where emissions may lead to exposure, the means by which these are controlled must be described in sufficient detail to enable the competent authority to make a decision whether to accept the statement or to calculate an emission rate according to the EU Technical Guidance Document.
- f) Changes which might affect exposure to man or the environment must be notified in advance, e.g. any change in the functional elements of the plant, new user or site.
- g) The information prescribed for the RTP is the following:
 - Annex VII. B plus the following tests from this Annex:
 - vapour pressure (3.4)
 - explosive properties (3.11)
 - self-ignition temperature (3.12)

¹ The type of construction and the technical specifications (e.g. leakproofness) of the closed functional element determines the effectiveness of the containment. To enable the competent authority to make a decision as to whether rigorous containment is achieved or not, it is essential that the notifier includes details on these aspects. The technical measures must normally fulfil the conditions of the “Criteria for the Assessment of Closed Systems during Handling of Chemical Agents”, which are included for guidance in section 7.5 and table 1 of this Annex. This must be stated by the notifier, however it is not necessary to address every type of closed functional element in the description provided of the technical measures. Any deviation from the conditions of the Criteria must be fully described, with justification.

- oxidising properties (3.13)
- granulometry (3.15)
- acute toxicity for daphnia (5.1.2)

The notifier must also include other relevant information to enable the competent authority to make an informed decision and to enable proper controls to be put in place by the user at the intermediate processing site. For example, if supplementary physicochemical and/or toxicological information and/or information about the environmental behaviour is available this data must also be submitted. Additionally, the notifier must review the available toxicity and ecotoxicity data on substances having close structural relationship to the notified substance. If relevant data are available, especially on chronic and reproductive toxicity and carcinogenicity, then a summary of these data must be provided.

h) Identities of the notifier, producer and the user(s).

5. Criteria for the assessment of closed systems during the handling of chemical agents

5.1 Use

An assessment index is used in the assessment of the plant. The assessment index classifies the handling of the substance and the resultant process-related exposure potential. The notifier shall examine the plant or plant unit in order to determine the assessment index. Each individual functional element must be assessed.

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 collection of examples relevant functional elements are indicated by **0.5** in bold type.

Functional elements of partially open type with highly effective exhaust ventilation (also indicated by the assessment index 0.5, but in normal type) are **not** regarded as closed according to the meaning of this rule.

In the case of functional elements assigned the assessment index 1, the safe adherence to the limit value on a permanent basis is not always assured. Such functional elements are

1 - closed type, leakproofness not assured

1 - partially open type with effective exhaust ventilation.

In the case of functional elements assigned the assessment indices 2 and 4 the adherence to the limit values is not always assured. Such functional elements are

2 - of a partially open type, opening as intended with simple exhaust ventilation

2 - open with simple exhaust ventilation

4 - open type or partially open type

4 - natural ventilation

The catalogue of examples in Table 1 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.

5.2 Checking

Use of this criterion requires adherence to the process parameters which have been laid down as well as the performance of the checks cited in the collection of examples (e.g. inspection and maintenance).

6. Application of a reduced test package

If the competent authority accepts the notifier's application for a RTP, then information from the tests and/or studies set out in point 7.4 above shall be required for the technical dossier referred to in Article 7. Note that for quantities below 1 tonne/annum the usual Annex VIIB/VIIC testing requirements apply.

Table 1
Collection of examples

No.	Functional element	Constructional type	examples of constructional type	assessment index		explanations
				without	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		
			- cutting ring and clamping ring connection ≤ DN 32	0.5		
			- NPT thread ≤ DN 50, Δ t ≤ 100°C	0.5		
			- cutting ring and clamping ring connection > DN 32	1	0.5 Assurance of leakproofness by means of monitoring and repair*	
			- NPT thread > DN 50, Δ t >100°C	1	0.5 Assurance of leakproofness by means of monitoring and repair*	
			- 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*	
						- reduce connections to number required - open connections as little as possible - leak tests prior to resumption of operation - use new seals in case of resumption of operation involving separated connections - where possible, flanges to be opened for operational reasons should not be equipped with tongue and groove (danger of misalignment)

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				Without	With additional measures	
1	2	3	4	5	6	7
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	<ul style="list-style-type: none"> - stuffing box seals - stuffing box seals with self-adjustment (spring-loaded) - double stuffing box with barrier seal - O-ring seal - stopcock liner seal - piston seal - bellows seal - diaphragm seal - magnetic clutch 	<ul style="list-style-type: none"> 2 1 1 1 1 1 0.5 0.5 0.5 	<ul style="list-style-type: none"> 1 in the case of regular monitoring and repair 0.5 technically leakproof 0.5 with monitoring of the barrier pressure system 0.5 technically leakproof 0.5 assurance of technically leakproofness by means of monitoring and repair 0.5 technically leakproof 	by means of regular visual checks or process control technology equipment

No.	functional element	constructional type	examples of constructional type	Assessment index		explanations
				Without	with additional measures	
1	2	3	4	5	6	7
1.3.2	Others	control rods	<ul style="list-style-type: none"> - stuffing box seals - stuffing box seals with self-adjustment (spring-loaded) - double stuffing box with barrier seal - O-ring seal - piston seal - bellows seal - diaphragm seal 	<p>2</p> <p>1</p> <p>1</p> <p>1</p> <p>1</p> <p>0.5</p> <p>0.5</p>	<p>1 in the case of regular monitoring and repair</p> <p>0.5 technically leakproof</p> <p>0.5 with monitoring of the barrier pressure system</p>	<p>by means of regular visual checks or process control technology equipment</p>

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				Without	with additional measures	
1	2	3	4	5	6	7
2	dynamic seals					
2.1	seals with revolving parts	hermetically sealed seals which are not contactless	- canned motor - magnetic clutches - single axial face seal - double axial face seal - double axial face seal with barrier fluid - stuffing box seal - stuffing box seal with self-adjustment (spring-loaded)	0.5 0.5 1 1 1 2 2	0.5 with monitoring of the barrier pressure system by means of regular checking, as a rule, 1 x day or, for example, process control technology equipment with alarm 1 in the case of regular monitoring and repair 0.5 technically leakproof	
		contactless seals	- labyrinth seal - gas-lubricated seal	2 1	0.5 with monitoring of the gas flow	

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				Without	with additional measures	
1	2	3	4	5	6	7
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		

No.	functional element	constructional type	examples of constructional type	assessment index		Explanations
				Without	with additional measures	
1	2	3	4	5	6	7
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 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) 0.5 emission-free form of use (e.g. master batch without abrasion)	if a hazardous substance is present in the container due account must be taken of this
		sack-slitting and emptying machine				
		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	

No.	functional element	constructional type	examples of constructional type	assessment index		explanations	
				without	with additional measures		
1	2	3	4	5	6	7	
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*

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				without	with additional measures	
1	2	3	4	5	6	7
3.1.3 3.1.3.1	containers 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* 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	The container's cover seal must meet the demands of no. 1.2
		open container		4	2 with other exhaust ventilation equipment 1 with effective exhaust ventilation equipment 0.5 with highly effective exhaust ventilation equipment	

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				Without	with additional measures	
1	2	3	4	5	6	7
3.1.3.2	container (filling)	with special filling equipment open filling		1 4	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* 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*	

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				Without	with additional measures	
1	2	3	4	5	6	7
3.1.4 3.1.4.1	drums drums (emptying)	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	
			- 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	

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				without	with additional measures	
1	2	3	4	5	6	7
3.1.4.1	drums (emptying) continuation	open container	- mechanical conveyance, e.g. by spiral conveyor - 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 4 0.5 with highly effective exhaust ventilation equipment	

No.	functional element	constructional type	examples of constructional type	assessment index		explanations
				without	with additional measures	
1	2	3	4	5	6	7
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	

No.	functional element	constructional type	Examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
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		

No.	functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
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 - without gas-displacement and without gas offtake at a safe point	1 4	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 no. 1
		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

No.	Functional element	constructional type	examples of constructional type	assessment index		explanations
				without	with additional measures	
1	2	3	4	5	6	7
3.2.1.2	small containers and drums (filling)	fixed connections (pipework, hose connections, articulated arm) open packing drums	- with gas-displacement or gas offtake at a safe point or transfer to a treatment or incineration plant - without gas-displacement and without gas offtake - with filling hose - encapsulation	1 4 4 1	0.5 Assurance of leakproofness by means of monitoring and repair*; leak test after establishing the connection, complete capture of the residual quantities 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 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 0.5 with integrated exhaust ventilation equipment and closing of the packing drums in the closed unit	with regard to connection elements see no. 1 regular checking of the exhaust ventilation equipment; the small container or drum must be closed immediately after the filling process regular checking of the exhaust ventilation equipment

No.	Functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
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 - without gas-displacement and without gas offtake	1 4	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 no. 1
		other hose connections		2		
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 - without gas-displacement and without gas offtake	1 4	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
		open filling	- filling pipe	4		

No.	Functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
3.3	Substance transfer points gases					With regard to the functional elements see no.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 connection; gas-displacement or offtake of residual gas at a safe point or transfer to a treatment or incineration plant	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.

No.	Functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
4	Sampling points					
4.1	Open sampling		valve, stopcock	4	2 with other exhaust ventilation equipment 1 with highly effective 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 parts - After-run of liquid from pipe connection pieces of tubes which are mounted on the sampling unit - Escape of product vapours - Overflow from overfilled sampling vessels

No.	Functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7

No.	functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
5	Storage in packing drums					
5.1	Solid substances, with the exception of certain explosives	Transport packaging according to ADR-regulations	- drums, containers	0.5		with sufficient ventilation (min. 2-fold change of air)
			- Bags; plastic, textile, paper and multi-layered sacks	0.5		with sufficient ventilation (min. 2-fold change of air)
5.2	Solid substances, certain explosives (containing nitro-glycerine)	Transport packaging according to ADR-regulations		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-regulations	- containers, metal drums, sheet iron cans, plastic drums, tubes, cans, containers	0.5		with sufficient ventilation (min. 2-fold change of air)

No.	functional element	constructional type	examples of constructional type	assessment index		Explanations
				without	with additional measures	
1	2	3	4	5	6	7
5.4	Gases	Transport packaging according to ADR-regulations	compressed gas cylinders, compressed gas containers, compressed gas drums	1	0.5 Assurance of leakproofness by means of monitoring and repair	with sufficient ventilation (min. 2-fold change of air) With regard to functional elements see no. 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.

***) "Assurance of leakproofness through monitoring and repair"**

The leakproofness of separable connections between plant units and parts of the equipment can be assured by taking the following measures on a permanent basis:

1. Monitoring or inspection measures in order to determine and assess the actual state of the separable connection according to EN 13306 (in preparation).

This must occur at predetermined times and in accordance with a plan geared to the specific needs of the company, the type of connection and its construction as well as to the nature and the properties of the chemical agents which are conveyed. Examples of such measures are :

- leak testing
- visual examination of the plant to establish clear leakage points such as places where liquids are leaking, examination to establish streaks, odours, noises, the formation of ice etc.
- inspection of the plant with mobile leak-indicating and leak-detection devices (e.g. gas test tubes, FID, portable gas detectors),
- the application of foaming agents to the separable connections,
- the use of gas detectors to monitor the atmosphere
- the use of an automatic leak-testing device at the articulated hose or the loading hose.

2. Repair measures to restore the desired state of the separable connection according to EN 13306 (in preparation).

The measures which are possibly required must be planned and performed on an individual basis in dependence on the

- particular hazardous substance
- the type and extent of the damage,
- the protection and safety measures which must be taken.

Before the plant returns to operation the repaired connections must be subjected to thorough leak testing.

ANNEX VII. B INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 8 (1) AND (3)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and subject to acceptance by the competent authority.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

In addition to the information requested below, Member States may, if they consider it necessary for the risk assessment, require that the notifier provides the following additional information:

- vapour pressure,
- daphnia acute toxicity test.

0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER: LOCATION OF THE PRODUCTION SITE

For substances manufactured outside the Community and for which, for the purpose of

notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community

1. IDENTITY OF THE SUBSTANCE

1.1. Name

1.1.1. Names in the IUPAC nomenclature

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

1.1.3. CAS number and CAS name (if available)

1.2. Molecular and structural formula

1.3. Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including isomers and by-products

1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: ppm, %

1.3.5. Spectral data (UV, IR, NMR or mass spectrum)

1.3.6. HPLC, GC

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

Apart from methods of detection and determination, information on analytical methods which are known to the notifier and which allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans

2. INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, associated with the production process.

Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process(es) used in production

2.0.2. Exposure estimate related to production:

- working environment
- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

2.1.1.1. Technological process(es) related to the use of the substance (where known)

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

- working environment
- environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product

2.1.1.4. Concentration of the substance in marketed preparations and products (where known)

2.1.2. Fields of application with approximate breakdown:

- industries
- farmers and skilled trades
- use by the public at large

- 2.1.3. Where known and where appropriate, the identity of the recipients of the substance
- 2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
- 2.2.1. Overall production and/or imports in tonnes per year:

- first calendar year
- the following calendar years

For substances manufactured outside the Community and for which, for the purposes of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:

- the first calendar year
- the following calendar years

2.3. Recommended methods and precautions concerning:

2.3.1. Handling

2.3.2. Storage

2.3.3. Transport

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e.g. poisoning)

2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.0. State of the substance at 20 °C and 101,3 kPa

3.1. Melting-point

3.2. Boiling-point

3.6. Water solubility

3.8. Partition coefficient n-octanol/water

3.9. Flash-point

3.10. Flammability

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

For tests 4.1.1 to 4.1.2 one route of administration is sufficient. Substances other than gases should be tested by oral administration. Gases should be tested by inhalation.

4.1.1. Administered orally

4.1.2. Administered by inhalation

4.1.5. Skin irritation

4.1.6. Eye irritation

4.1.7. Skin sensitization

4.3. Other effects

4.3.1. Mutagenicity

The substance should be examined in a bacteriological (reverse mutation) test with and without metabolic activation.

5. ECOTOXICOLOGICAL STUDIES

5.2. Degradation:

biotic

ANNEX VII. C INFORMATION REQUIRED FOR THE TECHNICAL DOSSIER ("BASE SET") REFERRED TO IN ARTICLE 8 (2)

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authority. The name of the body or bodies responsible for carrying out the studies shall be mentioned.

0. IDENTITY OF MANUFACTURER AND THE NOTIFIER IF THESE ARE NOT THE SAME; LOCATION OF THE PRODUCTION SITE

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community

1. IDENTITY OF THE SUBSTANCE

1.1. Name

1.1.1. Names in the IUPAC nomenclature

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

1.1.3. CAS number and CAS name (if available)

1.2. Molecular and structural formula

1.3. Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including isomers and by-products

1.3.3. Percentage of (significant) main impurities

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude:

..... ppm; %

1.3.5. Spectral data (UV, IR, NMR or mass spectrum)

1.3.6. HPLC, GC

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

Apart from methods of detection and determination, information on analytical methods which are known to the notifier and which allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans

2. INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure, associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process(es) used in production

2.0.2. Exposure estimate related to production:

- working environment

- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

- 2.1.1.1. Technological process(es) related to the use of the substance (where known)
 - 2.1.1.2. Exposure estimate(s) related to the use of the substance (where known):
 - working environment
 - environment
 - 2.1.1.3. Form under which the substance is marketed:
 - substance, preparation, product
 - 2.1.1.4. Concentration of the substance in marketed preparations and products (where known)
 - 2.1.2. Fields of application with approximate breakdown:
 - industries
 - farmers and skilled trades
 - use by the public at large
 - 2.1.3. Where known and where appropriate, the identity of the recipients of the substance
 - 2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
 - 2.2.1. Overall production and/or imports in tonnes per year:
 - the first calendar year
 - the following calendar years
- For substances manufactured outside the Community and for which, for the purposes of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above
- 2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:
 - the first calendar year
 - the following calendar years
 - 2.3. Recommended methods and precautions concerning:
 - 2.3.1. Handling
 - 2.3.2. Storage
 - 2.3.3. Transport
 - 2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
 - 2.3.5. Other dangers, particularly chemical reaction with water
 - 2.4. Emergency measures in the case of accidental spillage
 - 2.5. Emergency measures in the case of injury to persons (e.g. poisoning)
 - 2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

- 3.0. State of the substance at 20 °C and 101,3 kPa
- 3.9. Flash-point
- 3.10. Flammability

4. TOXICOLOGICAL STUDIES

4.1. Acute toxicity

One route of administration is sufficient. Substances other than gases should be tested by oral administration. Gases should be tested by inhalation.

4.1.1. Administered orally

4.1.2. Administered by inhalation.

ANNEX VII D SPECIFIC PROVISIONS CONCERNING THE TECHNICAL DOSSIER ("BASE SET") CONTAINED IN THE NOTIFICATIONS REFERRED TO IN ARTICLE 12

A. For the purpose of this Annex

- "homopolymer" is a polymer consisting of only one kind of monomer unit,
- "copolymer" is a polymer consisting of more than one kind of monomer unit,
- "polymer for which a reduced test package is acceptable", "RTP polymer", is a polymer that satisfies the criteria laid down in C.2,
- "family of polymers" is a group of polymers (either homopolymers or copolymers) with different number-average molecular weights or different compositions resulting from different ratios of monomer units. The difference in the number-average molecular weight or in the composition is determined not by unintentional process-related fluctuations but by deliberate alterations to the process conditions, the process itself remaining the same,
- "Mn" is the number-average molecular weight,
- "M" is the molecular weight.

B. Family approach

To avoid unnecessary testing, the grouping of polymers into families shall be possible.

The concept consists of testing representative members of a family with:

- Mn variable for homopolymers, or
- composition variable with Mn approximately constant for copolymers, or
- for $M_n > 1\ 000$, Mn variable with composition approximately constant for copolymers.

In certain cases where there are dissimilarities in the effects seen in the representative members, depending on the Mn- or composition-range, additional testing of other representative members shall be required.

C. Information required for the technical dossier referred to in Article 12

If it is not technically possible or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated and be subject to acceptance by the competent authorities.

Appropriate available information on the properties of the monomer(s) may be taken into account for the assessment of the properties of the polymer.

Without prejudice to the provisions of Article 3 (1) of Directive 67/548/EEC the tests must be conducted according to methods recognized and recommended by the competent international bodies where such recommendations exist.

The name of the body or bodies responsible for carrying out the studies shall be mentioned.

C.1. POLYMERS WITH STANDARD TEST PACKAGE

C.1.1. Polymers placed on the Community market in quantities of ≥ 1 t/a or total quantities of ≥ 5 t

In addition to the information and tests referred to in Article 7 (1), laid down in Annex VII A, the following polymer-specific information is required:

1. IDENTITY OF THE SUBSTANCE

1.2.1. Number-average molecular weight

1.2.2. Molecular weight distribution (MWD)

1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4. Indication of end groups and identity and frequency of reactive functional groups

1.3.2.1. Identity of non-reacted monomers

1.3.3.1. Percentage of non-reacted monomers

2. INFORMATION ON THE SUBSTANCE

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.6.1. Water extractivity

Without prejudice to Article 16 (1) of Directive 67/548/EEC, further tests may be required additionally in certain cases, e.g.:

- light-stability if the polymer is not specifically light-stabilized,
- long-term extractivity (leachate test); depending on the results of this test, appropriate tests on the leachate may be requested on a case by case basis.

C.1.2. Polymers placed on the Community market in quantities of < 1 t/a or total quantities of < 5 t but \geq 100 kg/a or total quantities \geq 500 kg

In addition to the information and tests referred to in Article 8 (1), laid down in Annex VII B, the following polymer-specific information is required:

1. IDENTITY OF THE SUBSTANCE

1.2.1. Number-average molecular weight

1.2.2. Molecular weight distribution (MWD)

1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4. Indication of end groups and identity and frequency of reactive functional groups

1.3.2.1. Identity of non-reacted monomers

1.3.3.1. Percentage of non-reacted monomers

2. INFORMATION ON THE SUBSTANCE

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.6.1. Water extractivity

C.1.3. Polymers placed on the Community market in quantities of < 100 kg/a or total quantities of < 500 kg

In addition to the information and tests referred to in Article 8 (2), laid down in Annex VII C, the following polymer-specific information is required:

1. IDENTITY OF THE SUBSTANCE

1.2.1. Number-average molecular weight

1.2.2. Molecular weight distribution (MWD)

1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4. Indication of end groups and identity and frequency of reactive functional groups

1.3.2.1. Identity of non-reacted monomers

1.3.3.1. Percentage of non-reacted monomers

2. INFORMATION ON THE SUBSTANCE

2.1.1.5. Statement, with relevant information, if the polymer has been developed to be environmentally degradable

C.2. POLYMERS FOR WHICH A REDUCED TEST PACKAGE IS ACCEPTABLE

Under certain conditions the base set test package for polymers can be reduced.

Substances with a high number-average molecular weight, a low content of low molecular weight species and a low solubility/extractivity will be regarded as being non-bioavailable.

Consequently, the following criteria shall be used to determine the polymers for which a reduced test package is acceptable:

For non-readily degradable polymers placed on the Community market in quantities of \geq 1 t/a or total quantities of \geq 5 t, the following criteria define those polymers for which a reduced test package is acceptable:

I. High number-average molecular weight (M_n) (1);

II. Extractivity in water (3.6.1)

< 10 mg/l excluding any contribution from additives and impurities;

III. Less than 1 % with $M < 1\ 000$; the percentage refers only to molecules (components) directly derived from and including monomer(s), excluding other components e.g. additives or impurities.

If all criteria are fulfilled, the polymer is regarded as a polymer for which a reduced test package is acceptable.

In the case of non-readily degradable polymers placed on the Community market in quantities $< 1\ t/a$ or total quantities of $< 5\ t$ it is sufficient that criteria I and II are fulfilled for the polymer to be considered a polymer for which a reduced test package is acceptable.

If it is not possible to prove the criteria with the assigned tests, the notifier has to demonstrate compliance with the criteria by other means.

Under certain circumstances toxicological and ecotoxicological tests may be required.

C.2.1. Polymers placed on the Community market in quantities of $\geq 1\ t/a$ or total quantities of $\geq 5\ t$

0. Identity of manufacturer and the identity of the notifier: Location of the production site
For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.

1. IDENTITY OF THE SUBSTANCE

1.1. Name

1.1.1. Name in the IUPAC nomenclature

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

1.1.3. CAS number and CAS name (if available)

1.2. Molecular and structural formula

1.2.1. Number-average molecular weight

1.2.2. Molecular weight distribution (MWD)

1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4. Indication of end groups and identity and frequency of reactive functional groups

1.3. Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including by-products

1.3.2.1. Identity of non-reacted monomers

1.3.3. Percentage of (significant) main impurities

1.3.3.1. Percentage of non-reacted monomers

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: . . . ppm, . . . %

1.3.5. Spectral data (UV, IR, NMR or mass spectrum)

1.3.6.1. GPC

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references.

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise

details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological processes in production.

2.0.2. Exposure estimates related to production:

- working environment
- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of use: description of the function and the desired effects

2.1.1.1. Technological process(es) related to the use of the substance (where known)

2.1.1.2. Exposure estimate(s) related to the use (where known):

- working environment
- environment

2.1.1.3. Form under which the substance is marketed: substance, preparation, product

2.1.1.4. Concentration of the substance in marketing preparations and products (where known)

2.1.2. Fields of application with approximate breakdown:

- industries
- farmers and skilled trades
- use by the public at large

2.1.3. Where known and where appropriate, the identify of the recipients of the substance

2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)

2.2. Estimated production and/or imports for each of the anticipated uses or fields of application

2.2.1. Overall production and/or imports in tonnes per year:

- the first calendar year
- the following calendar years

For the substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section O above.

2.2.2. Production and/or imports, broken down in accordance with 2.1.1 and 2.1.2 expressed as a percentage:

- the first calendar year
- the following calendar years

2.3. Recommended methods and precautions concerning:

2.3.1. Handling

2.3.2. Storage

2.3.3. Transport

2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)

2.3.5. Other dangers, particularly chemical reaction with water

2.3.6. If relevant, information concerning the susceptibility of the substance to explode when present in the form of a dust

2.4. Emergency measures in the case of accidental spillage

2.5. Emergency measures in the case of injury to persons (e. g. poisoning)

2.6. Packaging

3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE

3.0. State of the substance at 20° C and 101,3 kPa

3.1. Melting range (e. g. from the thermal stability test)

3.3. Relative density

3.6.1. Water extractivity

3.10. Flammability

3.11. Explosive properties

3.12. Auto-flammability

3.15. Particle size:

For those substances which may be marketed in a form which gives rise to the danger of exposure by the inhalator route, a test should be conducted to determine the particle distribution of the substances as it will be marketed.

3.16. Thermal stability

3.17. Extractivity with:

- water at pH 2 and 9 at 37° C

- cyclohexane

4. TOXICOLOGICAL STUDIES

On a case by case basis and without delaying in acceptance of the notification, the competent authorities may, on the basis of the presence of reactive groups, structural/physical characteristics, knowledge concerning the properties of low molecular weight components of the polymer or exposure potential, require certain tests to be carried out. In particular tests for inhalation toxicity (e. g. 4.1.2 or 4.2.1), may be required if exposure by the inhalatory route is considered possible.

5. ECOTOXICOLOGICAL STUDIES

On a case-by-case basis and without delaying the acceptance of the notification, the competent authorities may on the basis of the presence of reactive groups, structural/physical characteristics, knowledge concerning the properties of low molecular weight components of the polymer or exposure potential, require certain tests to be carried out. In particular, the following additional tests may be required:

- light-stability, if the polymer is not specifically lighth-stabilized

- long-term extextractivity (leachate test).

Depending on the results of this test, any appropriate test on the leachate may be requested on a case by case basis

6. POSSIBILITY OF RENDERING THE SUBSTANCE HARMLESS

6.1. For industry/skilled trades

6.1.1. Possibility of recycling

6.1.2. Possibility of neutralization of unfavourable effects

6.1.3. Possibility of destruction:

- controlled discharge

- incineration

- water purification station

- others

6.2. For the public at large

6.2.1. Possibility of recycling

6.2.2. Possibility of neutralization of unfavourable effects

6.2.3. Possibility of destruction:

- controlled discharge

- incineration

- water purification station

- others

C.2.2 Polymers placed on the Community market in quantities of < t/a or total quantities of < 5 t

0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER:

LOCATION OF THE PRODUCTION SITE

For substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identity and the addresses of the importers who will be bringing the substance into the Community.

1. IDENTITY OF THE SUBSTANCE

1.1. Name

1.1.1. Name in the IUPAC nomenclature

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

1.1.3. CAS number and CAS name (if available)

1.2. Molecular and structural formula

1.2.1. Number-average molecular weight

1.2.2. Molecular weight distribution (MWD)

1.2.3. Identity and concentration of starting monomers and starting substances which will be bound in the polymer

1.2.4. Indication of end groups and identity and frequency of reactive functional groups

1.3. Composition of the substance

1.3.1. Degree of purity (%)

1.3.2. Nature of impurities, including by-products

1.3.2.1. Identity of non-reacted monomers

1.3.3. Percentage of (significant) main impurities

1.3.3.1. Percentage of non-reacted monomers

1.3.4. If the substance contains a stabilizing agent or an inhibitor or other additives, specify: nature, order of magnitude: . . . ppm, . . . %

1.3.5. Spectral data (UV, IR, NMR or mass spectrum)

1.3.6.1. GPC

1.4. Methods of detection and determination

A full description of the methods used or the appropriate bibliographical references

Apart from methods of detection and determination, information shall be given on analytical methods which are known to the notifier and allow detection of a substance and its transformation products after discharge into the environment as well as determination of the direct exposure of humans.

2. INFORMATION ON THE SUBSTANCE

2.0. Production

Information given in the section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure associated with the production process. Precise details of the production process, particularly those of a commercially sensitive nature, are not required.

2.0.1. Technological process used in production

2.0.2. Exposure estimates related to production:

- working environment

- environment

2.1. Proposed uses

Information given in this section should be sufficient to allow an approximate but realistic estimation of human and environmental exposure to the substances as associated with the proposed/expected uses.

2.1.1. Types of uses: description of the function and the desired effects

2.1.1.1. Technological process(es) related to the use of the substance (where known)

2.1.1.2. Exposure estimate(s) related to the use (where known):

- working environment
- environment
- 2.1.1.3. Form under which the substance is marketed: substance, preparation, product
- 2.1.1.4. Concentration of the substance in marketing preparations and products (where known)
- 2.1.2. Fields of application with approximate breakdown:
 - industries
 - farmers and skilled trades
 - use by the public at large
- 2.1.3. Where known and where appropriate, the identity of the recipients of the substance
- 2.1.4. Waste quantities and composition of waste resulting from the proposed uses (where known)
- 2.2. Estimated production and/or imports for each of the anticipated uses or fields of application
- 2.2.1. Overall production and/or imports in tonnes per year:
 - the first calendar year
 - the following calendar years

For the substances manufactured outside the Community and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, this information must be given for each of the importers identified under section 0 above.
- 2.2.2. Production and/or imports, broken down in accordance with 2.1.2 expressed as a percentage:
 - the first calendar year
 - the following calendar years
- 2.3. Recommended methods and precautions concerning:
 - 2.3.1. Handling
 - 2.3.2. Storage
 - 2.3.3. Transport
 - 2.3.4. Fire (nature of combustion gases or pyrolysis, where proposed uses justify this)
 - 2.3.5. Other dangers, particularly chemical reaction with water
 - 2.3.6. If relevant, information concerning the susceptibility of the substance to explode when present in the form of a dust
- 2.4. Emergency measures in the case of accidental spillage
- 2.5. Emergency measures in the case of injury to persons (e. g. poisoning)
- 2.6. Packaging
- 3. PHYSICO-CHEMICAL PROPERTIES OF THE SUBSTANCE
- 3.0. State of the substance at 20 °C and 101,3 kPa
- 3.1. Melting range (e. f. from the thermal stability test)
- 3.6.1. Water extractivity
- 3.10. Flammability'

(1) The authorities receiving the notification shall decide on their own responsibility whether or not a polymer satisfies this criterion.