

SCHEDULE 2

(This Schedule sets out the provisions of Annex VII to the Directive)
INFORMATION REQUIRED IN THE TECHNICAL DOSSIERS

PART D

(The provisions set out in this Part were introduced into Annex VII of the Directive by Commission Directive [1993/105/EEC](#))

information required for the technical dossier for a notification under regulation 7

Without prejudice to the provisions of Article 3(1) of the Directive tests under this Part shall be according to methods recognized and recommended by the competent international bodies where such recommendations exist.

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.

A.

For the purpose of this Part

- ‘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 section C.2 of this Part.
- ‘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.
- ‘ M_n ’ is the number-average molecular weight.
- ‘MW’ is the molecular weight (of any particular molecule).

B.

Family approach

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

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

- M_n variable for homopolymers or

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	<ul style="list-style-type: none"> — composition variable with M_n approximately constant for copolymers or — for $M_n > 1000$, M_n variable with composition approximately constant for copolymers <p>In certain cases where there are dissimilarities in the effects seen in the representative members, depending on the M_n- or composition-range, additional testing of other representative members shall be required.</p>
C.	Information required for the technical dossier referred to in regulation 7
	Appropriate available information on the properties of the monomer(s) may be taken into account for the assessment of the properties of the polymer.
C.1	POLYMERS WITH STANDARD TEST PACKAGE
C.1.1	POLYMERS PLACED ON THE COMMUNITY MARKET IN QUANTITIES OF ≥ 1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF ≥ 5 TONNES)

In addition to the information and tests referred to in regulation 4(1), laid down in Part 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 regulation 16, further tests may be required additionally in certain cases, eg:

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- 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 TONNE PER ANNUM (OR TOTAL QUANTITIES OF < 5 TONNES) BUT ≥ 100 KGS PER ANNUM (OR TOTAL QUANTITIES OF ≥ 500 KGS)
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In addition to the information and tests referred to in regulation 6(1), laid down in Part 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 KGS PER ANNUM (OR TOTAL QUANTITIES OF < 500 KGS)

In addition to the information and tests referred to in regulation 6(2), laid down in Part 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)

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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 (RTP POLYMERS) IS ACCEPTABLE

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

CRITERIA FOR POLYMERS FOR WHICH A REDUCED TEST PACKAGE IS ACCEPTABLE

Substances with a high number-average molecular weight, a low content of low molecular weight species and low solubility/extractivity will be rded as being non-bioavailable. Consequently the following criteria shall be used to determine the polymers for which a reduced test package is acceptable:

- (a) for non-readily degradable polymers placed on the Community market in quantities of ≥ 1 t/a (or total quantities of ≥ 5 t), the following criteria define those polymers for which a reduced test package is acceptable:
 - (I) High number-average molecular weight (M_n). The competent authority shall decide whether or not a polymer satisfies this criterion;
 - (II) Extractivity in water (3.6.1) < 10 mg/l excluding any contribution from additives and impurities;
 - (III) Less than 1% with $MW < 1000$; the percentage refers only to molecules (components) directly derived from and including monomer(s), excluding other components e.g. additives or impurities.

If all the above criteria are fulfilled, the polymer is regarded as a polymer for which a reduced test package is acceptable.
- (b) 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 above are fulfilled.

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	RTP POLYMERS PLACED ON THE COMMUNITY MARKET IN QUANTITIES OF ≥ 1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF ≥ 5 TONNES): FULL LIST OF INFORMATION AND TESTS REQUIRED
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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 identities 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**
- 1.2.1 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

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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 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 2.1.1 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°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

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- 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 inhalatory route, a test should be conducted to determine the particle distribution of the substance 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 acceptance of the notification the competent authority may on the basis of the presence of reactive groups or structural/physical characteristics or knowledge about 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, 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 acceptance of the notification, the competent authority may on the basis of the presence of reactive groups, structural/physical characteristics or knowledge of 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 light-stabilized
 - Long-term extractivity (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**

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- 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 RTP POLYMERS PLACED ON THE COMMUNITY MARKET IN QUANTITIES OF < 1 TONNE PER ANNUM (OR TOTAL QUANTITIES OF < 5 TONNES): FULL LIST OF INFORMATION AND TESTS REQUIRED
- 0. IDENTITY OF MANUFACTURER AND THE IDENTITY OF THE NOTIFIER:
LOCATION OF THE PRODUCTION SITE:

For substances manufactured outside the Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and the addresses of the importers who will be bringing the substance into the Communities.
- 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**
- 1.2.1 Number-average molecular weight
- 1.2.2 Molecular weight distribution (MWD)

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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: <ul style="list-style-type: none"> — 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

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- 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 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 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

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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 degrees C and 101.3 kPa
3.1	Melting range (e.g. from the thermal stability test)
3.6.1	Water extractivity
3.10	Flammability
