SCHEDULE 1 Regulation 2(1)

CHARACTERISTIC PROPERTIES OF DANGEROUS SUBSTANCES

PART I

categories of danger and characteristic properties

Column 1 *Category of danger*	Column 2 *Property*
PHYSICO-CHEMICAL PROPERTIES	
Explosive	Solid, liquid, pasty or gelatinous substances which may also react exothermically without atmospheric oxygen thereby quickly evolving gases, and which under defined test conditions detonate, quickly deflagrate or upon heating explode when partially confined.
Oxidizing	Substances which give rise to a highly exothermic reaction in contact with other substances, particularly flammable substances.
Extremely flammable	Liquid substances having an extremely low flash point and a low boiling point and gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure.
Highly flammable	The following substances, namely— (a) substances which may become hot and finally catch fire in contact with air at ambient temperature without any application of energy, (b) solid substances which may readily catch fire after brief contact with a source of ignition and which continue to burn or to be consumed after removal of the source of ignition, (c) liquid substances having a very low flash point, or (d) substances which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities.
Flammable	Liquid substances having a low flash point.
HEALTH EFFECTS	
Very toxic	Substances which in very low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.

Column 1 *Category of danger*	Column 2 *Property*
Toxic	Substances which in low quantities cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.
Harmful	Substances which may cause death or acute or chronic damage to health when inhaled, swallowed or absorbed via the skin.
Corrosive	Substances which may, on contact with living tissues, destroy them.
Irritant	Non-corrosive substances which, through immediate, prolonged or repeated contact with the skin or mucous membrane, may cause inflammation.
Sensitizing	Substances which, if they are inhaled or if they penetrate the skin, are capable of eliciting a reaction of hypersensitization such that on further exposure to the substance, characteristic effects are produced.
Carcinogenic	Substances which, if they are inhaled or ingested or if they penetrate the skin, may induce cancer or increase its incidence.
Mutagenic	Substances which, if they are inhaled or ingested or if they penetrate the skin, may induce heritable genetic defects or increase their incidence.
Toxic for reproduction	Substances which, if they are inhaled or ingested or if they penetrate the skin, may produce or increase the incidence of, non-heritable adverse effects in the progeny or the impairment of male or female reproductive functions or capacity.
ENVIRONMENT	
Dangerous for the environment	Substances which, were they to enter into the environment would present or may present an immediate or delayed danger for one or more compartments of the environment.

PART II

criteria for the categories of danger “very toxic”, “toxic” and “harmful”

Substances shall be classified as “very toxic”, “toxic” or “harmful” in accordance with the following criteria:

(a) Where the acute toxicity in animals of the commercial substance has been determined by a method which permits estimation of the LD50 or LC50, classification as very toxic, toxic or harmful shall be effected using the following parameters as reference values:

Category of danger	*LD_{50} Oral in rat mg/kg body weight*	*LD_{50} Dermal in rat or rabbit mg/kg body weight*	*LC_{50} Inhalation in rat mg/litre/4 hrs*	
			gases and vapours	*aerosols and particulates*
Very toxic	≤25	≤50	≤0.5	≤0.25
Toxic	>25 to 200	>50 to 400	>0.5 to 2	>0.25 to 1
Harmful	>200 to 2000	>400 to 2000	>2 to 10	>1 to 5

(b) Where the acute oral toxicity in animals of the commercial substance has been determined using the fixed dose procedure, classification as very toxic, toxic or harmful shall be effected on the basis of the discriminating dose.This is the dose level which produces evident toxicity, but no mortality, and is one of four fixed dose levels (5, 50, 500 or 2000 mg/kg bodyweight). “Evident toxicity” is a term used to describe signs of toxicity following administration of a test substance, which are of a severity such that administration of the next higher fixed dose level would be expected to result in mortality.As this test method is based on the selection of doses from a series of fixed doses, it is inappropriate to give values for classification. The following parameters are used as reference values:

Category	*Discriminating dose (mg/kg bodyweight)*
Very toxic	<5
Toxic	5 to <50
Harmful	50 to <500

The 2000 mg/kg dose level is used primarily to obtain information on signs of toxicity that may occur with substances which are of low acute toxicity and are not classified on the basis of acute toxicity;

(c) If facts show that for the purposes of classification it is inadvisable to use the reference values given in paragraphs (a) and (b) because the substances produce other effects, the substances shall be classified according to the magnitude of these effects.

SCHEDULE 2

Regulations 4,6(1) and (2) and 7

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

PART A

information required for the technical dossier for a full notification under regulation 4(1)

Tests under this Part shall be according to methods recognised 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 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 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 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**
1.3	**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	Chromatographic data (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 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 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 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 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
2.1.4	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 Communities 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 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	**Oxidising 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 inhalative 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 to the Directive should be carried out.
4.3.2	Screening for toxicity related to reproduction
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 inhibition test on algae
5.1.6	Bacteriological 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, — abiotic: 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.

PART B

information required for the technical dossier for a notification under regulation 6(1)

Tests under this Part shall be according to methods recognised 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 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 Communities and for which, for the purpose of notification, the notifier has been designated as the manufacturer's sole representative, the identities and 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**
1.3	**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	Chromatographic data (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 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(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 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 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 Communities 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
2.4	**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 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 treated 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.**

PART C

information required for the technical dossier for a notification under regulation 6(2)

Tests under this Part shall be according to methods recognised 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.

0.	IDENTITY OF MANUFACTURER AND THE NOTIFIER IF THESE ARE NOT THE SAME: 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 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**
1.3	**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	Chromatographic data (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 Communities 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
2.4	**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**
3.9	**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.

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
- composition variable with Mn approximately constant for copolymers or
- for $M_n > 1000$, M_n 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 M_n- or composition-range, additional testing of other representative members shall be required.

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:

- 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)

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)
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 (Mn).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 witha 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
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 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
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**
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)
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 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
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**

SCHEDULE 3 Regulation 5

(This Schedule sets out the provisions of Annex VIII to the Directive)
ADDITIONAL INFORMATION AND TESTS REQUIRED UNDER REGULATION 5

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 indicated.

LEVEL 1

Physico-chemical studies

Further studies on physico-chemical properties are dependent upon the results of the studies laid down in Annex VII. Such further studies could include for example the development of analytical methods which make it possible to observe and detect a substance or its transformation products and studies on thermal decomposition products.

Toxicological studies

Fertility studies (one species, one generation, male and female, most appropriate route of administration).

If there are equivocal findings in the first generation, study of a second generation is required.

Depending upon the dosing schedule it may be possible in this study to obtain an indication of teratogenicity. A positive indication should be examined in a formal teratology study.

- Teratology study (one species, most appropriate route of administration).
- This study is required if teratogenicity has not been examined in the fertility study.
- Sub-chronic and/or chronic toxicity study, including special studies (one species, male and female, most appropriate route of administration) shall be required if the results of the repeated-dose study in Annex VII or other relevant information demonstrate the need for further appropriate investigation.
- The effects which would indicate the need for such a study could include for example:
  - (a) serious or irreversible lesions;
  - (b) a very low or absence of a “no effect” level;
  - (c) a clear relationship in chemical structure between the substance being studied and other substances which have been proved dangerous.

— Additional mutagenesis studies and/or screening study(ies) for carcinogenesis as prescribed in the testing strategy described in Annex V.When both tests in the base set are negative, further tests shall be conducted according to the specific properties and the proposed use of the substance.

— When a test or both tests were positive in the base set, a supplementary should include the same or different end points in other in vivo test methods.

— Basic toxicokinetic information.

Ecotoxicity studies

— Prolonged toxicity study with Daphnia magna (21 days).

— Tests on higher plants.

— Tests on earthworms.

— Further toxicity studies with fish.

— Tests for species accumulation: one species, preferably fish.

— Supplementary degradation study(ies), if sufficient degradation has not been proved by the studies laid down in Annex VII.

— Further studies on absorption/desorption dependent upon the results of the investigations laid down in Annex VII.

LEVEL 2

Toxicological studies

The test programme shall cover the following aspects unless there are strong reasons to the contrary, supported by evidence, that it should not be followed:

— Chronic toxicity study.

— Carcinogenicity study.

— Fertility study (e. g. three-generation study): only if an effect on fertility has been established at level 1.

— Developmental toxicity study on perinatal and postnatal effects.

— Teratology study (species not employed in the respective level 1).

— Additional toxicokinetic studies which cover biotransformation, pharmokinetics.

— Additional tests to investigate organ or system toxicity.

Ecotoxicological studies

— Additional tests for accumulation, degradation, mobility and absorption/desorption.

— Further toxicity studies with fish.

— Toxicity studies with birds.

— Additional toxicity studies with other organisms.

SCHEDULE 4

Regulation 24

FEES FOR NOTIFICATIONS ETC.

Column 1 *Subject matter*	Column 2 *Fee payable*
For the evaluation of a notification under regulation 4 ("base set") (see note 1)	£5500 (+£350 VAT)
For the evaluation of a notification under regulation 5(1)(a) (>10 tonnes per year)	£2000
For the evaluation of a notification under regulation 5(1)(b) (>100 tonnes per year)	£4200
For the evaluation of a notification under regulation 5(1)(c) (>1000 tonnes per year)	£3500
For a notification under regulation 6 (see note 2)	
(a) quantity of the new substance equal to or more than 100 kg (regulation 6(1))	£950 (+£87.50 VAT)
(b) quantity of the new substance up to 100 kg (regulation 6(2))	£800 (+£87.50 VAT)
For an application made by a notifier for an exemption relating to him under regulation 23	£2000
Note 1. Rebate where an adequate draft risk assessment is included	£2000 (and £350 VAT)
Note 2. Rebate where an adequate draft risk assessment is included	£500 (and £87.50 VAT)