APPENDIX 3

ANNEX VI TO DIRECTIVE 67/548/EEC

ANNEX V

(This Annex replaces the title and Part II of Annex VI to Council Directive 67/548/EEC, as last amended by Directive 79/831/EEC)

ANNEX VI

General classification and labelling requirements for dangerous substances and preparations

PART I

Save where otherwise provided in the separate Directives on dangerous preparations, the substances and preparations shall be classified as very toxic, toxic or harmful according to the following criteria:

(a) Classification as very toxic, toxic or harmful shall be effected by determining the acute toxicity of the commercial substance or preparation in animals, expressed in LD_{50} or LC_{50} values with the following parameters being taken as references values:

Category	LD_{50} absorbed orally in rat (mg/kg)	LD_{50} percutaneous absorption in rat or rabbit (mg/kg)	LC_{50} absorbed by inhalation in rat (mg/litre par 4 hours)
Very toxic	< 25	< 50	< 0,5
Toxic	25 – 200	50 – 400	0,5 – 2
Harmful	200 – 2 000	400 – 2 000	2 – 20

(b) If facts show that for the purposes of classification it is inadvisible to use the LD_{50} or LC_{50} values as a principal basis because the substances or preparations produce other effects, the substances or preparations shall be classified according to the magnitude of these effects.

PART II

Classification and labelling of dangerous substances and preparations; criteria for the choice of phrases indicating special risks (R-phrases) and safety advice (S-phrases)

CONTENTS

1. GENERAL INTRODUCTION

1.1. The object of classification is to identify all the toxicological, physico-chemical and ecotoxicological properties of substances and toxicological and physico-chemical properties of preparations which may constitute a risk during normal handling or use. Having identified any hazardous properties the substance or preparation must then be labelled to indicate the hazard(s) in order to protect the user, the general public and the environment.

1.2. This Annex sets out the general principles governing the classification and labelling of substances and preparations referred to in Article 3 (3) of Directive 67/548/EEC and in Article 3 (5) of Directive 88/379/EEC and other relevant Directives on dangerous preparations.

It is addressed to all those concerned (manufacturers, importers, national authorities) with methods of classifying and labelling dangerous substances and preparations.

1.3. The requirement of this Directive and of Directive 88/379/EEC are intended to provide a primary means by which the general public and persons at work are given essential information about dangerous substances and preparations. The label draws the attention of persons handling or using substances and preparations to the inherent danger of certain such materials.

The label may also serve to draw attention to more comprehensive product information on safety and use available in other forms.

1.4. The label takes account of all potential hazards which are likely to be faced in the normal handling and use of dangerous substances and preparations when in the form in which they are placed on the market, but not necessarily in any different form in which they may finally be used, e.g. diluted. The most severe hazards are highlighted by symbols, such hazards and those arising from other dangerous properties are specified in standard risk phrases, and safety phrases give advice on necessary precautions.

In the case of substances, the information is completed by the name of the substance under an internationally recognized chemical nomenclature, the preferred name being the one used in the European inventory of existing commercial chemical substances (Einecs), and the name and address of the person established in the Community who is responsible for placing the substance on the market.

In the case of preparations, the information is completed by the indication of the designation or the trade name of the preparation, the indication of the chemical name of the substances present in the preparation in accordance with Article 7 (1) (c) of Directive 88/379/EEC and the indication of the name, address and telephone number of the person established in the Community who is responsible for placing the preparation on the market.

1.5. With respect to substances referred to in the second subparagraph of Article 5 (2) of Directive 67/548/EEC, the labelling applied by the manufacturer or his representative remains valid until the substance is listed in Annex I or until a decision not to list it has been taken in accordance with the procedure laid down in Article 21.

1.6. For substances, the data required for classifiction and labelling may be obtained:

(a) as regards substances for which the information specified in Annex VII is required, most of the necessary data for classification and labelling appear in the 'base set'. This classification and labelling must be reviewed, if necessary, when further information is available (Annex VIII);

(b) as regards other substances (e.g. those referred to in Article 5 (2) of Directive 67/548/EEC), the data required for classification and labelling may if necessary be obtained from a number of different sources, for example the results of previous tests, information required by international rules on the transport of dangerous substances, information taken from reference works and the literature or information derived from practical experience.

For preparations, the data required for classification and labelling may be obtained:

(a) if it concerns physico-chemical data, by the application of the methods specified in Annex V to Directive 67/548/EEC. For gaseous preparations a calculation method may be used for flammable and oxidizing properties (see Chapter 9);

(b) — if it concerns data on health effects, by the application of the methods specified in Annex V to the Directive and/or by the application of the conventional method referred to in Article 3 (5) (a) to (i) of Directive 88/379/EEC,

— however if it concerns the evaluation of the carcinogenic, mutagenic and teratogenic properties, by the application of the conventional method referred to in Article 3 (5) (j) to (q) of Directive 88/379/EEC.

Note concerning the performance of animal tests

The performance of animal tests to establish experimental data is subject to the provisions of Directive 86/609/EEC regarding the protection of animals used for experimental purposes.

1.7. **Application of the guide criteria**

Several possibilities may occur according to whether it concerns substances or preparations. Classification must cover the toxicological and physico-chemical properties of substances and preparations and in addition, the ecotoxicological properties of substances. The object of choosing risk phrases is to ensure that the specific nature of the potential dangers identified in classification are expressed on the label. For this purpose it is necessary to consider the criteria given for the choice of symbol(s) and risk phrases in 2.2.1 to 2.2.6, 3.2.1 to 3.2.7 and Chapters 4 and 5 for substances only. For example, classification under 3.2.1 does not imply that the sections such as 3.2.2 or 3.2.4 can be ignored.

The criteria are applicable to gaseous substances and preparations but only in so far as they may be subject to the packaging and labelling provisions of this Directive or the separate Directive on preparations.

Notwithstanding the criteria given under 2.2.3, 2.2.4 and 2.2.5, substances and preparations in the form of aerosols shall be subject to the flammability criteria set out in 1.8 and 2.2 (c) of the Annex to Directive 75/324/EEC.

1.7.1. **Application of the guide criteria for substances**

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V. In other cases, the available data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling criteria.

Classification of substances containing impurities or additives which are classified as carcinogens

A substance containing an impurity or an additive which is classified as a carcinogen and labelled with R 45 must itself be classified as a carcinogen and labelled with R 45 if the concentration of the carcinogenic impurity or additive is equal to or exceeds:

— either the concentration of the impurity or the additive specified in Annex I, or

— the concentration of 0,1 % where the impurity or the additive appears in Annex I without a concentration limit. (However in the case of asbestos this general rule does not apply until a concentration limit has been fixed in Annex I. Substances which have asbestos impurities must be classified and labelled according to the principles in Article 5 (2)), or

— the concentration of 0,1 % where the impurity or the additive does not appear in Annex I.

NB: if a substance containing an impurity or additive which is classified as a carcinogen is used as part of a preparation, the preparation shall be classified as a carcinogen and labelled with R 45 only when the concentration of the carcinogenic impurity or additive equals or exceeds the limits shown above as a % weight of the impurity or additive in the preparation.

If the information regarding the carcinogenic impurity or additive on the label of the substance is insufficient to enable the manufacturer of a preparation to carry out the classification and labelling correctly, the person established within the Community responsible for placing the substance on the market, whether it be the manufacturer, the importer or the distributor, shall supply, upon justified request and if available, appropriate information about the impurity or additive responsible for the carcinogenic classification of the substance to enable the classification and labelling of the preparation.

1.7.2. Application of the guide criteria for preparations

The guidance criteria set out in this Annex are directly applicable when the data in question have been obtained from test methods comparable with those described in Annex V with the exception of the criteria of Chapter 4 for which only the conventional method is applicable. In other cases, the available data must be evaluated by comparing the test methods employed with those indicated in Annex V and the rules specified in this Annex for determining the appropriate classification and labelling criteria.

If the health hazards are assessed by applying the conventional method referred to in Article 3 (5) of Directive 88/379/EEC, the individual concentration limits to be used are those set out, either:

— in Annex I to Directive 67/548/EEC, or

— in Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to the Directive or appear in it without concentration limits.

In the case of preparations containing mixtures of gases, classification with respect to the health effects will be established by the calculation method on the basis of the individual concentration limits from Annex I to the Directive or, when these limits are not in Annex I, on the basis of the criteria of Annex I to Directive 88/379/EEC, as amended by Directive 90/462/EEC.

Preparations used as constituents of another preparation

The labelling of such preparations must be in conformity with the provisions of Article 7 according to the conditions foreseen in Article 3 of Directive 88/379/EEC. However, in certain cases, the information on the label of the preparation is insufficient to enable other manufacturers who wish to use it as a constituent of their own preparation(s) to carry out the classification and labelling of their preparation(s) correctly. In these cases, the person established within the Community responsible for placing the original preparation on the market, whether it be the manufacturer, the importer or the distributor, shall supply upon justified request and as soon as possible all necessary data concerning the dangerous substances present to enable correct classification and labelling of the new preparation. This data is also necessary to enable the person responsible for placing the new preparation on the market to comply with other requirements of Directive 88/379/EEC.

2. CLASSIFICATION ON THE BASIS OF PHYSICO-CHEMICAL PROPERTIES

2.1. Introduction

The test methods relating to explosive, oxidizing and flammable properties included in Annex V to this Directive serve to give specific meaning to the general definitions given in Article 2 (2) (a) to (e). Criteria follow directly from the test methods in Annex V as far as they are mentioned.

If adequate information is available to demonstrate in practice that the physico-chemical properties of substances and preparations (apart from organic peroxides) are different from those revealed by the test methods given in Annex V, then such substances and preparations should be classified according to the hazard they present, if any, to those handling the substances and preparations or to other persons.

2.2. Criteria for classification, choice of symbols, indication of danger and choice of risk phrases

In the case of preparations, the criteria referred to in Article 3 (2) of Directive 88/379/EEC need to be taken into consideration.

2.2.1. Explosive

Substances and preparations shall be classified as explosive and assigned the symbol 'E' and the indication of danger 'explosive' in accordance with the results of the tests given in Annex V and in so far as the substances and preparations are explosive as placed on the market. One risk phrase is obligatory, it is to be specified on the basis of the following:

R 2 Risk of explosion by shock, friction, fire or other sources of ignition

— Substances and preparations including certain organic peroxides but excepting those set out below.

R 3 Extreme risk of explosion by shock, friction, fire or other sources of ignition

— Substances and preparations which are particularly sensitive such as picric acid salts, PETN and certain undiluted organic peroxides such as dibenzoyl peroxide.

2.2.2. Oxidizing

Substances and preparations shall be classified as oxidizing and assigned the symbol 'O' and the indication of danger 'oxidizing' in accordance with the results of the tests given in Annex V. One risk phrase is obligatory, it is to be specified on the basis of the test results but subject to the following:

R 11 Highly flammable

— Organic peroxides which have flammable properties even when not in contact with other combustible material.

R 8 Contact with combustible material may cause fire

— Other oxidizing substances and preparations which may cause fire or enhance the risk of fire when in contact with combustible material.

R 9 Explosive when mixed with combustible material

— Other substances and preparations which become explosive when mixed with combustible materials, e.g. certain chlorates.

2.2.2.1. *Remarks concerning peroxides*

Organic peroxides are classified as dangerous on the basis of their structure (e.g. R-O-O-H; R_1-O-O-R_2). In general terms, organic peroxides shall be classified as oxidizing, and labelled as under 2.2.2, unless:

— tests carried out in accordance with the methods given in Annex V show the organic peroxide, in the form in which it is placed on the market, to have explosive properties, as under 2.2.1, or

— the organic peroxide is so diluted or phlegmatized to the point where it is no longer explosive, oxidizing or flammable.

2.2.3. Extremely flammable

Substances and preparations shall be classified as extremely flammable and assigned the symbol 'F+' and the indication of danger 'extremely flammable' in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the following criteria:

R 12 Extremely flammable

— Liquid substances and preparations which have a flash point lower than 0 °C and a boiling point (or in case of a boiling range the initial boiling point) lower than or equal to 35 °C.

2.2.4. Highly flammable

Substances and preparations shall be classified as highly flammable and assigned the symbol 'F' and the indication of danger 'highly flammable' in accordance with the results of the tests given in Annex V. Risk phrases shall be assigned in accordance with the following criteria:

R 17 Spontaneously flammable in air

— Substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy.

R 11 Highly flammable

— Solid substances and preparations 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.

— Liquid substances and preparations having a flash point below 21 °C but which are not extremely flammable.

R 12 Extremely flammable

— Gaseous substances and preparations which are flammable in air at normal pressure.

R 13 Extremely flammable liquefied gas

— Gaseous substances and preparations which are flammable in air at normal pressure when put on the market in liquefied form.

R 15 Contact with water liberates highly flammable gases

— Substances and preparations which, in contact with water or damp air, evolve highly flammable gases in dangerous quantities, at a minimum rate of one litre per kilogram per hour.

2.2.5. Flammable

Substances and preparations shall be classified as flammable in accordance with the results of the tests given in Annex V. The risk phrase shall be assigned in accordance with the criteria mentioned below.

R 10 Flammable

— Liquid substances and preparations having a flash point equal to or greater than 21 °C, and less than or equal to 55 °C.

However, in practice it has been shown that a preparation having a flash point equal to or greater than 21 °C and less than or equal to 55 °C need not be classified as flammable if the preparation could not in any way support combustion and only so long as there is no reason to fear risks to those handling these preparations or to other persons.

2.2.6. Other physico-chemical properties

Additional risk phrases shall be assigned to substances and preparations which have been classified by virtue of 2.2.1 to 2.2.5 above or by Chapters 3, 4 and 5 below, in accordance with the following criteria (based on experience obtained during compilation of Annex I):

R 1 Explosive when dry

For explosive substances and preparations put on the market in solution or in a wetted form; e.g. nitrocellulose with more than 12,6 % nitrogen.

R 4 Forms very sensitive explosive metallic compounds

For substances and preparations which may form sensitive explosive metallic derivatives, e.g. picric acid, styphnic acid.

R 5 Heating may cause an explosion

For thermally unstable substances and preparations not classified as explosive, e.g. perchloric acid > 50 %.

R 6 Explosive with or without contact with air

For substances and preparations which are unstable at ambient temperatures, e.g. acetylene.

R 7 May cause fire

For reactive substances and preparations: e.g. fluorine, sodium hydrosulphite.

R 14 Reacts violently with water

For substances and preparations which react violently with water, e.g. acetyl chloride, alkali metals, titanium tetrachloride.

R 16 Explosive when mixed with oxidizing substances

For substances and preparations which react explosively with an oxidizing agent, e.g. red phosphorus.

R 18 In use, may form flammable/explosive vapour-air mixture

For preparations not in themselves classified as flammable, which contain volatile components which are flammable in air.

R 19 May form explosive peroxides

For substances and preparations which may form explosive peroxides during storage, e.g. diethyl ether, 1,4-dioxan.

R 30 Can become highly flammable in use

For preparations not in themselves classified as flammable, which may become flammable due to the loss of non-flammable volatile components.

R 44 Risk of explosion if heated under confinement

For substances and preparations not in themselves classified as explosive in accordance with 2.2.1 above but which may nevertheless display explosive properties in practice if heated under sufficient confinement. For example, certain substances which would decompose explosively if heated in a steel drum do not show this effect if heated in less-strong containers.

For other additional risk phrases see 3.2.7.

3. CLASSIFICATION ON THE BASIS OF TOXICOLOGICAL PROPERTIES

3.1. Introduction

3.1.1. Classification is concerned with both the acute and long-term effects of these substances and preparations, whether resulting from a single instance of exposure or repeated or prolonged exposure.

If adequate evidence is available to demonstrate in practice that the toxic effect of substances and preparations on man is, or is likely to be different from that suggested by the experimental results obtained in animal tests or by the application of the conventional method referred to in Article 3 (5) of Directive 88/379/EEC, then such substances and preparations should be classified according to their toxicity in man. However, tests on man should be discouraged and should not normally be used to negate positive animal data.

3.1.2. The classification of substances must be made on the basis of the experimental data available in accordance with the following criteria which take into account the magnitude of these effects:

(a) for acute toxicity (lethal and irreversible effects after a single exposure), the parameters indicated in Part I A of Annex VI and under 3.2.1 to 3.2.3 are to be used;

(b) for sub-acute, sub-chronic or chronic toxicity, the criteria under 3.2.2 to 3.2.4 are to be used;

(c) for corrosive and irritant effects, the criteria under 3.2.5 and 3.2.6 are to be used;

(d) for sensitizing effects, the criteria under 3.2.3 to 3.2.6 are to be used;

(e) for specific effects on health (carcinogenic, mutagenic and teratogenic effects), the criteria in Chapter 4 are to be used.

3.1.3. For preparations, the classification relating to dangerous for health is carried out:

(a) on the basis of the conventional method referred to in Article 3 (5) of Directive 88/379/EEC in the absence of experimental data. In this case, the classification is based on the individual concentration limits:

— either taken from Annex I to Directive 67/548/EEC,

— or from Annex I to Directive 88/379/EEC where the substance or substances do not appear in Annex I to Directive 67/548/EEC or appear in it without concentration limits;

(b) or when experimental data are available, according to the criteria described under 3.1.2. excluding the carcinogenic, mutagenic and teratogenic properties referred to under 3.1.2 (e) which must be evaluated by the conventional method referred to in Article 3 (5 (j) to (q) of Directive 88/379/EEC.

Whichever method is used for the evaluation of the danger of a preparation, all the dangerous effects on health as defined in Annex I to Directive 88/379/EEC must be taken into consideration.

3.1.4. When the classification is to be established from experimental results obtained in animal tests the results should have validity for man in that the tests reflect, in an appropriate way, the risks to man.

3.2. Criteria for classification, choice of symbols, indication of danger, choice of risk phrases

3.2.1. Very toxic

Substances and preparations shall be classified as very toxic and assigned the symbol 'T+' and the indication of danger 'very toxic' in accordance with the criteria given in Part I of Annex VI, as specified below.

Risk phrases shall be assigned in accordance with the following criteria:

R 28 Very toxic if swallowed

— Acute toxicity results

LD_{50} oral, rat: < 25 mg/kg

R 27 Very toxic in contact with skin

— Acute toxicity results

LD_{50} dermal, rat or rabbit: < 50 mg/kg

R 26 Very toxic by inhalation

— Acute toxicity results

LC_{50} inhalation, rat: < 0,5 mg/litre per 4 hours

R 39 (*) Danger of very serious irreversible effects

— Strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 3.1.2 and 3.1.3).

3.2.2. Toxic

Substances and preparations shall be classified as toxic and assigned the symbol 'T' and the indication of danger 'toxic' in accordance with the criteria given in Part I of Annex VI, as specified below. Risk phrases shall be assigned in accordance with the following criteria.

R 25 Toxic if swallowed

— Acute toxicity results

LD_{50} oral, rat: $25 < LD_{50} < 200$ mg/kg

R 24 Toxic in contact with skin

— Acute toxicity results

LD_{50} dermal, rat or rabbit: $50 < LD_{50} < 400$ mg/kg

R 23 Toxic by inhalation

— Acute toxicity results

LC_{50} inhalation, rat: $0,5 < LC_{50} < 2$ mg/litre per 4 hours

R 39 (*) Danger of very serious irreversible effects

— Strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 3.1.2 and 3.1.3).

R 48 (**) Danger of serious damage to health by prolonged exposure

— Serious damage (clear functional disturbance or morphological change which have toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route.

Substances are classified at least as toxic when these effects are observed at levels of one order of magnitude lower (i.e. ten-fold) than those set out for R 48 in 3.2.3.

(*) In order to indicate the route of administration/exposure the following combinations should be used: R 39/26, R 39/27, R 39/28, R 39/26/27, R 39/26/28, R 39/27/28, R 39/26/27/28.

(**) In order to indicate the route of administration/exposure one of the following combinations shall be used: R 39/23, R 39/24, R 39/25, R 39/23/24, R 39/23/25, R 39/24/25, R 39/23/24/25.

(**) In order to indicate route of administration/exposure one of the following combinations shall be used: R 48/23, R 48/24, R 48/25, R 48/23/24, R 48/23/25, R 48/24/25, R 48/23/24/25.

3.2.3. Harmful

Substances and preparations shall be classified as harmful and assigned the symbol 'Xn' and the indication of danger 'harmful' in accordance with the criteria given in Part I of Annex VI, as specified below. Risk phrases shall be assigned in accordance with the following criteria:

R 22 Harmful if swallowed

— Acute toxicity results
LD_{50} oral, rat: $200 < LD_{50} < 2\,000$ mg/kg

R 21 Harmful in contact with skin

— Acute toxicity results
LD_{50} dermal, rat or rabbit: $400 < LD_{50} < 2\,000$ mg/kg

R 20 Harmful by inhalation

— Acute toxicity results
LC_{50} inhalation, rat: $2 < LC_{50} < 20$ mg/litre per 4 hours

R 40 (*) Possible risk of irreversible effects

— Strong evidence that irreversible damage other than the effects referred to in Chapter 4 is likely to be caused by a single exposure by an appropriate route, generally in the abovementioned dose range (see also 3.1.2 and 3.1.3).

R 42 May cause sensitization by inhalation

— If practical evidence is available which shows the substances and preparations to be capable of inducing a sensitization reaction in humans by inhalation, at a greater frequency than would be expected from the response of a general population.

R 48 (*) Danger of serious damage to health by prolonged exposure

— Serious damage (clear functional disturbance or morphological change which has toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route.

Substances are classified at least as harmful when these effects are observed at levels of the order of:

— oral, rat < 50 mg/kg (bodyweight) per day,

— dermal, rat or rabbit < 100 mg/kg (bodyweight) per day,

— inhalation, rat < 0,25 mg/litre per 6 hours per day.

These guide values can apply directly when severe lesions have been observed in a sub-chronic (90 days) toxicity test. When interpreting the results of a sub-acute (28 days) toxicity test these figures should be increased approximately three fold. If a chronic (two years) toxicity test is available it should be evaluated on a case-by-case basis. If results of studies of more than one duration are available, then those from the study of the longest duration should normally be used.

3.2.4. Comments regarding the use of R 48

Use of this risk phrase refers to the specific range of biological effects within the terms described below. It should be noted that the terms are not identical to the definitions of harmful and toxic in Article 2 (2) (g) and (h) of Directive 67/548/EEC. For application of this risk phrase serious damage to health is to be considered to include death, clear functional disturbance or morphological changes which are toxicologically significant. It is particularly important when these changes are irreversible. It is also important to consider not only specific severe changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs, or severe changes in general health status.

When assessing whether there is evidence for these types of effects reference should be made to the following guidelines:

(*) In order to indicate route of administration/exposure one of the following combinations shall be used: R 40/20, R 40/21, R 40/22, R 40/20/21, R 40/20/22, R 40/21/22, R 40/20/21/22.
(*) In order to indicate route of administration/exposure one of the following combinations shall be used: R 48/20, R 48/21, R 48/22, R 48/20/21, R 48/20/22, R 48/21/22, R 48/20/21/22.

1. Evidence indicating that R 48 should be applied:

(a) Substance-related deaths

(b) (i) Major functional changes in the central or peripheral nervous systems, including sight, hearing and the sense of smell, assessed by clinical observations or other appropriate methods (e.g. electrophysiology).

(ii) Major functional changes in other organ systems (for example the lung).

(c) Any consistent changes in clinical biochemistry, haematology or urinalysis parameters which indicate severe organ dysfunction. Haematological disturbances are considered to be particularly important if the evidence suggests that they are due to decreased bone marrow production of blood cells.

(d) Severe organ damage noted on microscopic examination following autopsy.

(i) Widespread or severe necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity (e.g. liver).

(ii) Severe morphological changes that are potentially reversible but are clear evidence of marked organ dysfunction (e.g. severe fatty change in the liver, severe acute tubular nephrosis in the kidney, ulcerative gastritis).

(iii) Evidence of appreciable cell death in vital organs incapable of regeneration (e.g. fibrosis of the myocardium or dying back of a nerve) or in stem cell populations (e.g. aplasia or hypoplasia of the bone marrow).

The above evidence will most usually be obtained from animal experiments. When considering data derived from practical experience special attention should be given to exposure levels.

2. Evidence indicating that R 48 should not be applied.

The use of this risk phrase is restricted to 'serious damage to health by prolonged exposure'. A number of substance-related effects may be observed in both humans and animals that would not justify the use of R 48. These effects are relevant when attempting to determine a no-effect level for a chemical substance. Examples of well documented changes which would not normally justify classification with R 48, irrespective of their statistical significance, include:

(a) clinical observations or changes in bodyweight gain, food consumption or water intake, which may have some toxicological importance but which do not, by themselves, indicate 'serious damage';

(b) small changes in clinical biochemistry, haematology or urinalysis parameters which are of doubtful or minimal toxicological importance;

(c) changes in organ weights with no evidence of organ dysfunction;

(d) adaptative responses (e.g. macrophage migration in the lung, liver hypertrophy and enzyme induction, hyperplastic responses to irritants). Local effects on the skin produced by repeated dermal application of a substance whihc are more appropriately classified with R 38 'irritating to skin';

(e) where a species-specific mechanism of toxicity (e.g. specific metabolic pathways) has been demonstrated.

3.2.5. Corrosive

A substance or a preparation is considered to be corrosive if, when it is applied to healthy intact animal skin, it produces full thickness destruction of skin tissue on at least one animal during the test for skin irritation cited in Annex V or during an equivalent method or if the results can be predicted, for example from strongly acid or alkaline reactions. Classification can be based on the results of validated *in vitro* tests.

The substance or preparation shall be classified as corrosive and assigned the symbol 'C' and the indication of danger 'corrosive'. Risk phrases shall be assigned in accordance with the following criteria:

'R 35 Causes severe burns

— If, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to three minutes exposure, or if this result can be predicted.

R 34 Causes burns

— If, when applied to healthy intact animal skin, full thickness destruction of skin tissue occurs as a result of up to four hours exposure, or if this result can be predicted.

3.2.6. Irritant

Non-corrosive substances and preparations shall be classified as irritant and assigned the symbol 'Xi' and the indication of danger 'irritant' in accordance with the criteria given below.

1. Inflammation of the skin

Inflammation of the skin which persists for at least 24 hours after an exposure period of up to four hours and corresponds to the following values determined on the rabbit according to the cutaneous irritation test method cited in Annex V:

— the mean value of the scores for either erythema and eschar formation or oedema formation, calculated over all the animals tested, is two or more,

— or, in the case where the Annex V test has been completed using three animals, either erythema and eschar formation or oedema formation equivalent to a mean value of two or more calculated for each animal separately has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48 and 72 hours) for an effect should be used in calculating the respective mean values.

The following risk phrase shall be assigned in accordance with the criteria given:

R 38 Irritating to skin

— If, when applied to healthy intact animal skin for up to four hours, significant inflammation is caused and which persists for 24 hours or more after the end of the exposure period.

Inflammation is significant if the mean value of the scores is two or more for either erythema and eschar formation or oedema formation. The same shall be the case where the test has been completed using three animals if the score for either erythema and eschar formation or oedema formation observed in two or more animals is equivalent to the value of two or more.

2. Ocular lesion

Ocular lesions which occur within 72 hours after exposure and which persist for at least 24 hours and correspond to the following values determined on the rabbit according to the eye irritation test method cited in Annex V:

— the mean value of the scores for each type of lesion, calculated over all the animals tested, is one of the following:

  — cornea opacitytwo or more,

  — iris lesion one or more,

  — redness of conjunctivae 2,5 or more,

  — oedema of conjunctivae (chemosis) two or more, or

— in the case where the Annex V test has been completed using three animals, either cornea opacity, iris lesion, redness of conjunctivae or oedema of conjunctivae (chemosis) equivalent to a mean value such as is quoted above, but calculated for each animal separately, has been observed in two or more animals.

In both cases all scores at each of the reading times (24, 48, 72 hours) and for an effect should be used in calculating the respective mean values.

The following risk phrases shall also be assigned in accordance with the criteria given:

R 36 Irritating to eyes

— If, when applied to the eye of the animal, significant ocular lesions are caused and which persist for 24 hours or more after instillation of the test material.

Ocular lesions are significant if the means of the scores have any of the values: Cornea opacity equal to or greater than 2 but less than 3; iris lesion equal to or greater than 1 but not greater than 1,5; redness of the conjunctivae equal to or greater than 2,5; oedema of the conjunctivae (chemosis) equal to or greater than 2. The same shall be the case where the test has been completed using three animals if the lesions, on two or more animals, are equivalent to any of the above values except that for iris lesion the value should be equal to or greater than 1 but less than 2 and for redness of conjunctivae the value should be equal to or greater than 2,5.

R 41 (*) Risk of serious damage to eyes

— If when applied to the eye of the animal severe ocular lesions are caused and which are present 24 hours or more after instillation of the test material.

Ocular lesions are severe if the means of the scores have any of the values:

Cornea opacity equal to or greater than 3; iris lesion greater than 1.5. The same shall be the case where the test has been completed using three animals if these lesions, on two or more animals, have any of the values:

Cornea opacity equal to or greater than 3; iris lesion equal to 2.

R 43 May cause sensitization by skin contact

— If practical experience shows the substances and preparations to be capable of inducing a sensitization reaction in a substantial number of persons by skin contact, or on the basis of a positive response in experimental animals.

In the case of the adjuvent type test method for skin sensitization detailed in Annex V or in the case of other adjuvant-type test methods, a response of at least 30 % of the animals is considered positive. For any other test method a response of at least 15 % of the animals is considered positive.

R 37 Irritating to respiratory system

— Substances and preparations which cause serious irritation to the respiratory system, based normally on practical observation.

3.2.7. Other toxicological properties

Additional risk phrases shall be assigned to substances and preparations classified by virtue of 2.2.1 to 3.2.6 above and/or Chapters 4 and 5, in accordance with the following criteria (based on experience obtained during compilation of Annex I):

R 29 Contact with water liberates toxic gas

For substances and preparations which in contact with water or damp air, evolve very toxic/toxic gases in potentially dangerous amounts, e.g. aluminium phosphide, phosphorus pentasulphide.

R 31 Contact with acids liberates toxic gas

For substances and preparations which react with acids to evolve toxic gases in dangerous amounts, e.g. sodium hypochlorite, barium polysulphide. For substances used by members of the general public, the use of S 50 (do not mix with ..... (to be specified by the manufacturer)) would be more suitable.

R 32 Contact with acids liberates very toxic gas

For substances and preparations which react with acids to evolve very toxic gases in dangerous amounts; e.g. salts of hydrogen cyanide, sodium azide. For substances used by members of the general public, the use of S 50 (do not mix with ..... (to be specified by the manufacturer)) would be more suitable.

R 33 Danger of cumulative effects

For substances and preparations when accumulation in the human body is likely and may cause some concern which, however, is not sufficient to justify the use of R 48.

Previously assigned to substances of Annex I and preparations which were likely to cause damage to health by prolonged exposure or which were likely to be retained and then accumulated within the human body. Now to be progressively replaced when appropriate by R 48.

When substances labelled with R 33 are present in preparations, R 33 shall be included in the label at all concentrations where a label is required by the Directive on dangerous preparations.

For other risk phrases see 2.2.6.

(*) The of R 34 or R 35 precludes the use of R 41.

4. CLASSIFICATION ON THE BASIS OF SPECIFIC EFFECTS ON HUMAN HEALTH

4.1. Introduction

4.1.1. This chapter sets out the procedure for the classification of substances which may have the effects mentioned below.

4.1.2. If a manufacturer or his representative has information available which indicates that a substance should be classified and labelled in accordance with the criteria given in 4.2.1, 4.2.2 or 4.2.3, he or his representative shall provisionally label the substance in accordance with these criteria, unless the conclusions reached by the application of the criteria mentioned in 3.2.1 to 3.2.5 indicate the need for a more severe classification.

4.1.3. The manufacturer or his representative shall submit as soon as possible a document summarizing all relevant information to one Member State in which the substance is placed on the market. This summary document should include a bibliography containing all relevant references, including any relevant unpublished data.

4.1.4. Furthermore, a manufacturer or his representative who has new data which are relevant to the classification and labelling of a substance in accordance with the criteria given in 4.2.1, 4.2.2 or 4.2.3, shall submit this data as soon as possible to one Member State in which the substance is placed on the market.

4.1.5. In order to obtain as quickly as possible a harmonized classification for the Community by the procedure defined in Article 21 of Directive 67/548/EEC, Member States which have relevant information available justifying the classification of a substance in one of these categories, whether submitted by the manufacturer or not, should forward such information together with suggestions for classification and labelling, to the Commission as soon as possible.

The Commission will forward to the other Member States the classification and labelling proposal that it receives. Any Member State may ask the Commission for the information it has received.

Any Member State which has good reason to believe that the suggested classification and labelling is inappropriate as far as the carcinogenic, mutagenic or teratogenic effects are concerned shall notify the Commission thereof.

4.1.6. The provisional labelling applied by a manufacturer or his representative shall remain valid until the entry into force of a decision on the inclusion or non-inclusion of the substance concerned in Annex I.

4.2. Criteria for classification, indication of danger, choice of risk phrases

4.2.1. Carcinogenic substances

For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1

Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Category 2

Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

— appropriate long-term animal studies,

— other relevant information.

Category 3

Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in category 2.

4.2.1.1. The following symbols and specific risk phrases apply:

Categories 1 and 2:

T; R 45 may cause cancer

However for substances and preparations which present a carcinogenic risk only when inhaled, for example, as dust, vapour or fumes, (other routes of exposure e.g. by swallowing or in contact with skin do not present any carcinogenic risk), the following symbol and specific risk phrase should be used:

T; R 49 may cause cancer by inhalation

Category 3:

Xn; R 40 possible risk of irreversible effects

4.2.1.2. Comments regarding the categorization of carcinogenic substances

The placing of a substance into category 1 is done on the basis of epidemiological data; placing into categories 2 and 3 is based primarily on animal experiments.

For classification as a category 2 carcinogen either positive results in two animal species should be available or clear positive evidence in one species, together with supporting evidence such as genotoxicity data, metabolic or biochemical studies, induction of benign tumours, structural relationship with other known carcinogens, or data from epidemiological studies suggesting an association.

Category 3 actually comprises 2 sub-categories:

(a) substances which are well investigated but for which the evidence of a tumour-inducing effects is insufficient for classification in category 2. Additional experiments would not be expected to yield further relevant information with respect to classification,

(b) substances which are insufficiently investigated. The available data are inadequate, but they raise concern for man. This classification is provisional; further experiments are necessary before a final decision can be made.

For a distinction between categories 2 and 3 the arguments listed below are relevant which reduce the significance of experimental tumour induction in view of possible human exposure. These arguments, especially in combination, would lead in most cases to classification in category 3, even though tumours have been induced in animals:

— carcinogenic effects only at very high dose levels exceeding the 'maximal tolerated dose'. The maximal tolerated dose is characterized by toxic effects which, although not yet reducing lifespan, go along with physical changes such as about 10 % retardation in weight gain,

— appearance of tumours, especially at high dose levels, only in particular organs of certain species known to be susceptible to a high spontaneous tumour formation,

— appearance of tumours, only at the site of application, in very sensitive test systems (e.g., i.p. or s.c. application of certain locally active compounds), if the particular target is not relevant to man,

— lack of genotoxicity in short-term tests *in vivo* and *in vitro*,

— existence of a secondary mechanism of action with the implication of a practical threshold above a certain dose level (e.g. hormonal effets on target organs or on mechanisms of physiological regulation, chronic stimulation of cell proliferation),

— existence of a species-specific mechanism of tumour formation (e.g. by specific metabolic pathways) irrelevant for man.

For a distinction between category 3 and no classification arguments are relevant which exclude a concern for man:

— a substance should not be classified in any of the categories if the mechanism of experimental tumour formation is clearly identified, with good evidence that this process cannot be extrapolated to man,

— if the only available tumour data are liver tumours in certain sensitive strains of mice, without any other supplementary evidence, the substance may not be classified in any of the categories,

— particular attention should be paid to cases where the only available tumour data are the occurrence of neoplasms at sites and in strains where they are well known to occur spontaneously with a high incidence.

4.2.2. Mutagenic substances

4.2.2.1. For the purposes of classification and labelling, and having regard to the current state of knowledge, such substances are divided into three categories:

Category 1:

Substances known to be mutagenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

Category 2:

Substances which should be regarded as if they are mutagenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:

— appropriate animal studies,

— other relevant information.

Category 3:

Substances which cause concern for man owing to possible mutagenic effects. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in category 2.

4.2.2.2. The following symbols and specific risk phrases apply:

Category 1:

T; R 46 may cause heritable genetic damage

Category 2:

Xn; R 46 may cause heritable genetic damage

Category 3:

Xn; R 40 possible risk of irreversible effects

4.2.2.3. Comments regarding the categorization of mutagenic substances

Definition of terms:

A mutation is a permanent change in the amount or structure of the genetic material in an organism, resulting in a change of the phenotypic characteristics of the organism. The alterations may involve a single gene, a block of genes, or a whole chromosome. Effects involving single genes may be a consequence of effects on single DNA bases (point mutations) or of large changes, including deletions, within the gene. Effects on whole chromosomes may involve structural or numerical changes. A mutation in the germ cells in sexually reproducing organisms may be transmitted to the offspring. A mutagen is an agent that gives rise to an enhanced occurrence of mutations.

It should be noted that substances are classified as mutagens with specific reference to inherited genetic damage. However, the type of results leading to classification of chemicals in category 3: 'induction of genetically relevant events in somatic cells', is generally also regarded as an alert for possible carcinogenic activity.

Method development for mutagenicity testing is an ongoing process. For many new tests no standardized protocols and evaluation criteria are presently available. For the evaluation of mutagenicity data the quality of the test performance and the degree of validation of the test method have to be considered.

Category 1:

To place a substance in category 1, positive evidence from human mutation epidemiology studies will be needed. Examples of such substances are not known to date. It is recognized that it is extremely difficult to obtain reliable information from studies on the incidence of mutations in human populations, or on possible increases in their frequencies.

Category 2:

To place a substance in category 2, positive results are needed from assays showing (a) mutagenic effects, or (b) other cellular interactions relevant to mutagenicity, in germ cells of mammals *in vivo*, or (c) mutagenic effects in somatic cells of mammals *in vivo* in combination with clear evidence that the substance or a relevant metabolite reaches the germ cells.

With respect to placement in category 2, at present the following methods are appropriate:

2 (a) *In vivo* germ cell mutagenicity assays:
- — specific locus mutation test,
- — heritable translocation test,
- — dominant lethal mutation test.

These assays actually demonstrate the appearance of affected progeny or a defect in the developing embryo.

2 (b) *In vivo* assays showing relevant interaction with germ cells (usually DNA):
- — assays for chromosomal abnormalities, as detected by cytogenetic analysis, including aneuploidy, caused by malsegregation of chromosomes,
- — test for sister chromatid exchanges (SCE's),
- — test for unscheduled DNA synthesis (UDS),
- — assay of (covalent) binding of mutagen to germ cell DNA,
- — assaying other kinds of DNA damage.

These assays provide evidence of a more or less indirect nature. Positive results in these assays would normally be supported by positive results from *in vivo* somatic cell mutagenicity assays, in mammals or in man (see under category 3, preferably methods as under 3 (a)).

2 (c) *In vivo* assays showing mutagenic effects in somatic cells of mammals (see under 3 (a)), in combination with toxicokinetic methods, or other methodologies capable of demonstrating that the compound or a relevant metabolite reaches the germ cells.

For 2 (b) and 2 (c), positive results from host-mediated assays or the demonstration of unequivocal effects in *in vitro* assays can be considered as supporting evidence.

Category 3

To place a substance in category 3, positive results are needed in assays showing (a) mutagenic effects or (b) other cellular interaction relevant to mutagenicity, in somatic cells in mammals *in vivo*. The latter especially would normally be supported by positive results from *in vitro* mutagenicity assays.

For effects in somatic cells *in vivo* at present the following methods are appropriate:

3 (a) *In vivo* somatic cell mutagenicity assays:
- — bone marrow micronucleus test or metaphase analysis,
- — metaphase analysis of peripheral lymphocytes,
- — mouse coat colour spot test.

3 (b) *In vivo* somatic cell DNA interaction assays:
- — test for SCE's in somatic cells,
- — test for UDS in somatic cells,
- — assay for the (covalent) binding of mutagen to somatic cell DNA,
- — assay for DNA damage, e.g. by alkaline elution, in somatic cells.

Substances showing positive results only in one or more *in vitro* mutagenicity assays should normally not be classified. Their further investigation using *in vivo* assays, however, is strongly indicated. In exceptional cases, e.g. for a substance showing pronounced responses in several *in vitro* assays, for which no relevant *in vivo* data are available, and which shows resemblance to known mutagens/carcinogens, classification in category 3 could be considered.

4.2.3. Teratogenic substances

4.2.3.1. For the purpose of classification and labelling, and having regard to the current state of knowledge, such substances are divided into two categories:

Category 1

Substances known to be teratogenic to man.

There is sufficient evidence to establish a causal association between human exposure to a substance and subsequent non-heritable birth defects in offspring.

Category 2

Substances which should be regarded as if they are teratogenic to man.

There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in non-heritable birth defects in offspring, generally on the basis of:

— appropriate animal studies,

— other relevant information.

4.2.3.2. The following symbols and specific risk phrases apply:

Category 1

T; R 47 may cause birth defects

Category 2

Xn; R 47 may cause birth defects

4.2.4. Procedure for the classification of preparations concerning specific effects on health

If a preparation contains one or more substances classified with respect to the criteria laid out above, it must be classified according to the criteria referred to in Article 3 (5) (j) to (q) of Directive 88/379/EEC (the limits of concentration are either in Annex I to this Directive, or in Annex I to Directive 88/379/EEC where the substance or substances under consideration do not appear in Annex I or appear in it without concentration limits).

5. CLASSIFICATION ON THE BASIS OF ENVIRONMENTAL EFFECTS

5.1. Introduction

The primary objective of classifying substances dangerous for the environment is to alert the user to the hazards these substances present to ecosystems. Although the present criteria refer to aquatic ecosystems it is recognized that certain substances may simultaneously or alternatively affect other ecosystems whose constituents may range from soil microflora and microfauna to primates.

The criteria set out below follow directly from the test methods set out in Annex V, in so far as they are mentioned. The test methods required for the 'base set' referred to in Annex VII are limited and the information derived from them may be insufficient for an appropriate classification. Classification may require additional data derived from level 1 (Annex VIII) or other equivalent studies. Furthermore, classified substances may be subject to review in the light of other new data.

For the purposes of classification and labelling and having regard to the current state of knowledge such substances are divided into two groups according to their acute and/or long-term effects in aquatic systems or their acute and/or long-term effects in non-aquatic systems. In addition those substances classified according to the criteria set out under 5.2.1.1. and 5.2.2 will be assigned the symbol 'N' and the appropriate indication of danger after the pertinent amendment to Directive 67/548/EEC enters into force.

5.2. **Criteria for classification, indication of danger, choice of risk phrases**

5.2.1. Aquatic environment

5.2.1.1. Substances shall be classified as dangerous for the environment (*) and assigned risk phrases in accordance with the following criteria:

R 50 Very toxic to aquatic organisms
and
R 53 May cause long-term adverse effects in the aquatic environment

Acute toxicity:		96 hr LC_{50} (for fish)	< 1 mg/litre
	or	48 hr EC_{50} (for Daphnia)	< 1 mg/litre
	or	72 hr IC_{50} (**) (for algae)	< 1 mg/litre
	and	the substance is not readily degradable (***)	
	or	the log Pow (log octanol/water partition coefficient) > 3,0 (unless the experimentally determined BCF < 100)	

R 50 Very toxic to aquatic organisms

Acute toxicity:		96 hr LC_{50} (for fish)	< 1 mg/litre
	or	48 hr EC_{50} (for Daphnia)	< 1 mg/litre
	or	72 hr IC_{50} (**) (for algae)	< 1 mg/litre

R 51 Toxic to aquatic organisms
and
R 53 May cause long-term adverse effects in the aquatic environment

acute toxicity:		96 hr LC_{50} (for fish)	1 mg/litre	< LC_{50}	< 10 mg/litre
	or	48 hr EC_{50} (for Daphnia)	1 mg/litre	< EC_{50}	< 10 mg/litre
	or	72 hr IC_{50} (**) (for algae)	1 mg/litre	< IC_{50}	< 10 mg/litre
	and	the substance is not readily degradable (***)			
	or	the log Pow > 3.0 (unless the experimentally determined BCF < 100)			

5.2.1.2. Substances shall be classified as dangerous for the environment in accordance with the criteria set out below. Risk phrases shall also be assigned in accordance with the following criteria

R 52 Harmful to aquatic organisms
and
R 53 May cause long-term adverse effects in the aquatic environment

acute toxicity:		96 hr LC_{50} (for fish):	10 mg/litre	< LC_{50}	< 100 mg/litre
	or	48 hr EC_{50} (for Daphnia):	10 mg/litre	< EC_{50}	< 100 mg/litre
	or	72 hr IC_{50} (**) (for algae):	10 mg/litre	< IC_{50}	< 100 mg/litre
	and	the substance is not readily degradable (***). This criterion applies unless there exists additional scientific evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance nor its degradation products will consitute a potential long-term and/or delayed danger to the aquatic environment.			

(*) After the pertinent amendment to Directive 67/548/EEC enters into force, the symbol 'N' and the appropriate indication of danger will be assigned to these substances.

(**) Where it can be demonstrated in the case of highly coloured substances that algal growth is inhibited solely as a result of a reduction in light intensity, then the 72 h IC_{50} for algae should not be used as a basis for classification.

(***) Substances are considered readily degradable if the following criteria hold true:

(A) If in 28-day biodegradation studies the following levels of degradation are achieved:
— in tests based upon dissolved organic carbon: 70 %,
— in tests based upon oxygen depletion or carbon dioxide generation: 60 % of the theoretical maxima.
These levels of biodegradation must be achieved within 10 days of the start of degradation, which point is taken as the time when 10 % of the substance has been degraded.

OR

(B) If in those cases where only COD and BOD_5 data are available when the ration BOD_5/COD is greater than or equal to 0,5.

OR

(C) If other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of > 70 % within a 28-day period.

Such additional scientific evidence should normally be based on the studies required at level 1 (Annex VIII), or studies of equivalent value, and could include:

(i) a proven potential to degrade rapidly in the aquatic environment;

(ii) an absence of chronic toxicity effects at a concentration of 1,0 mg/litre, e.g. a no-observed effect concentration or greater than 1,0 mg/litre determined in a prolonged toxicity study with fish or Daphnia.

At least one of the following phrases:

R 52 Harmful to aquatic organisms

R 53 May cause long-term adverse effects in the aquatic environment

Substances not falling under the criteria listed above in this chapter, but which on the basis of the available evidence concerning their toxicity, persistence, potential to accumulate and predicted, or observed, environmental fate and behaviour may nevertheless present a danger immediate or long-term and/or delayed, to the structure and/or functioning of aquatic ecosystems. Poorly water soluble substances i.e. substances with a solubility of less than 1 mg/litre will be covered by this criteria if:

(a) they are not readily degradable (*); and

(b) the log Pow > 3,0 (unless the experimentally determined BCF < 100).

This criterion applies unless there exists additional evidence concerning degradation and/or toxicity sufficient to provide an adequate assurance that neither the substance nor its degradation products will constitute a potential long-term and/or delayed danger to the aquatic environment.

Such additional scientific evidence should normally be based on the studies required at level 1 (Annex VIII), or studies of equivalent value, and could include:

(i) a proven potential to degrade rapidly in the aquatic environment;

(ii) an absence of chronic toxicity effects at the solubility limit, e.g. a no-observed effect concentration of greater than a solubility limit determined in a prolonged toxicity study with fish or Daphnia.

5.2.2. Non-aquatic environment

Substances shall be classified as dangerous for the environment (**) in accordance with the criteria set out below.

At least one of the following phrases shall be assigned in accordance with the following criteria:

R 54 Toxic to flora
R 55 Toxic to fauna
R 56 Toxic to soil organisms
R 57 Toxic to bees
R 58 May cause long-term adverse effects in the environment
R 59 Dangerous for the ozone layer

} (**)

Substances which on the basis of the available evidence concerning their toxicity, persistence, potential to accumulate and predicted or observed environmental fate and behaviour may present a danger, immediate or long-term and/or delayed, to the structure and/or functioning of natural ecosystems other than those covered under 5.2.1 above.

(*) Substances are considered readily degradable if the following criteria hold true:

(A) If in 28-day biodegradation studies the following levels of degradation are achieved:

— in tests based upon dissolved organic carbon: 70 %,

— in tests based upon oxygen depletion or carbon dioxide generation: 60 % of the theoretical maxima.

These levels of biodegradation must be achieved within 10 days of the start of degradation, which point is taken as the time when 10 % of the substance has been degraded.

OR

(B) If in those cases where only COD and BOD_5 data are available when the ration BOD_5/COD is greater than or equal to 0,5.

OR

(C) If other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and/or abiotically) in the aquatic environment to a level of > 70 % within a 28-day period.

(**) After the pertinent amendment to Directive 67/548/EEC enters into force, the symbol 'N' and the appropriate indication of danger will be assigned to these substances.

(***) Detailed criteria, along with other risk phrases will be elaborated later.

6. CHOICE OF SAFETY ADVICE PHRASES

6.1. Safety phrases for substances and preparations

Safety advice phrases (S-phrases) shall be assigned to substances and preparations in accordance with the following general criteria. In addition, for certain preparations, safety advice is listed in Annex II to Directive 88/379/EEC. Whenever the manufacturer is mentioned in Chapter 6 it refers to the person responsible for placing the substance or preparation on the market.

S 1 *Keep locked up*

— Applicability :

— Very toxic and toxic substances and preparations.

— Criteria for use :

— Recommended for very toxic and toxic substances and preparations likely to be used by members of the general public.

S 2 *Keep out of reach of children*

— Applicability :

— All dangerous substances and preparations.

— Criteria for use :

— Obligatory only for all dangerous substances and preparations likely to be used by members of the general public or likely to be used in places to which the general public have access unless there is no reason to fear any danger particularly to children.

S 3 *Keep in a cool place*

— Applicability :

— Organic peroxides.

— Other dangerous substances and preparations having a boiling point < 40 °C.

— Criteria for use :

— Obligatory for organic peroxides unless S 47 is used.

— Recommended for other dangerous substances and preparations having a boiling point < 40 °C.

S 4 *Keep away from living quarters*

— Applicability :

— Very toxic and toxic substances and preparations.

— Criteria for use :

— Normally limited to very toxic and toxic substances and preparations when desirable to supplement S 13 ; for example when there is an inhalation risk and the substance or preparation should be stored away from living quarters. The advice is not intended to preclude proper use of the substance or preparation in living quarters.

S 5 *Keep contents under...* (appropriate liquid to be specified by the manufacturer)

— Applicability :

— Spontaneously flammable solid substances and preparations.

— Criteria for use :

— Normally limited to special cases, e.g. sodium, potassium or white phosphorous.

S 6 *Keep under...* (inert gas to be specified by the manufacturer)

— Applicability :

— Dangerous substances and preparations which must be kept under an inert atmosphere.

— Criteria for use :

— Normally limited to special cases, e.g. certain organo-metallic compounds.

S 7 *Keep container tightly closed*

— Applicability :

— Organic peroxides.

— Substances and preparations which can give off very toxic, toxic, harmful, extremely flammable or highly flammable vapours.

— Substances and preparations which in contact with moisture give off highly flammable gases.

— Highly flammable solids.

— Criteria for use :

— Obligatory for organic peroxides in the combination of S 3/7/9.

— Recommended for the other fields of application mentioned above.

S 8 *Keep container dry*

— Applicability :

— Substances and preparations which may react violently with water.

— Substances and preparations which on contact with water liberate highly flammable gases.

— Substances and preparations which on contact with water liberate very toxic or toxic gases.

— Criteria for use :

— Normally limited to the fields of application mentioned above when necessary to reinforce warnings given by R 14, R 15 in particular, and R 29.

S 9 *Keep container in a well-ventilated place*

— Applicability :

— Organic peroxides.

— Volatile substances and preparations which may give off very toxic, toxic or harmful vapours.

— Extremely flammable or highly flammable liquids and gases.

— Criteria for use :

— Obligatory for organic peroxides in the combination S 3/7/9.

— Recommended for volatile substances and preparations which may give off very toxic, toxic or harmful vapours.

— Recommended for extremely flammable or highly flammable liquids or gases.

S 12 *Do not keep the container sealed*

— Applicability :

— Substances and preparations which will by giving off gases or vapours be liable to burst the container.

— Criteria for use :

— Normally limited to the special cases mentioned above.

S 13 *Keep away from food, drink and animal feedingstuffs*

— Applicability :

— Very toxic, toxic and harmful substances and preparations.

— Criteria for use :

— Recommended when such substances and preparations are likely to be used by members of the general public.

S 14 *Keep away from ...* (incompatible materials to be indicated by the manufacturer)

— Applicability :

— Organic peroxides.

— Criteria for use :

— Obligatory for and normally limited to organic peroxides. However, may be useful in exceptional cases when incompatibility is likely to produce a particular risk.

S 15 *Keep away from heat*

— Applicability :

— Substances and preparations which may decompose or which may react spontaneously under the effect of heat.

— Criteria for use :

— Normally limited to special cases, e.g. monomers, but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.

S 16 *Keep away from sources of ignition — no smoking*

— Applicability :

— Extremely flammable or highly flammable liquids and gases.

— Criteria for use :

— Recommended for the substances and preparations mentioned above but not assigned if risk phrases R 2, R 3 and/or R 5 have already been applied.

S 17 *Keep away from combustible material*

— Applicability :

— Substances and preparations which may form explosive or spontaneously flammable mixtures with combustible material.

— Criteria for use :

— Available for use in special cases, e.g. to emphasize R 8 and R 9.

S 18 *Handle and open container with care*

— Applicability :

— Substances and preparations liable to produce an overpressure in the container.

— Substances and preparations which may form explosive peroxides.

— Criteria for use :

— Normally limited to the abovementioned cases when there is risk of damage to the eyes and/or when the substances and preparations are likely to be used by members of the general public.

S 20 *When using do not eat or drink*

— Applicability :

— Very toxic, toxic and corrosive substances and preparations.

— Criteria for use :

— Normally limited to special cases (e.g. arsenic and arsenic compounds ; fluoracetates) in particular when any of these are likely to be used by members of the general public.

S 21 *When using do not smoke*

— Applicability :

— Substances and preparations which produce toxic products on combustion.

— Criteria for use :

— Normally limited to special cases (e.g. halogenated compounds).

S 22 *Do not breathe dust*

— Applicability :

— All solid dangerous substances and preparations.

— Criteria for use :

— Recommended for those substances and preparations mentioned above which are liable to form inhalable dusts, and when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have been ascribed. However, may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 42.

S 23 *Do not breathe gas/fumes/vapour/spray* (appropriate wording to be specified by the manufacturer)

— Applicability :

— All liquid or gaseous dangerous substances and preparations.

— Criteria for use :

— Recommended when it is necessary to draw the attention of the user to inhalation risks not mentioned in the risk phrases which have to be ascribed. However, may be used in exceptional cases to emphasize such risk phrases, in particular to emphasize R 42.

— Recommended for substances and preparations in the form of aerosols which are likely to be used by members of the general public.

S 24 *Avoid contact with skin*

— Applicability :

— All dangerous substances and preparations.

— Criteria for use :

— Recommended when it is necessary to draw the attention of the user to skin contact risks not mentioned in the risk phrases which have to be ascribed. However, may be used to emphasize such risk phrases, in particular to emphasize R 43.

S 25 *Avoid contact with eyes*

— Applicability :

— Corrosive or irritant substances and preparations.

— Criteria for use :

— Normally limited to special cases, i.e. when it is considered essential to emphasize the risk to eyes denoted by use of R 34, R 35, R 36 or R 41. Thus important if these substances and preparations are likely to be used by members of the general public and eye or face protection may not be available.

S 26 *In case of contact with eyes, rinse immediately with plenty of water and seek medical advice*

— Applicability :

— Corrosive or irritant substances and preparations.

— Criteria for use :

— Obligatory for corrosive substances and preparations and those to which R 41 has already been ascribed.

— Recommended for irritant substances to which the risk phrase R 36 has already been ascribed.

S 27 *Take off immediately all contaminated clothing*

— Applicability:

— Organic peroxides.

— Very toxic, toxic or corrosive substances and preparations.

— Criteria for use:

— Obligatory for organic peroxides.

— Recommended for very toxic and toxic substances and preparations which are easily absorbed by the skin and for corrosive substances and preparations unless safety phrase S 36 can be considered sufficient by itself.

S 28 *After contact with skin, wash immediately with plenty of...* (to be specified by the manufacturer)

— Applicability:

— Very toxic, toxic or corrosive substances and preparations.

— Criteria for use:

— Recommended for the substances and preparations mentioned above, in particular when water is not the most appropriate rinsing fluid.

S 29 *Do not empty into drains*

— Applicability:

— Extremely or highly flammable liquids.

— Criteria for use:

— Recommended for those extremely or highly flammable liquids which are immiscible with water. The intention is to avoid accidents (e.g. fire explosion) and not to emphasize general pollution problems.

S 30 *Never add water to this product*

— Applicability:

— Substances and preparations which react violently with water.

— Criteria for use:

— Normally limited to special cases (e.g. sulphuric acid) and may be used, as appropriate, to give the clearest possible information, either to emphasize R 14 or as an alternative to R 14.

S 33 *Take precautionary measures against static discharges*

— Applicability:

— Extremely or highly flammable substances and preparations.

— Criteria for use:

— Recommended for substances and preparations used in industry which do not absorb moisture. Virtually never used for substances and preparations as placed on the market for use by members of the general public.

S 34 *Avoid shock and friction*

— Applicability:

— Explosive substances and preparations.

— Criteria for use:

— Obligatory for and normally limited to explosive organic peroxides.

S 35 *This material and its container must be disposed of in a safe way*

— Applicability :

— Explosive substances and preparations.

— Very toxic and toxic substances and preparations.

— Criteria for use :

— Obligatory for explosive substances and preparations other than organic peroxides.

— Recommended for very toxic and toxic substances and preparations, particularly when such substances and preparations are likely to be used by members of the general public.

S 36 *Wear suitable protective clothing*

— Applicability :

— Very toxic, toxic or harmful substances and preparations.

— Corrosive substances and preparations.

— Criteria for use :

— Recommended for substances and preparations used in industry which are :

— very toxic, toxic or corrosive, and/or

— harmful and easily absorbed by the skin, and/or

— liable to damage health by prolonged exposure.

S 37 *Wear suitable gloves*

— Applicability :

— Very toxic, toxic, harmful or corrosive substances and preparations.

— Organic peroxides.

— Substances and preparations irritating to the skin.

— Criteria for use :

— Recommended for very toxic, toxic and corrosive substances and preparations when S 36 is not used (e.g. viz general public).

— Recommended for organic peroxides as combination S 37/39.

— Recommended for substances and preparations irritating to the skin particularly when R 38 is not shown on the label.

S 38 *In case of insufficient ventilation wear suitable respiratory equipment*

— Applicability :

— Very toxic or toxic substances and preparations.

— Criteria for use :

— Normally limited to special cases involving the use of very toxic or toxic substances and preparations in industry or in agriculture.

S 39 *Wear eye/face protection*

— Applicability :

— Organic peroxides.

— Corrosive substances and preparations, including irritants which give rise to risk of serious damage to the eyes.

— Very toxic and toxic substances and preparations.

— Criteria for use :

— Recommended for organic peroxides as the combination S 37/39.

— Recommended for the corrosive substances and preparations mentioned above, in particular when there is a risk of splashing.

— Normally limited to exceptional cases for very toxic and toxic substances and preparations, where there is a risk of splashing and they are likely to be easily absorbed by the skin.

S 40 *To clean the floor and all objects contaminated by this material use...* (to be specified by the manufacturer)

— Applicability :

— All dangerous substances and preparations.

— Criteria for use :

— Normally limited to those dangerous substances and preparations for which water is not considered to be a suitable cleansing agent (e.g. where absorption by powdered material, dissolution by solvent etc. is necessary) and where it is important for health and/or safety reasons to provide a warning on the label.

S 41 *In case of fire and/or explosion do not breathe fumes*

— Applicability :

— Dangerous substances and preparations which on combustion give off very toxic or toxic gases.

— Criteria for use :

— Normally limited to special cases.

S 42 *During fumigation/spraying wear suitable respiratory equipment* (appropriate wording to be specified by the manufacturer)

— Applicability :

— Substances and preparations intended for such use but which may endanger the health and safety of the user unless proper precautions are taken.

— Criteria for use :

— Normally limited to special cases.

S 43 *In case of fire use...* (indicate in the space the precise type of fire-fighting equipment. If water increases the risk add : Never use water)

— Applicability :

— Extremely flammable, highly flammable and flammable substances and preparations.

— Criteria for use :

— Obligatory for substances and preparations which in contact with water or damp air, evolve highly flammable gases.

— Recommended for extremely flammable, highly flammable and flammable substances and preparations, particularly when they are immiscible with water.

S 44 *If you feel unwell seek medical advice* (show the label where possible)

— Applicability :

— Toxic substances and preparations.

— Criteria for use :

— Obligatory for the substances and preparations mentioned above when used in industry and not likely to be used by members of the general public.

S 45 *In case of accident or if you feel unwell seek medical advice immediately* (show the label where possible)

— Applicability :

— Very toxic substances and preparations.

— Toxic substances and preparations.

— Criteria for use :

— Obligatory for the very toxic substances and preparations mentioned above.

— Obligatory for toxic substances and preparations mentioned above when likely to be used by members of the general public.

S 46 *If swallowed, seek medical advice immediately and show this container or label*

— Applicability :

— All dangerous substances and preparations other than those which are toxic or very toxic.

— Criteria for use :

— Obligatory for all dangerous substances and preparations mentioned above which are likely to be used by members of the general public, unless there is no reason to fear any danger from swallowing, particularly by children.

S 47 *Keep at temperature not exceeding... °C* (to be specified by the manufacturer)

— Applicability :

— Substances and preparations which become unstable at a certain temperature.

— Criteria for use :

— Normally limited to special cases (e.g. certain organic peroxides).

S 48 *Keep wetted with...* (appropriate material to be specified by the manufacturer)

— Applicability :

— Substances and preparations which may become very sensitive to sparks, friction or impact if allowed to dry out.

— Criteria for use :

— Normally limited to special cases, e.g. nitrocelluloses.

S 49 *Keep only in the original container*

— Applicability :

— Substances and preparations sensitive to catalytic decomposition.

— Criteria for use :

— Substances and preparations sensitive to catalytic decomposition e.g. certain organic peroxides.

S 50 *Do not mix with...* (to be specified by the manufacturer)

— Applicability :

— Substances and preparations which may react with the specified product to evolve very toxic or toxic gases.

— Organic peroxides.

— Criteria for use :

— Recommended for substances and preparations mentioned above which are likely to be used by members of the general public, when it is a better alternative to R 31 or R 32.

— Obligatory with certain peroxides which may give violent reaction with accelerators or promoters.

S 51 *Use only in wellventilated areas*

— Applicability :

— Substances and preparations likely to or intended to produce vapours, dusts, sprays, fumes, mists, etc. which give rise to inhalation risks or to a fire or explosion risk.

— Criteria for use :

— Recommended when use of S 38 would not be appropriate. Thus important when such substances and preparations are likely to be used by members of the general public.

S 52 *Not recommended for interior use on large surface areas*

— Applicability :

— Volatile, very toxic, toxic and harmful substances and preparations containing them.

— Criteria for use :

— Recommended when damage to health is likely to be caused by prolonged exposure to these substances by reason of their volatilization from large treated surfaces in the home or other enclosed places where persons congregate.

S 53 *Avoid exposure — obtain special instructions before use*

— Applicability :

— Carcinogenic, mutagenic and/or teratogenic substances and preparations.

— Criteria for use :

— Obligatory for the abovementioned substances and preparations to which at least one of the following R—phrases have been assigned : R 45, R 46, R 47 or R 49.

6.2. Safety phrases assigned to substances dangerous for the environment

The complexity of the environment and the variety of uses to which chemical substances are put are such that it is not possible to specify precisely the most appropriate safety phrases. Those assigning safety phrases should consider such supplementary information as may be provided with the substances and select phrases from the following :

S 54 *Obtain the consent of pollution control authorities before discharging to wastewater treatment plants*

— Applicability and criteria for use :

— Applies to substances which may affect the functioning of sewage treatment plant processes and sludge disposal.

— Recommended for substances which are very toxic, toxic or harmful to aquatic organisms or which may cause long-term adverse effects in the aquatic environment.

— Recommended when such substances are used in industry.

S 55 *Treat using the best available techniques before discharge into drains or the aquatic environment.*

— Applicability and criteria for use :

— Recommended for substances which are very toxic, toxic or harmful to aquatic organisms or substances which may cause long-term adverse effects for which treatment techniques are available.

— Recommended when such substances are used in industry.

S 56 *Do not discharge into drains or the environment, dispose to an authorised waste collection point*

— Applicability and criteria for use :

— Recommended for substances which are very toxic or toxic to aquatic organisms or which may cause long-term adverse effects in the aquatic environment.

S 57 *Use appropriate containment to avoid environmental contamination*

— Applicability and criteria for use :

— Recommended for substances which are very toxic or toxic to aquatic organisms and particularly for substances which may cause long-term adverse effects in the aquatic or non-aquatic environment.

— Substances toxic to flora, fauna, soil or other organisms.

— Recommended when such substances are used in industry.

S 58 *To be disposed of as hazardous waste*

— Applicability and criteria for use :

— Recommended for substances which are very toxic, toxic or harmful to aquatic organisms or substances which may cause long-term adverse effects in the non-aquatic or aquatic environment.

— Recommended for substances toxic to flora, fauna, bees or other organisms.

S 59 *Refer to manufacturer/supplier for information on recovery/recycling*

— Applicability and criteria for use :

— Obligatory for substances dangerous for the ozone layer.

— Recommended for substances which are toxic to flora, fauna, soil organisms, bees or substances which may cause long-term adverse effects in the environment.

S 60 *This material and/or its container must be disposed of as hazardous waste*

— Applicability and criteria for use :

— This phrase should be used in place of S 58 in cases where contaminated containers require disposal.

— Recommended for substances which are very toxic, toxic or harmful to aquatic organisms or substances which may cause long—term adverse effects in the non—aquatic or aquatic environment.

— Recommended for substances toxic to flora, fauna, bees or other organisms.

7. LABELLING

7.1. When a substance or preparation has been classified the appropriate label is determined with reference to the requirements of Article 16 of Directive 67/548/EEC (79/831/EEC) and Article 7 of Directive 88/379/EEC for substances and preparations respectively. This section explains how the label is determined and, in particular, gives guidance on how to choose the appropriate risk and safety phrases.

The label of a substance or a preparation should be derived from the total number of symbols, risk phrases and safety phrases assigned. It is based on :

(a) the determination of the categories of danger and indications of danger ;

(b) the determination and final choice of the phrases indicating particular risks (R-phrases) ;

(c) the determination and final choice of the phrases indicating safety advice (S-phrases) ;

(d) the final choice of the name or names which will appear on the label.

7.2. Choice of R-phrases

7.2.1. For substances, R-phrases will be selected according to the following criteria and priorities :

(a) in the case of health effects :

(i) R-phrases corresponding to the category of danger illustrated by a symbol — these phrases must appear on the label ;

(ii) R-phrases corresponding to other categories of danger which are not illustrated by a symbol by virtue of Article 16 (4) of Directive 67/548/EEC ;

(b) in the case of danger arising from physico-chemical properties :

— the criteria described under 7.2.1 (a) above are applicable, except that the risk phrases 'extremely flammable' or 'highly flammable' need not be indicated where they repeat the wording of the indication of danger used with a symbol ;

(c) in the case of danger for the environment :

— the R-phrases corresponding to the classification category dangerous for the environment
— these phrases must appear on the label.

7.2.2. For preparations, R-phrases will be selected according to the following criteria and priorities :

(a) in the case of dangers which give rise to health effects :

(i) R-phrases which correspond to the category of danger illustrated by a symbol. In certain cases the R-phrases must be adapted according to the tables of Annex I to Directive 88/379/EEC. More specifically, the R-phrases of the constituent(s) which are responsible for the assignment of the preparation to a danger category must appear on the label ;

(ii) R-phrases which correspond to the other categories of danger which have been attributed to the constituents but which are not illustrated by a symbol by virtue of Article 7 (d) of Directive 88/379/EEC ;

(b) in the case of dangers arising from physico-chemical properties :

— the criteria described under 7.2.2 (a) are applicable, except that the risk phrases 'extremely flammable' or 'highly flammable' need not be indicated where they repeat the wording of the indication of danger used with a symbol.

7.3. **Final choice of risk and safety phrases**

Although the final choice of the most appropriate risk and safety phrases is primarily governed by the need to give all necessary information, consideration should also be given to the clarity and impact of the label. With clarity in mind, the necessary information should be expressed in a minimum number of phrases.

7.3.1. Risk phrases

As a general rule, applying to substances and preparations, a maximum of four R-phrases shall suffice to describe the risk ; for this purpose the combined phrases listed in Annex III shall be regarded as single phrases. However, the standard phrases must cover all the principal hazards associated with the preparation.

However, where there is a need to identify environmental hazards additional R-phrases shall be added as required.

7.3.2. Safety phrases

The final choice of safety phrases must have regard to the risk phrases indicated on the label and to the intended use of the substance or preparation :

— safety phrases which give obvious advice in relation to risk phrases are generally omitted from the label unless used to give particular emphasis to a specific warning,

— certain safety phrases, e.g. S 2, have particular relevance to substances and preparations intended to be used by the public, other phrases have particular relevance to persons at work. Phrases should be chosen with the intended use in view,

— particular attention must be given, in the choice of safety phrases, to the foreseen conditions of use of certain substances and preparations, e.g. spraying or other aerosol effects,

— as a general rule, a maximum of four S-phrases shall suffice to formulate the most appropriate safety advice ; for this purpose the combined phrases listed in Annex IV shall be regarded as single phrases,

— in the case of danger to the environment a minimum of one and a maximum of four S-phrases should be used,

— some R-phrases become superfluous if a careful selection is made of S-phrases and vice-versa, S-phrases which obviously correspond to R-phrases will appear on the label only if it is intended to emphasize a specific warning.

7.4. **Chemical name(s) to be displayed on the label:**

(a) for substances:

the name is established according to an internationally recognized chemical nomenclature as defined in 1.4.

(b) for preparations:

the choice of the names to be displayed on the label follows the rules of Article 7 (1) (c) of Directive 88/379/EEC.

Note

In the case of concentrate preparations which are intended for the perfume industry:

— the person responsible for placing them on the market may identify merely the one sensitizing substance judged by him to be primarily responsible for the sensitization hazard;

— in the case of a natural substance, the chemical name may be of the type: 'essential oil of ...', 'extract of ...', rather than the name of the constituents of that essential oil.

7.5. **Note**

It is important to remember that Annex II of Directive 88/379/EEC has special provisions concerning the labelling of certain preparations.

8. SPECIAL CASES: SUBSTANCES

8.1. **Metals in massive form**

These substances are classified in Annex I to Directive 67/548/EEC or shall be classified in accordance with Article 5 (2) of Directive 67/548/EEC. However, some of these substances although classified in accordance with Article 2 of Directive 67/548/EEC do not present a danger to human health by inhalation, ingestion or contact with skin in the form in which they are placed on the market. Such substances do not require a label according to Article 16 of this Directive. However, all the information which should have appeared on the label shall be transmitted to the user by the person responsible for placing the metal on the market.

9. SPECIAL CASES: PREPARATIONS

9.1. *Gaseous preparations (gas mixtures)*

For gaseous preparations, consideration must be given to:

— the evaluation of the physico-chemical properties,

— the evaluation of health hazards.

9.1.1. Evaluation of physico-chemical properties

9.1.1.1. *Flammability*

The flammable properties of these preparations are determined in accordance with Article 3 (2) of Directive 88/379/EEC according to the methods specified in Part A of Annex V to Directive 67/548/EEC. These preparations will be classified according to the results of the tests carried out and with respect to the criteria of Annex V and to the criteria of the labelling guide. However, by derogation, in the case where gaseous preparations are produced to order in small amounts, the flammability of these gaseous mixtures can be evaluated by the following calculation method:

The expression of the gaseous mixture

$$A_1F_1 + \ldots + A_iF_i + \ldots A_nF_n + B_1I_1 + \ldots B_iI_i + \ldots B_pI_p$$

where: A_i and B_i are the molar fractions
F_i flammable gas
I_i inert gas
n number of inert gases
p number of inert gases

can be transformed in a form where all the Ii (inert gases) are expressed by a nitrogen equivalent using a coefficient Ki and where the equivalent content of inflammable gas A'_i is expressed as follows:

$$A'_i = A_i \times \left(\frac{100}{(A_i + K_iB_i)}\right)$$

By using the value of the maximum content of flammable gas which, in a mixture with nitrogen, gives a composition which is not flammable in air (Tci), the following expression can be obtained :

$$\sum_i A'_i/Tci < 1$$

The gas mixture is flammable if the value of the above expression is greater than one and the preparation is classified highly flammable ; furthermore, the phrase R 12 or R 13 will be assigned according to the case.

Coefficients of equivalency (Ki)

The values of the coefficients of equivalency Ki, between the inert gases and nitrogen and the values of the maximum contents of flammable gas (Tci) may be found in Tables 1 and 2 of the ISO Standard ISO/DIS 10156.

Maximum content of flammable gas (Tci)

The value of the maximum content of flammable gas (Tci) may be found in Table 2 of the ISO Standard ISO/DIS 10156. When a Tci value for a flammable gas does not appear in the above standard, the corresponding lower explosivity limit (LEL) will be used. If no LEL value exists, the value of Tci will be set at 1 % by volume.

Remarks

— The expression above can be used to allow an appropriate labelling of gaseous preparations, however, it should not be regarded as a method for replacing experimentation for the determination of technical safety parameters.

— Furthermore, this expression gives no information as to whether a mixture containing oxidizing gases can be prepared safely. When estimating flammability these oxidizing gases are not taken into account.

— The expression above will give reliable results only if the flammable gases do not influence each other as far as their flammability is concerned. This has to be considered, e.g. with halogenated hydrocarbons.

9.1.1.2. *Oxidizing properties*

Given the fact that Annex V to Directive 67/548/EEC does not contain a method to determine the oxidizing properties of gaseous mixtures, the evaluation of these properties must be realized according to the following estimation method.

The principle of the method is comparison of the oxidizing potential of gases in a mixture with that of the oxidizing potential of oxygen in air. The concentrations of gases in the mixture are expressed in % vol.

It is considered that the gas mixture is as oxidant as or more oxidant than air, if the following condition is verified :

$$\sum_i x_i C_i > 21$$

where : x_i is the concentration of gas i in % vol
C_i is the coefficient of oxygen equivalency

In this case, the preparation is classified as oxidizing and the phrase R 8 will be assigned.

Coefficients of equivalency between oxidizing gases and oxygen

The coefficients used in the calculation to determine the oxidizing capacity of certain gases in a mixture with respect to the oxidizing capacity of oxygen in air, listed under 5.2 in the ISO Standard ISO/DIS 10156, are the following.

O_2	1
N_2O	0,6

When no value for the C_i coefficient exists for a gas in the cited standard a value of 40 is attributed to this coefficient.

9.1.2. Evaluation of the health effects

This evaluation of the dangers of a preparation for health is made according to Article 3 (3).

When the evaluation of the health hazards is made according to the conventional method described in Article 3 (5) of Directive 88/379/EEC by reference to individual concentration limits, the individual concentration limits to be used are expressed in per cent by volume and appear:

— either in Annex I to Directive 67/548/EEC for the gas(es) considered,

— or in Annex I to Directive 88/379/EEC, Tables I A to VI A, when the gas(es) considered are not in Annex I, or appear there without concentration limits.

9.1.3. Labelling

For mobile gas holders the requirements concerning labelling are considered to be satisfied when they are in agreement with Article 8 (5) (b).

However, by way of derogation from Article 8 (1) and (2), for gas cylinders with a water capacity of less than or equal to 150 litres, the format and dimensions of the label can follow the prescriptions of the ISO Standard ISO/DP 7225. In this case, the label can bear the generic name or industrial/commercial name of the preparation provided that the dangerous component substances of the preparation are shown on the body of the gas cylinder in a clear and indelible way.

9.2. Alloys, preparations containing polymers, preparations containing elastomers

These preparations shall be classified according to the requirements of Article 3 and labelled according to the requirements of Article 7 of Directive 88/379/EEC.

However some of these preparations although classified in accordance with Article 3 (3) do not present a danger to human health by inhalation, ingestion or contact with skin in the form in which they are placed on the market. Such preparations do not require a label according to Article 7; however all the information which would have appeared on the label shall be transmitted to the professional user by means of an information system in a format foreseen in Article 10 of the abovementioned Directive.

COMMISSION STATEMENT

With regard to 4.1.5, and in particular to the last paragraph of 4.1.5, the Commission states that, should it envisage making use of the procedure of Article 21 of Directive 67/548/EEC, it is prepared to consult in advance appropriate experts designated by Members States and having special qualifications with respect to either carcinogenicity, mutagenicity or teratogenicity.

This consultation will take place in the framework of the normal consultation procedure with national experts and/or in the framework of existing committees. The same will be the case when substances already included in Annex I must be reclassified in respect of their carcinogenic, mutagenic or teratogenic effects.

ANNEX 4

TOXIC SUBSTANCES CONTROL ACT: PREMANUFACTURE NOTIFICATION

tion of records must be submitted. The reporting period will be specified by the letter or notice but in no case will such reporting period be less than 45 days from the date of the letter or the effective date of the notice.

(c) *How to report.* When required to report, firms must submit copies of records (preferably by certified mail) to: Document Processing Center (TS-790) Rm. L-100, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. ATTN: 8(c) Allegations.

(Approved by the Office of Management and Budget under control number 2070-0017)

[48 FR 38187, Aug. 22, 1983, as amended at 49 FR 23183, June 5, 1984; 52 FR 20084, May 29, 1987; 53 FR 12523, Apr. 15, 1988]

§ 717.19 Confidentiality.

(a) Any person submitting copies of records may assert a business confidentiality claim covering all or part of the submitted information. Any information covered by a claim will be disclosed by EPA only as provided in procedures set forth at Part 2 of this title.

(b) If no claim accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

(c) To asset a claim of confidentiality for information contained in a submitted record, the respondent must submit two copies of the document.

(1) One copy must be complete. In that copy, the respondent must indicate what information, if any, is claimed as confidential by marking the specific information on each page with a label such as "confidential", "proprietary", or "trade secret" and briefly state the basis of the claim.

(2) If some information is claimed as confidential, the respondent must submit a second copy of the record. The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 30 days from the date of receipt of notification to submit the required second copy. If the respondent fails to submit the second copy within the 30 days, EPA will place the first copy in the public file.

PART 720—PREMANUFACTURE NOTIFICATION

Subpart A—General Provisions

Sec.

Subpart B—Applicability

Subpart C—Notice Form

Subpart D—Disposition of Notices

Subpart E—Confidentiality and Public Access to Information

AUTHORITY: 15 U.S.C. 2604, 2607, and 2613.

SOURCE: 48 FR 21742, May 13, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 720.1 Scope.

This part establishes procedures for the reporting of new chemical substances by manufacturers and importers under section 5 of the Toxic Substances Control Act, 15 U.S.C. 2604. The rule defines the persons and chemical substances subject to the reporting requirements, prescribes the contents of section 5 notices, and establishes procedures for submitting notices. The rule also establishes EPA policy regarding claims of confidentiality for, and public disclosure of, various categories of information submitted in connection with section 5 notices.

(Approved by the Office of Management and Budget under control number 2070-0012)

§ 720.3 Definitions.

(a)(1) For the purposes of this part, the terms "cosmetic," "device," "drug," "food," and "food additive" have the meanings contained in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 *et seq.*, and the regulations issued under it. In addition, the term "food" includes poultry and poultry products, as defined in the Poultry Products Inspection Act, 21 U.S.C. 453 *et seq.;* meats and meat food products, as defined in the Federal Meat Inspection Act, 21 U.S.C. 60 *et seq.;* and eggs and egg products, as defined in the Egg Products Inspection Act, 21 U.S.C. 1033 *et seq.*

(2) The term "pesticide" has the meaning contained in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136 *et seq.* and the regulations issued under it.

(3) The terms "byproduct material," "source material," and "special nuclear material" have the meanings contained in the Atomic Energy Act of 1954, 42 U.S.C 2014 *et seq.* and the regulations issued under it.

(b) "Act" means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

(c) "Article" means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in § 720.36(g)(5), except that fluids and particles are not considered articles regardless of shape or design.

(d) "Byproduct" means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

(e) "Chemical substance" means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical, except that "chemical substance" does not include:

(1) Any mixture.

(2) Any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide.

(3) Tobacco or any tobacco product.

(4) Any source material, special nuclear material, or byproduct material.

(5) Any pistol, firearm, revolver, shells, or cartridges.

(6) Any food, food additive, drug, cosmetic, or device, when manufac-

tured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

(f) "Commerce" means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State, or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

(g) "Customs territory of the United States" means the 50 States, Puerto Rico, and the District of Columbia.

(h) "Director" means the Director of the EPA Office of Toxic Substances.

(i) "Distribute in commerce" means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after introduction into commerce.

(j) "EPA" means the U.S. Environmental Protection Agency.

(k) "Health and safety study" or "study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying data and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological, or other studies of a chemical substance or mixture, and any test performed under the Act. Chemical identity is always part of a health and safety study.

(1) Not only is information which arises as a result of a formal, disciplined study included, but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health or the environment would be included.

(2) Examples include:

(i) Long- and short-term tests of mutagenicity, carcinogenicity, or teratogenicity; data on behavioral disorders; dermatoxicity; pharmacological effects; mammalian absorption, distribution, metabolism, and excretion; cumulative, additive, and synergistic effects; acute, subchronic, and chronic effects; and structure/activity analyses.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: Acute toxicity tests, chronic toxicity tests, critical life stage tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of human and environmental exposure, including workplace exposure, and impacts of a particular chemical substance or mixture on the environment, including surveys, tests, and studies of: Biological, photochemical, and chemical degradation; air, water, and soil transport; biomagnification and bioconcentration; and chemical and physical properties, e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol/water partition coefficient, and water solubility.

(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.

(v) Any assessments of risk to health and the environment resulting from the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance.

(l) "Importer" means any person who imports a chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. "Importer" includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20; or

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR Part 144. (See "principal importer.")

(m) "Impurity" means a chemical substance which is unintentionally present with another chemical substance.

(n) "Intermediate" means any chemical substance that is consumed, in whole or in part, in chemical reactions used for the intentional manufacture of another chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rates of such chemical reactions.

(o) "Inventory" means the list of chemical substances manufactured or processed in the United States that EPA compiled and keeps current under section 8(b) of the Act.

(p) "Known to or reasonably ascertainable by" means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

(q) "Manufacture" means to produce or manufacture in the United States or import into the customs territory of the United States.

(r) "Manufacture or import for commercial purposes" means:

(1) To import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer or importer, and includes, among other things, "manufacture" of any amount of a chemical substance or mixture:

(i) For commercial distribution, including for test marketing.

(ii) For use by the manufacturer, including use for product research and development or as an intermediate.

(2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

(s) "Manufacture solely for export" means to manufacture or import for commercial purposes a chemical substance solely for export from the United States under the following restrictions on activities in the United States:

(1) Distribution in commerce is limited to purposes of export or processing solely for export as defined in § 721.3 of this chapter.

(2) The manufacturer or importer, and any person to whom the substance is distributed for purposes of export or processing solely for export (as defined in § 721.3 of this chapter), may not use the substance except in small quantities solely for research and development in accordance with § 720.36.

(t) "Manufacturer" means a person who imports, produces, or manufactures a chemical substance. A person who extracts a component chemical substance from a previously existing chemical substance or a complex combination of substances is a manufacturer of that component chemical substance. A person who contracts with a manufacturer to manufacture or produce a chemical substance is also a manufacturer if (1) the manufacturer manufactures or produces the substance exclusively for that person, and (2) that person specifies the identity of the substance and controls the total amount produced and the basic technology for the plant process.

(u) "Mixture" means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except "mixture" does include (1) any combination which occurs, in whole or in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

(v) "New chemical substance" means any chemical substance which is not included on the Inventory.

(w) "Nonisolated intermediate" means any intermediate that is not intentionally removed from the equipment in which it is manufactured, in-

cluding the reaction vessel in which it is manufactured, equipment which is ancillary to the reaction vessel, and any equipment through which the chemical substance passes during a continuous flow process, but not including tanks or other vessels in which the substance is stored after its manufacture.

(x) "Person" means any natural person, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency or instrumentality of the Federal Government.

(y) "Possession or control" means in possession or control of the submitter, or of any subsidiary, partnership in which the submitter is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the submitter in the research, development, test marketing, or commercial marketing of the chemical substance in question. (A parent company owns or controls another company if the parent owns or controls 50 percent or more of the other company's voting stock. A parent company owns or controls any partnership in which it is a general partner). Information is included within this definition if it is:

(1) In files maintained by submitter's employees who are:

(i) Associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

(ii) Reasonably likely to have such data.

(2) Maintained in the files of other agents of the submitter who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question in the course of their employment as such agents.

(z) "Principal importer" means the first importer who, knowing that a new chemical substance will be imported rather than manufactured domestically, specifies the identity of the chemical substance and the total amount to be imported. Only persons who are incorporated, licensed, or doing business in the United States may be principal importers.

(aa) "Process" means the preparation of a chemical substance or mixture, after its manufacture, for distribution in commerce (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

(bb) "Processor" means any person who processes a chemical substance or mixture.

(cc) "Small quantities solely for research and development" (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

(dd) "State" means any State of the United States and the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

(ee) "Technically qualified individual" means a person or persons (1) who, because of education, training, or experience, or a combination of these factors, is capable of understanding the health and environmental risks associated with the chemical substance which is used under his or her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or re-

quired within the scope of conducting a research and development activity.

(ff) "Test data" means data from a formal or informal test or experiment, including information concerning the objectives, experimental methods and materials, protocols, results, data analyses, recorded observations, monitoring data, measurements, and conclusions from a test or experiment.

(gg) "Test marketing" means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor, to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

(hh) "United States," when used in the geographic sense, means all of the States.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986]

Subpart B—Applicability

§ 720.22 Persons who must report.

(a)(1) Any person who intends to manufacture a new chemical substance in the United States for commercial purposes must submit a notice unless the substance is excluded under § 720.30.

(2) If a person contracts with a manufacturer to manufacture or produce a new chemical substance, and (i) the manufacturer manufactures or produces the substance exclusively for that person, and (ii) that person specifies the identity of the substance, and controls the total amount produced and the basic technology for the plant process, that person must submit the notice. If it is unclear who must report, EPA should be contacted to determine who must submit the notice.

(3) Only manufacturers that are incorporated, licensed, or doing business in the United States may submit a notice.

(b)(1) Any person who intends to import a new chemical substance into the United States for commercial purposes must submit a notice, unless the substance is excluded under § 720.30 or unless the substance is imported as part of an article.

(2) When several persons are involved in an import transaction, the notice must be submitted by the principal importer. If no one person fits the principal importer definition in a particular transaction, the importer should contact EPA to determine who must submit the notice for that transaction.

§ 720.25 Determining whether a chemical substance is on the Inventory.

(a) A new chemical substance is a chemical that is not on the Inventory.

(b)(1) A chemical substance is listed on the Inventory by specific chemical name if its identity is not confidential. If its identity is confidential, it is listed by specific name in the confidential portion of the Inventory. The confidential chemical substance is also listed on the public Inventory by a generic name which masks the specific identity. A person who intends to manufacture or import a chemical substance not listed on the Inventory by specific chemical name may ask EPA whether the substance is included on the confidential Inventory. EPA will answer such an inquiry only if EPA determines that the person has a *bona fide* intent to manufacture or import the chemical substance for commercial purposes.

(2) To establish a *bona fide* intent to manufacture or import a chemical substance, the person who proposes to manufacture or import the substance must submit to EPA:

(i) The specific chemical identity of the substance that the person intends to manufacture or import.

(ii) A signed statement that the person intends to manufacture or import that chemical substance for commercial purposes.

(iii) A description of the research and development activities conducted to date, and the purpose for which the person will manufacture or import the chemical substance.

(iv) An elemental analysis.

(v) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances),

or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the substance.

(3) If an importer cannot provide all the information required by paragraph (b)(2) of this section because it is claimed confidential business information by its foreign manufacturer or supplier, the foreign manufacturer or supplier may supply the information directly to EPA.

(4) EPA will review the information submitted by the proposed manufacturer or importer under this paragraph to determine whether it has a *bona fide* intent to manufacture or import the chemical substance. If necessary, EPA will compare this information either to the information requested for the confidential chemical substance under § 710.7(e)(2)(v) of this chapter or the information requested under § 720.85(b)(3)(iii).

(5) If the proposed manufacturer or importer has shown a *bona fide* intent to manufacture or import the substance, and provide sufficient unambiguous chemical identity information so EPA can make a conclusive determination of the chemical substance's Inventory status, EPA will search the confidential Inventory and inform the proposed manufacturer or importer whether the chemical substance is on the confidential Inventory.

(6) If the chemical substance is found on the confidential Inventory, EPA will notify the person(s) who originally reported the chemical substance that another person has demonstrated a *bona fide* intent to manufacture or import the substance and therefore was told that the chemical substance is on the Inventory.

(7) A disclosure of a confidential chemical identity to a person with a *bona fide* intent to manufacture or import the particular chemical substance will not be considered a public disclosure of confidential business information under section 14 of the Act.

(8) EPA will answer an inquiry on whether a particular chemical substance is on the confidential Inventory within 30 days after receipt of a complete submission under paragraph (b)(2) of this section.

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§ 720.30 Chemicals not subject to notification requirements.

The following substances are not subject to the notification requirements of this part:

(a) Any substance which is not a "chemical substance" as defined in § 720.3(e).

(b) Any mixture as defined in § 720.3(u).[1]

(c) Any new chemical substance which will be manufactured or imported in small quantities solely for research and development under § 720.36.

(d) Any new chemical substance which will be manufactured or imported solely for test-marketing purposes under an exemption granted under § 720.38.

(e) Any new chemical substance manufactured solely for export if, when the substance is distributed in commerce:

(1) The substance is labeled in accordance with section 12(a)(1)(B) of the Act.

(2) The manufacturer knows that the person to whom the substance is being distributed intends to export it or process it solely for export as defined in § 721.3 of this chapter.

(f) Any new chemical substance which is manufactured or imported under the terms of a rule promulgated under section 5(h)(4) of the Act.

(g) Any byproduct if its only commercial purpose is for use by public or private organizations that (1) burn it as a fuel, (2) dispose of it as a waste, including in a landfill or for enriching soil, or (3) extract component chemical substances from it for commercial purposes. (This exclusion only applies to the byproduct; it does not apply to

[1] A new chemical substance that is manufactured or imported as part of a mixture is subject to the requirements of this part. This exclusion applies only to a mixture as a whole and not to any chemical substances which are part of the mixture.

the component substances extracted from the byproduct.)

(h) The chemical substances described below: (Although they are manufactured for commercial purposes under the Act, they are not manufactured for distribution in commerce as chemical substances per se and have no commercial purpose separate from the substance, mixture, or article of which they are a part.)

(1) Any impurity.

(2) Any byproduct which is not used for commercial purposes.

(3) Any chemical substance which results from a chemical reaction that occurs incidental to exposure of another chemical substance, mixture, or article to environmental factors such as air, moisture, microbial organisms, or sunlight.

(4) Any chemical substance which results from a chemical reaction that occurs incidental to storage or disposal of another chemical substance, mixture, or article.

(5) Any chemical substance which results from a chemical reaction that occurs upon end use of another chemical substance, mixture, or article such as an adhesive, paint, miscellaneous cleanser or other housekeeping product, fuel additive, water softening and treatment agent, photographic film, battery, match, or safety flare, and which is not itself manufactured or imported for distribution in commerce or for use as an intermediate.

(6) Any chemical substance which results from a chemical reaction that occurs upon use of curable plastic or rubber molding compounds, inks, drying oils, metal finishing compounds, adhesives, or paints, or any other chemical substance formed during the manufacture of an article destined for the marketplace without further chemical change of the chemical substance except for those chemical changes that occur as described elsewhere in this paragraph.

(7) Any chemical substance which results from a chemical reaction that occurs when (i) a stabilizer, colorant, odorant, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, binder, emulsifier, deemulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutralizer, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intented, or (ii) a chemical substance, which is intended solely to impart a specific physiochemical characteristic, functions as intended.

(8) Any nonisolated intermediate.

(i) Any chemical substance which is manufactured solely for non-commercial research and development purposes. Non-commercial research and development purposes include scientific experimentation, research, or analysis conducted by academic, government, or independent not-for-profit research organizations (e.g., universities, colleges, teaching hospitals, and research institutes), unless the activity is for eventual commercial purposes.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15101, Apr. 22, 1986]

§ 720.36 Exemption for research and development.

(a) This part does not apply to a chemical substance if the following conditions are met:

(1) The chemical substance is manufactured or imported only in small quantities solely for research and development.

(2) The manufacturer or importer notifies all persons in its employ or to whom it directly distributes the chemical substance, who are engaged in experimentation, research, or analysis on the chemical substance, including the manufacture, processing, use, transport, storage, and disposal of the substance associated with research and development activities, of any risk to health, identified under paragraph (b) of this section, which may be associated with the substance. The notification must be made in accordance with paragraph (c) of this section.

(3) The chemical substance is used by, or directly under the supervision of, a technically qualified individual.

(b)(1) To determine whether notification under paragraph (a)(2) of this section is required, the manufacturer or importer must review and evaluate the following information to deter-

mine whether there is reason to believe there is any potential risk to health which may be associated with the chemical substance:

(i) Information in its possession or control concerning any significant adverse reaction by persons exposed to the chemical substance which may reasonably be associated with such exposure.

(ii) Information provided to the manufacturer or importer by a supplier or any other person concerning a health risk believed to be associated with the substance.

(iii) Health and environmental effects data in its possession or control concerning the substance.

(iv) Information on health effects which accompanies any EPA rule or order issued under sections 4, 5, or 6 of the Act that applies to the substance and of which the manufacturer or importer has knowledge.

(2) When the research and development activity is conducted solely in a laboratory and exposure to the chemical substance is controlled through the implementation of prudent laboratory practices for handling chemical substances of unknown toxicity, and any distribution, except for purposes of disposal, is to other such laboratories for further research and development activity, the information specified in paragraph (b)(1) of this section need not be reviewed and evaluated. (For purposes of this paragraph, a laboratory is a contained research facility where relatively small quantities of chemical substances are used on a non-production basis, and where activities involve the use of containers for reactions, transfers, and other handling of substances designed to be easily manipulated by a single individual.)

(c)(1) The manufacturer or importer must notify the persons identified in paragraph (a)(2) of this section by means of a container labeling system, conspicuous placement of notices in areas where exposure may occur, written notification to each person potentially exposed, or any other method of notification which adequately informs persons of health risks which the manufacturer or importer has reason to believe may be associated with the substance, as determined under paragraph (b)(1) of this section.

(2) If the manufacturer or importer distributes a chemical substance manufactured or imported under this section to persons not in its employ, the manufacturer or importer must in written form:

(i) Notify those persons that the substance is to be used only for research and development purposes.

(ii) Provide the notice of health risks specified in paragraph (c)(1) of this section.

(3) The adequacy of any notification under this section is the responsibility of the manufacturer or importer.

(d) A chemical substance is not exempt from reporting under this part if any amount of the substance, including as part of a mixture, is processed, distributed in commerce, or used, for any commercial purpose other than research and development, except where the chemical substance is processed, distributed in commerce, or used only as an impurity or as part of an article.

(e) Quantities of the chemical substance, or of mixtures or articles containing the chemical substance, remaining after completion of research and development activities may be:

(1) Disposed of as a waste in accordance with applicable Federal, state, and local regulations, or

(2) Used for the following commercial purposes:

(i) Burning it as a fuel.

(ii) Reacting or otherwise processing it to form other chemical substances for commercial purposes, including extracting component chemical substances.

(f) Quantities of research and development substances existing solely as impurities in a product or incorporated into an article, in accordance with paragraph (d) of this section, and quantities of research and development substances used solely for commercial purposes listed in paragraph (e) of this section, are not subject to the requirements of paragraphs (a), (b), and (c) of this section, once research and development activities have been completed.

(g) A person who manufactures or imports a chemical substance in small

quantities solely for research and development is not required to comply with the requirements of this section if the person's exclusive intention is to perform research and development activities solely for the purpose of determining whether the substance can be used as a pesticide.

[51 FR 15102, Apr. 22, 1986]

§ 720.38 Exemptions for test marketing.

(a) Any person may apply for an exemption to manufacture or import a new chemical substance for test marketing. EPA may grant the exemption if the person demonstrates that the chemical substance will not present an unreasonable risk to injury to health or the environment as a result of the test marketing.

(b) Persons applying for a test-marketing exemption should provide the following information:

(1) All existing data regarding health and environmental effects of the chemical substance, including physical/chemical properties or, in the absence of such data, a discussion of toxicity based on structure-activity relationships (SAR) and relevant data on chemical analogues.

(2) The maximum quantity of the chemical substance which the applicant will manufacture or import for test marketing.

(3) The maximum number of persons who may be provided the chemical substance during test marketing.

(4) The maximum number of persons who may be exposed to the chemical substance as a result of test marketing, including information regarding duration and route of such exposures.

(5) A description of the test-marketing activity, including its length and how it can be distinguished from full-scale commercial production and research and development.

(c) In accordance with section 5(h)(6) of the Act, after EPA receives an application for exemption under this section, the Agency will file with the Office of the Federal Register a notice containing a summary of the information provided in the application, to the extent it has not been claimed confidential.

(d) No later than 45 days after EPA receives an application, the Agency will either approve or deny the application. Thereafter, EPA will publish a notice in the FEDERAL REGISTER explaining the reasons for approval or denial.

(e) In approving an application for exemption, EPA may impose any restrictions necessary to ensure that the substance will not present an unreasonable risk of injury to health and the environment as a result of test marketing.

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Subpart C—Notice Form

§ 720.40 General.

(a) *Use of the notice form.* Each person who is required by Subpart B to submit a notice must complete, sign, and submit a notice containing the information in the form and manner set forth in EPA Form No. 7710-25 [2] under Appendix A of this part. Except as otherwise provided in Subpart C, each notice must be submitted with all referenced attachments. The information on the form and all attachments (unless the attachment appears in the open scientific literature) must be in English. All information submitted must be true and correct.

(b) *When to submit a notice.* Each person who is required to submit a notice must submit the notice at least 90 calendar days before manufacture or import of the new chemical substance for commercial purposes begins.

(c) *Where to submit a notice.* Each person who submits a notice must submit it to the address listed on the notice form.

(d) *General notice requirements.* Each person who submits a notice must provide the information described in § 720.45 and specified on the notice form, to the extent such information is known to or reasonably as-

[2] Copies may be obtained from: Industry Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

certainable by the submitter. In accordance with § 720.50, the notice must also include any test data in the submitter's possession or control and descriptions of other data which are known to or reasonably ascertainable by the submitter and which concern the health and environmental effects of the new chemical substance.

(e) *Agency or joint submissions.* (1) A manufacturer or importer may designate an agent to submit the notice. Both the manufacturer or importer and the agent must sign the certification on the form.

(2) A manufacturer or importer may authorize another person, (e.g., a foreign manufacturer or supplier, or a toll manufacturer) to report some of the information required in the notice to EPA on its behalf. If separate portions of a joint notice are not submitted together, the submitter should indicate which information will be supplied by another person and identify that person. The other person must submit the information on the appropriate part of the notice form. The manufacturer or importer and any other person supplying the information must sign the certification provided on their respective notice forms.

(3) If EPA receives a submission which does not include information required by this rule, which the submitter indicates that it has authorized another person to provide, the notice review period will not begin until EPA receives that information.

(f) *New information.* During the notice review period, if the submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the notice, the submitter must that information to the address listed on the notice form within ten days of receiving the new information, but no later than five days before the end of the notice review period. The new submission must clearly identify the submitter and the notice to which the new information is related. If the new information becomes available during the last five days of the notice review period, the submitter must immediately inform its EPA contract for that notice by telephone.

(g) *Chemical substances subject to a section 4 test rule.* (1) Except as provided in paragraph (g)(3) of this section, if (i) A person intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part, and (ii) The chemical substance is subject to a test rule promulgated under section 4 of the Act before the notice is submitted, section 5(b)(1) of the Act requires the person to submit the test data required by the testing rule with the notice. The person must submit the data in the form and manner specified in the test rule and in accordance with § 720.50. If the person does not submit the test data, the submission is incomplete and EPA will follow the procedures in § 720.65.

(2) If EPA has granted the submitter an exemption under section 4(c) of the Act from the requirement to conduct tests and submit data, the submitter may not submit a notice until EPA receives the test data.

(3) If EPA has granted the submitter an exemption under section 4(c) of the Act and if another person previously has submitted the test data to EPA, the exempted person may either submit the test data or provide the following information as part of the notice:

(i) The name, title, and address of the person who submitted the test data to EPA.

(ii) The date the test data were submitted to EPA.

(iii) A citation for the test rule.

(iv) A description of the exemption and a reference identifying it.

(h) *Chemical substances subject to a section 5(b)(4) rule.* (1) If a person (i) intends to manufacture or import a new chemical substance which is subject to the notification requirements of this part and which is subject to a rule issued under section 5(b)(4) of the Act; and (ii) is not required by a rule issued under section 4 of the Act to submit test data for the substance before the submission of a notice, the person must submit to EPA data described in paragraph (h)(2) of this section at the time the notice is submitted.

(2) Data submitted under paragraph (h)(1) of this section must be data

which the person submitting the notice believes show that the manufacture, processing, distribution in commerce, use and disposal of the substance, or any combination of such activities, will not present an unreasonable risk of injury to health or the environment.

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§ 720.45 Information that must be included in the notice form.

Each person who submits a notice must include the information specified in the notice form to the extent it is known to or reasonably ascertainable by the submitter. However, no person is required to include information which relates solely to exposure of human or ecological populations outside of the United States. The notice form requires the following information relating to the manufacture, processing, distribution in commerce, use, and disposal of the new chemical substance:

(a)(1) For substances whose composition can be represented by a definite structural diagram (Class 1 substances), the notice must provide the chemical name (preferably Chemical Abstracts Service (CAS) or International Union of Pure and Applied Chemistry (IUPAC) nomenclature), the molecular formula, CAS Registry Number (if available), and a structural diagram.

(2) For chemical substances that cannot be fully represented by a structural diagram (Class 2 substances), the notice must provide the chemical name, the CAS Registry Number (if available), and molecular formula. The notice must identify the immediate precursors and reactants by name and CAS Registry Number (if the number is available). The notice must include a partial or incomplete structural diagram if possible. Chemical names for such substances should be developed according to the guidelines in the TSCA Chemical Substance Inventory, Initial Inventory, Volume 1.

(3) For polymers, the notice must identify monomers and other reactants used in the manufacture of the polymer by chemical name and CAS Registry Number (if available). The notice must indicate the typical percent of each monomer and other reactant in the polymer (by weight percent of total polymer); the maximum residual of each monomer present in the polymer; and a partial or incomplete structural diagram, if possible. The notice must provide estimates of the minimum number-average molecular weight of the polymer and the amount of low weight species below 500 and below 1,000 molecular weight and describe how the estimates were obtained.

(b) The impurities anticipated to be present in the substance by name, CAS Registry number, and weight percent of the total substance.

(c) Known synonyms or trade names of the new chemical substance.

(d) A description of the byproducts resulting from the manufacture, processing, use, and disposal of the new chemical substance.

(e) The estimated maximum amount to be manufactured or imported during the first year of production and the estimated maximum amount to be manufactured or imported during any 12-month period during the first three years of production.

(f) A description of intended categories of use by function and application, the estimated percent of production volume devoted to each category of use, and the percent of the new substance in the formulation for each commercial or consumer use.

(g) For sites controlled by the submitter:

(1) The identity of sites where the new substance will be manufactured, processed, or used.

(2) A process description of each manufacture, processing, and use operation which includes a diagram of the major unit operations and chemical conversions, the identity and entry point of all feedstocks, and the points of release of the new chemical substance.

(3) Worker exposure information, including worker activities, physical form of the new substance to which workers may be exposed, the number of workers, and the duration of activities.

(4) Information on release of the new substance to the environment, including the quantity and media of release and type of control technology used.

(h) For sites not controlled by the submitter, a description of each type of processing and use operation involving the new chemical substance, including identification of the estimated number of processing or use sites, situations in which worker exposure to and/or environmental release of the new chemical substance will occur, the number of workers exposed and the duration of exposure, and controls which limit worker exposure and environmental release.

§ 720.50 Submission of test data and other data concerning the health and environmental effects of a substance.

(a) *Test data on the new chemical substance in the possession or control of the submitter.* (1) Except as provided in paragraph (d) of this section, each notice must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities. This includes test data concerning the new chemical substance in a pure, technical grade, or formulated form.

(2) A full report or standard literature citation must be submitted for the following types of test data:

(i) Health effects data.

(ii) Ecological effects data.

(iii) Physical and chemical properties data.

(iv) Environmental fate characteristics.

(v) Monitoring data and other test data related to human exposure to or environmental release of the chemical substance.

(3)(i) If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references and the name and address of the laboratory that developed the data.

(ii) If the data appear in the open scientific literature, the submitter need only provide a standard literature citation. A standard literature citation includes author, title, periodical name, date of publication, volume, and page numbers.

(4)(i) If a study, report, or test is incomplete when a person submits a notice, the submitter must identify the nature and purpose of the study; name and address of the laboratory developing the data; progress to date; types of data collected; significant preliminary results; and anticipated completion date.

(ii) If a test or experiment is completed before the notice review period ends, the person must submit the study, report, or test to the address listed on the notice form, as specified in paragraph (a)(3)(i) of this section, within ten days of receiving it, but no later than five days before the end of the review period. If the test or experiment is completed during the last five days of the review period, the submitter must immediately inform its EPA contact for that notice by telephone.

(5) For test data in the submitter's possession or control which are not listed in paragraph (a)(2) of this section, a person is not required to submit a complete report. The person must submit a summary of the data. If EPA so requests, the person must submit a full report within ten days of the request, but no later than five days before the end of the review period.

(6) All test data described by paragraph (a) are subject to these requirements, regardless of their age, quality, or results.

(b) *Other data concerning the health and environmental effects of the new chemical substance that are known to or reasonably ascertainable by the submitter.* (1) Except as provided in paragraph (d) of this section, any person who submits a notice must describe the following data, including any data from a health and safety study, if the data are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance, of any mix-

ture or article containing the new chemical substance, or of any combination of such activities:

(i) Any data, other than test data, in the submitter's possession or control.

(ii) Any data, including test data, which are not in the submitter's possession or control, but which are known to or reasonably ascertainable by the submitter. For the purposes of this section, data are known to or reasonably ascertainable by the submitter if the data are known to any of its employees or other agents who are associated with the research and development, test marketing, or commercial marketing of the substance.

(2) Data that must be described include data concerning the new chemical substance in a pure, technical grade, or formulated form.

(3) The description of data reported under this paragraph must include:

(i) If the data appear in the open scientific literature, a standard literature citation, which includes the author, title, periodical name, date of publication, volume, and pages.

(ii) If the data are not contained in the open scientific literature, a description of the type of data and summary of the results, if available, and the names and addresses of persons the submitter believes may have possession or control of the data.

(4) All data described by this paragraph are subject to these requirements, regardless of their age, quality, or results; and regardless of whether they are complete at the time the notice is submitted.

(c) [Reserved]

(d) *Data that need not be submitted*—(1) *Data previously submitted to EPA.* (i) A person need not submit any data previously submitted to EPA with no claims of confidentiality if the notice includes the office or person to whom the data were submitted, the date of submission, and, if appropriate, a standard literature citation as specified in paragraph (a)(3)(ii) of this section.

(ii) For data previously submitted to EPA with a claim of confidentiality, the person must resubmit the data with the notice and any claim of confidentiality, under § 720.80.

(2) *Efficacy data.* This part does not require submission of any data related solely to product efficacy. This does not exempt a person from submitting any of the data specified in paragraph (a), (b), or (c) of this section.

(3) *Non-U.S. exposure data.* This part does not require submission of any data which relates only to exposure of humans or the environment outside the United States. This does not exclude nonexposure data such as data on health effects (including epidemiological studies), ecological effects, physical and chemical properties, or environmental fate characteristics.

[48 FR 21742, May 13, 1983, as amended at 51 FR 15102, Apr. 22, 1986]

§ 720.57 Imports.

(a) Except as otherwise provided in this section, the provisions of this Subpart C apply to each person who submits a notice for a new chemcial substance which he or she intends to import for a commercial purpose. In addition, each importer must comply with this section.

(b) EPA will hold the principal importer, or the importer that EPA determines must submit the notice when there is no principal importer under § 720.22(b)(2), liable for complying with this part, for completing the notice form and for the completeness and truthfulness of all information which it submits.

Subpart D—Disposition of Notices

§ 720.60 General.

This subpart establishes procedures that EPA will follow in reviewing notices.

§ 720.62 Notice that notification is not required.

When EPA receives a notice, EPA will review it to determine whether the chemical substance is subject to the requirements of this part. If EPA determines that the chemical substance is not subject to these requirements, EPA will notify the submitter that section 5 of the Act does not prevent the manufacture or import of the

substance and that the submission is not a notice under this part.

(Approved by the Office of Management and Budget under control number 2070-0012)

§ 720.65 Acknowledgment of receipt of a notice; errors in the notice; incomplete submissions; false and misleading statements.

(a) *Notification to submitter.* EPA will acknowledge receipt of each notice by sending the submitter a letter that identifies the premanufacture notice number assigned to the new chemical substance and the date on which the review period begins. The review period will begin on the date the notice is received by the Office of Toxic Substances Document Control Officer. The acknowledgment does not constitute a finding by EPA that the notice, as submitted, is in compliance with this part.

(b) *Errors in the notice.* (1) Within 30 days of receipt of the notice, EPA may request that the submitter remedy errors in the notice. The following are examples of such errors:

(i) Failure to date the notice form.

(ii) Typographical errors that cause data to be misleading or answers to any questions to be unclear.

(iii) Contradictory information.

(iv) Ambiguous statements or information.

(2) In the request to correct the notice, EPA will explain the action which the submitter must take to correct the notice.

(3) If the submitter fails to correct the notice within 15 days of receipt of the request, EPA may extend the notice period under section (5)(c) of the Act, in accordance with § 720.75(c).

(c) *Incomplete submissions.* (1) A submission is not complete, and the notification period does not begin, if:

(i) The wrong person submits the notice form.

(ii) The submitter does not sign the notice form.

(iii) Some or all of the information in the notice or the attachments are not in English, except for published scientific literature.

(iv) The submitter does not use the notice form.

(v) The submitter does not provide information that is required by section 5(d)(1)(B) and (C) of the Act and § 720.50.

(vi) The submitter does not provide information required on the notice form and by § 720.45 or indicate that it is not known to or reasonably ascertainable by the submitter.

(vii) The submitter does not submit a second copy of the submission with all confidential information deleted for the public file, as required by § 720.80(b)(2).

(viii) The submitter does not include any information required by section 5(b)(1) of the Act and pursuant to a rule promulgated under section 4 of the Act, as required by § 720.40(g).

(ix) The submitter does not submit data which the submitter believes show that the chemical substance will not present an unreasonable risk of injury to health or the environment, if EPA has listed the chemical substance under section 5(b)(4) of the Act, as required in § 720.40(h).

(2)(i) If EPA receives an incomplete submission, the Director, or his or her delegate, will notify the submitter within 30 days of receipt that the submission is incomplete and that the notice review period will not begin until EPA receives a complete notice.

(ii) If EPA obtains additional information during the notice review period that indicates the original submission was incomplete, the Director, or his or her delegate, may declare the submission incomplete within 30 days after EPA obtains the additional information and so notify the submitter.

(3) The notification that a submission is incomplete under paragraph (c)(2) (i) or (ii) of this section will include:

(i) A statement of the basis of EPA's determination that the submission is incomplete.

(ii) The requirements for correcting the incomplete submission.

(iii) Information on procedures under paragraph (c)(4) of this section for filing objections to the determination or requesting modification of the requirements for completing the submission.

(4) Within ten days after receipt of notification by EPA that a submission

is incomplete, the submitter may file written objections requesting that EPA accept the submission as a complete notice or modify the requirements necessary to complete the submission.

(5)(i) EPA will consider the objections filed by the submitter. The Director, or his or her delegate, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within ten days of receiving the objections.

(ii) If the Director, or his or her delegate, determines, in response to the objection, that the submission was complete, the notice review period will be deemed suspended on the date EPA declared the notice incomplete, and will resume on the date that the notice is declared complete. The submitter need not correct the notice as EPA originally requested. If EPA can complete its review within 90 days from the date of the original submission, the Director, or his or her delegate, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(iii) If the Director, or his or her delegate, modifies the requirements for completing the submission or concurs with EPA's original determination, the notice review period will begin when EPA receives a complete notice.

(d) *Materially false or misleading statements.* If EPA discovers at any time that person submitted materially false or misleading statements in the notice, EPA may find that the notice was incomplete from the date it was submitted, and take any other appropriate action.

§ 720.70 Notice in the Federal Register.

(a) *Filing of* FEDERAL REGISTER *notice.* In accordance with section 5(d)(2) of the Act, after EPA receives a notice, EPA will file with the Office of the Federal Register a notice including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific chemical identity listed in the notice will be published in the FEDERAL REGISTER unless the submitter has claimed chemical identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 720.85(a)(3).

(2) The categories of use of the new chemical substance will be published as reported in the notice unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 720.87(b) will be published.

(3) A list of data submitted in accordance with § 720.50(a) will be published. In addition, for test data submitted in accordance with § 720.40(g), a summary of the data will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

§ 720.75 Notice review period.

(a) *Length of notice review period.* The notice review period specified in section 5(a) of the Act runs for 90 days from the date the Document Control Officer for the Office of Toxic Substances receives a complete notice, or the date EPA determines the notice is complete under § 720.65(c), unless the Agency extends the period under section 5(c) of TSCA and paragraph (c) of this section.

(b) *Suspension of the running of the notice review period.* (1) A submitter may voluntarily suspend the running of the notice review period if the Director or his or her delegate agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the notice review period. The suspension must be for a specified period of time.

(2) A request for suspension may be made in writing to the TSCA Document Processing Center (TS-790), Rm. L-100, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice. EPA will send the submitter a written con-

firmation that the suspension has been granted.

(i) An oral request may be granted for 15 days only. To obtain a longer suspension, the Document Control Officer for the Office of Toxic Substances must receive written confirmation of the oral request. The notice review period is suspended as of the date of the oral request.

(ii) If the submitter has not made a previous oral request, the running of the notice review period is suspended as of the date of receipt of the written request by the Document Control Officer for the Office of Toxic Substances.

(c) *Extension of notice review period.* (1) At any time during the notice review period, EPA may determine that good cause exists to extend the notice review period specified in paragraph (a) of this section.

(2) If EPA makes such a determination, EPA will:

(i) Notify the submitter that EPA is extending the notice review period for a specified length of time, and state the reasons for the extension.

(ii) Issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the notice review period and gives the reasons for the extension.

(3) The initial extension may be for a period of up to 90 days. If the initial extension is for less than 90 days, EPA may make additional extensions. However, the total period of extensions may not exceed 90 days for any notice.

(4) The following are examples of situations in which EPA may find that good cause exists for extending the notice review period:

(i) EPA has reviewed the notice and determined that there is a significant possibility that the chemical substance will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial 90-day period.

(ii) EPA has reviewed the submission and is seeking additional information.

(iii) EPA has received significant additional information during the notice review period.

(iv) The submitter has failed to correct a notice after receiving EPA's request under § 720.65(b).

(d) *Notice of expiration of notice review period.* EPA will notify the submitter that the notice review period has expired or that EPA has completed its review of the notice. Expiration of the review period does not constitute EPA approval or certification of the new chemical substance, and does not mean that EPA may not take regulatory action against the substance in the future. After expiration of the statutory notice review period, in the absence of regulatory action by EPA under section 5(e), 5(f), or 6(a) of the Act, the submitter may manufacture or import the chemical substance even if the submitter has not received notice of expiration.

(e) *Withdrawal of a notice by the submitter.* (1) A submitter may withdraw a notice during the notice review period. A statement of withdrawal must be made in writing to the TSCA Document Processing Center (TS-790), Rm. L-100, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The withdrawal is effective upon receipt of the statement by the Document Control Officer.

(2) If a manufacturer or importer which withdrew a notice later resubmits a notice for the same chemical substance, a new notice review period begins.

(Approved by the Office of Management and Budget under control number 2070-0012)

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988]

§ 720.78 Recordkeeping.

(a) Any person who submits a notice under this part must retain documentation of information in the notice, including (1) other data, as defined in § 720.50(b), in the submitter's possession or control; and (2) records of production volume for the first three years of production or import, the date of commencement of manufacture or import, and documentation of this information. This information must be retained for five years from the date of commencement of manufacture of import.

(b)(1) Persons who manufacture or import a chemical substance under

§ 720.36 must retain the following records:

(i) Copies of, or citations to, information reviewed and evaluated under § 720.36(b)(1) to determine the need to make any notification of risk.

(ii) Documentation of the nature and method of notification under § 720.36(c)(1) including copies of any labels or written notices used.

(iii) Documentation of prudent laboratory practices used instead of notification and evaluation under § 720.36(b)(2).

(iv) The names and addresses of any persons other than the manfacturer or importer to whom the substance is distributed, the identity of the substance to the extent known, the amount distributed, and copies of the notifications required under § 720.36(c)(2). These records are not required when substances are distributed as impurities or incorporated into an article, in accordance with paragraph (d) of this section.

(2) A person who manufactures or imports a chemical substance under § 720.36 and who manufactures or imports the substance in quantities greater than 100 kilograms per year must retain records of the identity of the substance to the extent known, the production volume of the substance, and the person's disposition of the substance. The person is not required to maintain records of the disposition of products containing the substance as an impurity or of articles incorporating the substances.

(3) Records under this paragraph must be retained for 5 years after they are developed.

(c) Any person who obtains a test-marketing exemption under this part must retain documentation of information in the application and documentation of compliance with any restrictions imposed by EPA when it granted the application. This information must be retained for five years from the final date of manufacture or import under the exemption.

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[48 FR 21742, May 13, 1983; 48 FR 33872, July 26, 1983, as amended at 51 FR 15102, Apr. 22, 1986]

Subpart E—Confidentiality and Public Access to Information

§ 720.80 General provisions.

(a) A person may assert a claim of confidentiality for any information which he or she submits to EPA under this part.

(b) Any claim of confidentiality must accompany the information when it is submitted to EPA.

(1)(i) For information submitted on the notice form, the claim(s) must be asserted on the form in the manner prescribed on the notice form.

(ii) When a person submits information in an attachment, the claim(s) must be asserted in the attachment as described on the notice form.

(2) The person must submit two copies of each notice form and any attachments if any information is claimed confidential.

(i) One copy of the form and attachments must be complete. In that copy, the submitter must mark the information which is claimed confidential in the manner prescribed on the notice form.

(ii) The second copy must be complete except that all information claimed as confidential in the first copy must be deleted. EPA will place the second copy in the public file.

(iii) If the submitter does not provide the second copy, the submission is incomplete and the notice review period does not begin to run until EPA receives the second copy, in accordance with § 720.65(c)(1)(vi).

(c) EPA will disclose information that is subject to a claim of confidentiality asserted under this section only to the extent permitted by the Act, this subpart, and Part 2 of this title.

(d) If a notice submitter does not assert a claim of confidentiality for information at the time it is submitted to EPA, EPA may make the information public and place it in the public file without further notice to the submitter.

(Approved by the Office of Management and Budget under control number 2070-0012)

§ 720.85 Chemical identity.

(a) *Claims applicable to the period prior to commencement of manufacture or import.* (1)(i) A person who submits information to EPA under this part may assert a claim of confidentiality for the chemical identity of the new chemical substance. This claim will apply only to the period prior to the commencement of manufacture or import for commercial purposes. A submitter may assert this claim only if the submitter believes that public disclosure prior to commencement of manufacture or import of the fact that anyone intends to manufacture or import the specific chemical substance for commercial purposes would reveal confidential business information.

(ii) If the notice includes a health and safety study concerning the new chemical substance and if the claim for confidentiality with respect to the chemical identity is denied in accordance with § 720.90(c), EPA will deny a claim asserted under this paragraph.

(2) Any person who asserts a claim of confidentiality for chemical identity under this paragraph must provide one of the following items at the time the notice is submitted:

(i) The generic name which was accepted by EPA in the prenotice consultation conducted under paragraph (a)(3) of this section.

(ii) One generic name that is only as generic as necessary to protect the confidential chemical identity of the particular chemical substance. The name should reveal the specific chemical identity to the maximum extent possible. The generic name will be subject to EPA review and approval at the time a notice of commencement is submitted.

(3)(i) Any person who intends to assert a claim of confidentiality for the chemical identity of a new chemical substance may seek a determination by EPA of an appropriate generic name for the substance before submitting a notice. For this purpose, the person should submit to EPA:

(A) The chemical identity of the substance.

(B) A proposed generic name(s) which in only as generic as necessary to protect the confidential chemical identity of the new chemical substance. The name(s) should reveal the chemical identity of the substance to the maximum extent possible.

(ii) Within 30 days, EPA will inform the submitter either that one of the proposed generic names is adequate or that none is adequate and further consultation is necessary.

(4) If a submitter claims chemical identity to be confidential under this paragraph, and if the submitter complies with paragraph (a)(2) of this section, EPA will issue for publication in the FEDERAL REGISTER notice described in § 720.70 the generic name proposed by the submitter or one agreed upon by EPA and the submitter.

(b) *Claims applicable to the period after commencement of manufacture or import.* (1) Any claim of confidentiality under paragraph (a) of this section is applicable only until the substance is manufactured or imported for commercial purposes and becomes eligible for inclusion on the Inventory. To maintain the confidential status of the chemical identity when the substance is added to the Inventory, a submitter must reassert the confidentiality claim and substantiate the claim in the notice of commencement of manufacture required uner § 720.102. A submitter may not claim the chemical indentity confidential for the period after commencement of manufacture or import unless the submitter claimed the chemical identity confidential for the period prior to commencement of manufacture or import under paragraph (a) of this section.

(2)(i) A person who believes that public disclosure of the fact that anyone manfactures or imports the new chemical substance for commercial purposes would reveal confidential business information may assert a claim of confidentiality under this paragraph.

(ii) If the notice includes a health and safety study concerning the new chemical substance, and if the claim for confidentiality with respect to the chemical identity is denied in accordance with § 720.90(c), EPA will deny a claim asserted under this paragraph.

(3) Any person who asserts a confidentiality claim for chemical identity must:

(i) Comply with the requirements of paragraph (a)(3) of this section regarding submission of a generic name.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

(iv) Provide a detailed written substantiation of the claim, by answering the following questions:

(A) What harmful effects to your competitive position, if any, do you think would result if EPA publishes on the Inventory the identity of the chemical substance? How could a competitor use such information given the fact that the identity of the substance otherwise would appear on the Inventory of chemical substances with no link between the substance and your company or industry? How substantial would the harmful effects of disclosure be? What is the casual relationship between the disclosure and the harmful effects?

(B) For what period of time should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential for purposes of the Inventory?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured on imported for a commercial purpose by anyone?

(E) Is the fact that someone is manufacturing or importing this chemical substance for commercial purposes available to the public, e.g., in technical journals or other publications; in libraries; or in State, local, or Federal agency public files?

(F) What measures have you taken to prevent undesired disclosure of the fact that you are manufacturing or importing this substance for a commercial purpose?

(G) To what extent has the fact that you are manufacturing or importing this chemical substance for a commercial purpose been disclosed to others? What precautions have you taken in regard to these disclosures? Has this information been disclosed to the public or to competitors?

(H) In what form does this particular chemical substance leave the site of manufacture, e.g., as part of a product; in an effluent or emission stream? If so, what measures have you taken to guard against discovery of its identity?

(I) If the chemical substance leaves the site of manufacture in a product that is available to either the public or your competitors, can they identify the substance by analyzing the product?

(J) For what purpose do you manufacture or import the substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, copies of such determinations must be included in the substantiation.

(L) If the notice includes a health and safety study concerning the new chemical substance, the submitter must also answer the questions in § 720.90(b)(2).

(4) If the submitter does not meet the requirements of this paragraph, EPA will deny the claim of confidentiality.

(5)(i) EPA will publish a generic name on the public Inventory if:

(A) The submitter asserts a claim of confidentiality in accordance with this paragraph.

(B) No claim for confidentiality of the specific chemical identity as part of a health and safety study has been denied in accordance with Part 2 of this Title or § 720.90.

(ii) Publication of a generic name on the public Inventory does not create a category for purposes of the Inventory. Any person who has a *bona fide* intent to manufacture or import a chemical substance which is described by a generic name on the public Inventory may submit an inquiry to EPA under § 720.25(b) to determine whether the particular chemical substance is included on the confidential Inventory.

(iii) Upon receipt of a request described in § 720.25(b), EPA may require the submitter which originally asserted confidentiality for a chemical substance to submit to EPA the information listed in paragraph (b)(3)(iii) of this section.

(iv) Failure to submit any of the information required under paragraph (b)(3)(iii) of this section within ten days of a request by EPA under this paragraph is a waiver of the original submitter's confidentiality claim. In this event, EPA may place the specific chemical identity on the public Inventory without further notice to the original submitter.

(6) If a submitter asserts a claim of confidentiality under this paragraph, EPA will examine the generic chemical name proposed by the submitter.

(i) If EPA determines that the generic name proposed by the submitter is only as generic as necessary to protect the confidential identity of the particular chemical substance, EPA will place that generic name on the public Inventory.

(ii) If EPA determines that the generic name proposed by the submitter is more generic than necessary to protect the confidential identity, EPA will propose in writing, for review by the submitter, an alternative generic name that will reveal the chemical identity of the chemical substance to the maximum extent possible.

(iii) If the generic name proposed by EPA is acceptable to the submitter, EPA will place that generic name on the public Inventory.

(iv) If the generic name proposed by EPA is not acceptable to the submitter, the submitter must explain in detail why disclosure of that generic name would reveal confidential business information and propose another generic name which is only as generic as necessary to protect the confidential identity. If EPA does not receive a response from the submitter within 30 days after the submitter receives the proposed name, EPA will place EPA's chosen generic name on the public Inventory. If the submitter does provide the information requested, EPA will review the response. If the submitter's proposed generic name is acceptable, EPA will publish that generic name on the public Inventory. If the submitter's proposed generic name is not acceptable, EPA will notify the submitter of EPA's choice of a generic name. Thirty days after this notification, EPA will place the chosen generic name on the public Inventory.

§ 720.87 Categories or proposed categories of uses of a new chemical substance.

(a) A person who submits information to EPA under this Part on the categories or proposed categories of use of a new chemical substance may assert a claim of confidentiality for this information.

(b) A submitter that asserts such a claim must:

(1) Report the categories or proposed categories of use of the chemical substance.

(2) Provide, in nonconfidential form, a description of the uses that is only as generic as necessary to protect the confidential business information. The generic use description will be included in the FEDERAL REGISTER notice described in § 720.70.

(c) The person must submit the information required by paragraph (b) of this section in the manner specified in the notice form.

§ 720.90 Data from health and safety studies.

(a) *Information other than specific chemical identity.* Except as provided in paragraph (b) of this section, EPA

will deny any claim of confidentiality with respect to information included in a health and safety study, unless the information would disclose confidential business information concerning:

(1) Processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(3) Informaton which is not in any way related to the effects of a substance on human health or the environment, such as the name of the submitting company, cost or other financial data, product development or marketing plans, and advertising plans, for which the person submits a claim of confidentiality in accordance with § 720.80.

(b) *Specific chemical identity*—(1) *Claims applicable to period prior to commencement of manufacture.* A claim of confidentiality for the period prior to commencement of manufacture or import for the chemical identity of a chemical substance for which a health and safety study was submitted must be asserted in conjunction with a claim asserted under § 720.85(a).

(2) *Claims applicable to period after commencement of manufacture or import for commercial purposes.* To maintain the confidential status of the chemical identity of a chemical substance for which a health and safety study was submitted after commencement of manufacture or import, the claim must be reasserted and substantiated in conjunction with a claim under § 720.85(b). In addition to the questions set forth in § 720.85(b)(3)(iv) of this part, the submitter must answer the following questions:

(i) Would disclosure of the chemical identity disclose processes used in the manufacture or processing of a chemical substance or mixture? Describe how this would occur. In responding to the question in § 720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this process information.

(ii) Would disclosure of the chemical identity disclose the portion of a mixture comprised by any of the substances in the mixture? Describe how this would occur. In responding to the question in § 720.85(b)(3)(iv)(A), explain what harmful competitive effects would occur from disclosure of this information.

(iii) Do you assert that disclosure of the chemical identity is not necessary to interpret any of the health and safety studies you have submitted? If so, explain how a less specific identity would be sufficient to interpret the studies.

(c) *Denial of confidentiality claim.* EPA will deny a claim of confidentiality for chemical identity under paragraph (b) of this section, unless:

(1) The information would disclose processes used in the manufacture or processing of a chemical substance or mixture.

(2) In the case of a mixture, the information would disclose the portion of the mixture comprised by any of the substances in the mixture.

(3) The specific chemical identity is not necessary to interpret a health and safety study.

(d) *Use of generic names.* When EPA discloses a health and safety study containing a specific chemical identity, which the submitter has claimed confidential, and if the Agency has not denied the claim under paragraph (c) of this section, EPA will identify the chemical substance by the generic name selected under § 720.85.

(Approved by the Office of Management and Budget under control number 2070-0012)

§ 720.95 Public file.

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential. In addition, EPA may add materials to the public file, subject to subpart E of this part. Any of the nonconfidential material described in this subpart will be available for public inspection in the TSCA Public Docket Office, Rm. NE-G004, 401 M St., SW., Washington, DC, between the hours of 8 a.m. and 4 p.m. weekdays, excluding legal holidays.

[48 FR 21742, May 13, 1983, as amended at 53 FR 12523, Apr. 15, 1988]

Subpart F—Commencement of Manufacture or Import

§ 720.102 Notice of commencement of manufacture or import.

(a) *Applicability.* Any person who commences the manufacture or import of a new chemical substance for a non-exempt commercial purpose for which that person previously submitted a section 5(a) notice under this part must submit a notice of commencement of manufacture or import.

(b) *When to report.* (1) If manufacture or import for commercial purposes begins on or after the effective date of this rule, the submitter must submit the notice to EPA on, or no later than 30 calendar days, after the first day of such manufacture or import.

(2) If manufacture or import for commercial purposes began or will begin before the effective date of this rule, the submitter must submit the notice by the effective date of this rule.

(c) *Information to be reported.* The notice must contain the following information: Specific chemical identity, premanufacture notice number, and the date when manufacture or import commences. If the person claimed chemical identity confidential in the commencement notice, and wants the identity to be listed on the confidential Inventory, the claim must be reasserted and substantiated in accordance with § 720.85(b). Otherwise, EPA will list the specific chemical identity on the public Inventory.

(d) *Where to submit.* Notices of commencement of manufacture or import should be submitted to: TSCA Document Processing Center (TS-790), Rm. L-100, Office of Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(Approved by the Office of Management and Budget under control number 2070-0012)

[48 FR 21742, May 13, 1983, as amended at 48 FR 41140, Sept. 13, 1983; 51 FR 15103, Apr. 22, 1986; 53 FR 12523, Apr. 15, 1988]

Subpart G—Compliance and Inspections

§ 720.120 Compliance.

(a) Failure to comply with any provision of this part is a violation of section 15 of the Act (15 U.S.C 2614).

(b) A person who manufactures or imports a new chemical substance before a notice is submitted and the notice review period expires is in violation of section 15 of the Act even if that person was not requied to submit the notice under § 720.22.

(c) Using for commercial purposes a chemical substance or mixture which a person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 5 of this rule is a violation of section 15 of the Act (15 U.S.C. 2614).

(d) Failure or refusal to establish and maintain records or to permit access to or copying of records, as required by the Act, is a violation of section 15 of the Act (15 U.S.C. 2614).

(e) Failure or refusal to permit entry or inspection as required by section 11 is a violation of section 15 of the Act (15 U.S.C. 2614).

(f) Violators may be subject to the civil and criminal penalties in section 16 of the Act (15 U.S.C. 2615) for each violation. Persons who submit materially misleading or false information in connection with the requirements of any provision of this rule may be subject to penalties calculated as if they never filed their notices.

(g) EPA may seek to enjoin the manufacture or processing of a chemical substance in violation of this rule or act to seize any chemical substance manufactured or processed in violation of this rule or take other actions under the authority of section 7 of this Act (15 U.S.C. 2606) or section 17 or this Act (15 U.S.C. 2616).

§ 720.122 Inspections.

EPA will conduct inspections under section 11 of the Act to assure compliance with section 5 of the Act and this rule, to verify that information submitted to EPA under this rule is true and correct, and to audit data submitted to EPA under this rule.

APPENDIX A—PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES

O.M.B. No. 2070-0012: Approval Expires 3-3-86

EPA United States Environmental Protection Agency

PREMANUFACTURE NOTICE FOR NEW CHEMICAL SUBSTANCES

When completed send this form to:

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-793
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

AGENCY USE ONLY

Date of receipt

Enter the total number of pages in the Premanufacture Notice ——→

Document control number | EPA case number

GENERAL INSTRUCTIONS

You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.

Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (**Instructions Manual**).

Part I. GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information.

Part II. HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III. LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. In part III, list these attachments, any test data or other data, and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The **Instructions Manual** identifies categories of optional information that you may want EPA to review.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the **Instructions Manual.**

Indicate below the categories of information you have claimed as confidential in the notice.

1 ☐ SUBMITTER IDENTITY
2 ☐ CHEMICAL IDENTITY
3 ☐ PRODUCTION VOLUME
4 ☐ USE INFORMATION
5 ☐ PROCESS INFORMATION
6 ☐ PORTIONS OF A MIXTURE
7 ☐ OTHER INFORMATION

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data, not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test data

- **Environmental fate data**
  - Spectra (UV, visible, and infrared)
  - Density of liquids and solids
  - Water solubility
  - Melting point/melting range
  - Boiling point/boiling range
  - Vapor pressure
  - Partition coefficient, n-octanol/water
  - Biodegradation
  - Hydrolysis (as a function of pH)
  - Photochemical degradation
  - Adsorption/desorption to soil types
  - Dissociation constant
  - Other physical/chemical properties
- **Health effects data**
  - Mutagenicity
  - Carcinogenicity
  - Teratogenicity
  - Acute toxicity
  - Repeated dose toxicity
  - Metabolism studies
  - Sensitization
  - Irritation
- **Environmental effects data**
  - Microbial and algal toxicity
  - Terrestrial vascular plant toxicity (e.g., seed germination studies, growth inhibition)
  - Acute and chronic toxicity to animals (e.g., fish, birds, mammals, invertebrates)

Other data

- **Risk assessments**
- **Structure/activity relationships**
- **Test data not in the possession or control of the submitter**

EPA Form 7710-25 (4-26-83)

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in part I, section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

		Confidential
Signature of authorized official	Date	
Signature of agent — *(if applicable)*	Date	

Part I — GENERAL INFORMATION

Section A — SUBMITTER IDENTIFICATION

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

			Confidential
1a. Person submitting notice	Name of authorized official	Title	
	Company		
	Mailing address (number and street)		
	City, State, ZIP code		
b. Agent *(if applicable)*	Name of authorized official	Title	
	Company		
	Mailing address (number and street)		
	City, State, ZIP code		
c. *If you are submitting this notice as part of a joint submission, mark (X) this box.* → ☐			
2. Technical contact	Name	Title	
	Company		
	Mailing address (number and street)		
	City, State, ZIP code	Telephone: Area code	Number
3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number →			*Mark (X) if none* → ☐
4. If you have submitted a test-marketing exemption (TME) application for the chemical substance covered by this notice, enter the TME number assigned by EPA →			*Mark (X) if none* → ☐
5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA →			*Mark (X) if none* → ☐

6. Type of Notice — *Mark (X)* 1 ☐ Manufacture 2 ☐ Import

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 or 2 as appropriate. Complete all other items.

If another person will submit chemical identity information for you, mark (X) the box at the right. ☐ → Identify the name, company, and address of that person in a continuation sheet.

Confi-dential

1. Class 1 or 2 chemical substances (for definitions of class 1 and class 2 substances, see the **Instructions Manual**)

a. Class of substance — *Mark (X)* 1 ☐ Class 1 2 ☐ Class 2

b. Chemical name (preferably CAS or IUPAC nomenclature)

c. Molecular formula and CAS Registry Number (if known)

d. For a class 1 substance, provide a structural diagram. For a class 2 substance — (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (if possible).

☐ *Mark (X) this box if you attach a continuation sheet.*

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Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION — Continued

2. **Polymers** (For a definition of polymer, see the **Instructions Manual**.)

a. Indicate the **lowest** number-average molecular weight composition of the polymer you intend to manufacture. Indicate the **maximum** weight percent of low molecular weight species below 500 and below 1,000 absolute molecular weight of that composition. Describe the methods of measurement or the bases for your estimates.

Confidential

☐ *Mark (X) this box if you attach a continuation sheet.*

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) — Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) — Indicate the **typical** weight percent of each monomer or other reactant in the polymer.
(3) — Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.
(4) — Indicate the **maximum** weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.

Monomer or other reactant and CAS Registry Number (1)	Confidential	Typical composition (2)	Identity *Mark (X)* (3)	Confidential	Maximum residual (4)	Confidential
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ *Mark (X) this box if you attach a continuation sheet.*

c. Provide a representative structural diagram of the polymer, if possible.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I — GENERAL INFORMATION — Continued

Section B — CHEMICAL IDENTITY INFORMATION — Continued

3. Impurities

(a) — Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."

(b) — Estimate the maximum weight percent of each impurity. If there are unidentified impurities, estimate their total weight percent.

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confidential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ *Mark (X) this box if you attach a continuation sheet.*

4. Synonyms — *Enter any synonyms for the new chemical substance identified in subsection 1 or 2.* Confidential

☐ *Mark (X) this box if you attach a continuation sheet.*

5. Trade identification — List trade names for the new chemical substance identified in subsection 1 or 2.

☐ *Mark (X) this box if you attach a continuation sheet.*

6. Generic chemical name — If you claim chemical identity as confidential, enter the generic chemical name that you developed with EPA during prenotice communication. If you have not developed a generic name with EPA, provide a generic name that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Read the TSCA Chemical Substance Inventory, Initial Inventory, Volume I for guidance on developing generic names.

☐ *Mark (X) this box if you attach a continuation sheet.*

7. Byproducts — Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance at sites you control. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confidential

☐ *Mark (X) this box if you attach a continuation sheet.*

Part I— GENERAL INFORMATION — Continued

Section C — PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Production volume — Estimate the **maximum** production volume during the first 12 months of production. Also estimate the **maximum** production volume for any consecutive 12-month period during the first three years of production.

Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)	Confidential

2. Use Information

You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" box next to any item you claim as confidential.

a. (1) — Describe each intended category of use of the new chemical substance by function and application.
(2) — Estimate the percent of total production for the first three years devoted to each category of use.
(3) — Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
(4) — Mark (X) whether the use is site-limited, industrial, commercial, or consumer. Mark more than one column if appropriate.
Read the **Instructions Manual** for examples.

Category of use (1)	Confidential	Production (percent) (2)	Confidential	Formulation (percent) (3)	Confidential	*Mark (X) appropriate column(s)* (4) Site-limited	Industrial	Commercial	Consumer	Confidential
		%		%						
		%		%						
		%		%						
		%		%						

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Generic use description — If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic use descriptions.

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Hazard Information — Include in the notice a copy or reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new chemical substance. List in part III any hazard information you include.

☐ *Mark (X) this box if you attach hazard information.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control.

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Operation description

a. Identity— Enter the identity of the site at which the operation will occur. (Confidential)

Name

Site address (number and street)

City, County, State, ZIP code

If the same operation will occur at more than one site, enter the number of sites. ⟶
Identify the additional sites on a continuation sheet.

☐ *Mark (X) this box if you attach a continuation sheet.*

b. Type — *Mark (X)*

1 ☐ Manufacturing 2 ☐ Processing 3 ☐ Use

c. Amount and Duration — *Complete 1 or 2 as appropriate*

	Maximum kg/batch	*Hours/batch*	*Batches/year*
1. Batch			
	Maximum kg/day	Hours/day	Days/year
2. Continuous			

d. Process description

(1) *Diagram the major unit operation steps and chemical conversions.*

(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts).

(3) Identify by number the points of release to the environment of the new chemical substance.

☐ *Mark (X) this box if you attach a continuation sheet.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section A — INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER — Continued

2. Occupational Exposure

You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) — Describe the activities in which workers may be exposed to the new chemical substance. Include activities in which workers wear protective equipment.
(2) — Indicate the physical form(s) of the new chemical substance at the time of exposure.
(3) — Estimate the maximum number of workers involved in each activity.
(4) and (5) — Estimate the maximum duration of the activity for any worker in hours per day and days per year.

Worker activity (1)	Confi-dential	Physical form(s) (2)	Confi-dential	Maximum number (3)	Confi-dential	Maximum duration		Confi-dential
						Hrs/day (4)	Days/yr (5)	

☐ *Mark (X) this box if you attach a continuation sheet.*

3. Environmental Release and Disposal

You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.

(1) — Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
(2) — Estimate the amount of the new chemical substance released directly to the environment or into control technology (in kg/day or kg/batch).
(3) — Identify the media (air, land, or water) to which the new substance will be released from that release point.
(4) — Describe control technology, if any, that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method.
(5) — Identify the destination(s) of releases to water.

Release Number (1)	Amount of new substance released (2)	Confi-dential	Media of release (3)	Control technology (4)	Confi-dential

(5) Mark (X) the destination(s) of releases to water.
1 ☐ POTW (publicly owned treatment works)
2 ☐ Navigable waterway
3 ☐ Other — *Specify* _____

☐ *Mark (X) this box if you attach a continuation sheet.*

Part II — HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE — Continued

Section B — INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for each type of processing or use operation involving the new chemical substance at sites you do not control.

To claim information in this section as confidential, circle or bracket the specific information that you claim as confidential.

Operation description

Describe the typical processing or use operation. Identify the unit operation steps which may occur during the operation. Estimate the number of sites at which the operation is likely to occur. Identify situations in which worker exposure to and/or environmental release of the new chemical substance may occur. Estimate the percent of new chemical substance as formulated in products manufactured for commercial purposes in the operation or as used in the operation. Estimate the number of workers exposed and the duration of exposure. Identify controls which limit worker exposure and environmental release if typically used. Identify byproducts which may result from the operation.

☐ *Mark (X) this box if you attach a continuation sheet.*