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# Article 17 of the Preparations Directive 1999/45/EC is differently implemented in EU Member States

A survey on how Poisons Information Centres become informed on dangerous preparations

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# Rapport in het kort

**Artikel 17 van de Preparatenrichtlijn 1999/45/EG is verschillend geïmplementeerd in EU lidstaten**

Een onderzoek naar hoe Vergiftigingen Informatie Centra worden geïnformeerd over gevaarlijke preparaten

Onderzoek naar de aanlevering van informatie over gevaarlijke preparaten door bedrijven aan Vergiftigingen Informatie Centra laat zien dat dit in elke EU lidstaat anders geregeld is. Dit komt doordat in de Europese Preparatenrichtlijn 1999/45/EG hierover geen duidelijke regels zijn vastgelegd.

De invoering van het 'Globally Harmonised System of classification and labelling of chemicals' (GHS) in de EU gaat de Preparatenrichtlijn vervangen. Dit is een goed moment om op Europees niveau de aanlevering van productinformatie te harmoniseren en de vereisten wettelijk vast te leggen.

De aangeleverde productinformatie wordt gebruikt voor medische doeleinden, met name het verstrekken van informatie in geval van vergiftigingen. Dit rapport laat zien dat in zes landen een Vergiftigingen Informatie Centrum hiervoor direct is aangewezen als ontvangende instantie. In de meeste andere landen wordt de productinformatie aan hen ter beschikking gesteld door een (ander) ontvangend overheidsorgaan.

In EU lidstaten gelden verschillende vereisten voor de op te geven productsamenstelling en de concentraties van de ingrediënten. Eveneens verschillen de procedures voor aanlevering en is er een aanzienlijke variatie in de gebruikte formulieren en/of applicaties voor elektronische aanlevering.

Voor het bereiken van harmonisatie is het noodzakelijk dat de ontvangende instanties eerst consensus bereiken over de vereiste productinformatie. Daarna moet overeenstemming worden bereikt over een gemeenschappelijk formaat voor aanlevering.

Trefwoorden: Preparatenrichtlijn, 1999/45/EG, gevaarlijke preparaten, Vergiftigingen Informatie Centra, veiligheidsinformatieblad.

# Abstract

**Article 17 of the Preparations Directive 1999/45/EC is differently implemented in EU Member States**
A survey on how Poisons Information Centres become informed on dangerous preparations

A survey on the notification of information on dangerous preparations by companies to Poisons Information Centres shows that each EU Member State has made different arrangements. This is the result of missing guidelines in the Preparations Directive 1999/45/EC.

The implementation of the 'Globally Harmonised System of classification and labelling of chemicals' (GHS) in the EU will replace the Preparations Directive. This is a good opportunity to harmonize product notification at an EU level and have it legally enforced.

The notified product information is used for medical purposes, particularly to provide information on poisonings with these preparations. This report shows that in six countries the Poisons Information Centre (PIC) directly receives the information on the dangerous preparations. In most other countries, a governmental authority is appointed that makes the information available to the PICs.

Between EU Member States different requirements are set concerning the notification of the composition of the product and the concentrations of the ingredients. There are also different procedures for notification and a considerable variety in used forms and/or applications for electronic notification.

Harmonisation of product notification can be achieved if the receiving authorities first reach consensus on the required product information. Next, an agreement on an acceptable format for notification must be reached.

Key words: Preparations Directive, 1999/45/EC, dangerous preparations, Poisons Information Centres, Material Safety Data Sheet.

# Preface

The authors kindly thank all competent authorities who returned a filled-in questionnaire and/or helped us to gather the information on the product notification procedures in these countries. We hope that this document will be helpful in the process of European harmonisation of product notification.

Note for companies:
It is advised to contact the competent authorities in different EU countries for specific guidelines on how to notify product information and/or register products. The requirements indicated in this report are a summary and therefore are not always suitable to use for notification in a particular country.

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# Samenvatting

**Introductie**
Artikel 17 van de Europese Preparatenrichtlijn Nr. 1999/45/EG geeft aan dat elke EU lidstaat een instantie moet aanwijzen waar informatie over gevaarlijke preparaten moet worden gedeponeerd. De informatie mag alleen worden gebruikt om te reageren op medische verzoeken als personen dreigen te worden, dan wel zijn, blootgesteld aan gevaarlijke preparaten.
De richtlijn geeft niet aan welke informatie moet worden aangeleverd en op welke manier. In Nederland is het Nationaal Vergiftigingen Informatie Centrum (NVIC) aangewezen als de ontvangende instantie. Artikel 17 is geïmplementeerd in de nationale wetgeving; het gebruik van een speciaal formulier en het opgeven van de exacte samenstelling en concentratie zijn wettelijk verplicht.

Tien jaar na de implementatie verloopt de aanlevering van adequate productinformatie bij het NVIC echter nog steeds niet naar wens. Aanlevering via een speciaal formulier is voor leveranciers veel werk en er is weerstand tegen een opgave van de complete samenstelling. Voor hen is het efficiënter om voor dit doel gebruik te maken van het veiligheidsinformatieblad (VIB), een gangbaar formaat dat is ontwikkeld om de professionele gebruiker te informeren. Zoals beschreven in de Europese Richtlijn Nr. 2001/88/EG, hoeven op een VIB alleen gevaarlijke ingrediënten boven specifieke concentratiegrenzen te worden opgegeven. Vanwege de afwezigheid van richtlijnen voor de op te geven concentratie van de ingrediënten leidt dit in de praktijk vaak tot het gebruik van ruime concentratieranges.
Het NVIC is echter van mening dat het VIB onvoldoende specifieke informatie geeft voor het uitvoeren van een goede risico-evaluatie. Het is hierdoor moeilijker om medisch personeel adequaat te informeren in geval van acute vergiftigingen.

In Nederland is het NVIC opnieuw in discussie getreden met de industrie en diverse branche organisaties om de aanlevering van productinformatie te verbeteren. In het kader hiervan heeft het ministerie van Volksgezondheid, Welzijn en Sport aan het NVIC gevraagd de procedures en vereisten van verschillende EU lidstaten in kaart te brengen. Voordat de Nederlandse situatie wordt aangepast, zou dit een goed moment zijn om te bekijken of er een basis is voor harmonisatie op Europees niveau, vooral met de nieuwe EU-GHS regelgeving in zicht.

**Methoden**
Dit onderzoek is uitgevoerd voor de initiële 15 lidstaten van de Europese Unie (de EU15), zijnde België, Frankrijk, Spanje, Portugal, Italië, Oostenrijk, Duitsland, Ierland, Denemarken, Zweden, Finland, Luxemburg, Griekenland, het Verenigd Koninkrijk en Nederland. Noorwegen is hieraan toegevoegd om de groep van Scandinavische landen met een Product Register te completeren.

Een vragenlijst werd verstuurd naar de bevoegde instanties. Drie belangrijke onderwerpen kwamen hierin aan bod: informatie over de bevoegde instantie, de vereisten voor de op te geven samenstelling en de concentraties van de ingrediënten en de aanleveringsmethoden. Indien nodig, werden vervolgvragen gesteld via e-mail, telefonisch of via persoonlijk contact. Veertien landen reageerden op het verzoek.

**Resultaten**

In zes landen ontvangt een Vergiftigingen Informatie Centrum direct de informatie over gevaarlijke producten (6/14). In de andere landen is een (ander) overheidsorgaan aangewezen. De meeste van hen (6/8) stellen de informatie beschikbaar aan de Vergiftigingen Informatie Centra in hun land.

Net als in Nederland, wordt in de meeste landen (10/14) door de bevoegde instantie exactere informatie over de samenstelling van het product en de concentratie van de ingrediënten gevraagd dan aanwezig op een VIB. Slechts in vier landen wordt een VIB geaccepteerd voor het aanleveren van productinformatie.
Verschillende vereisten worden gesteld om de kwaliteit van de productinformatie boven het VIB-niveau te tillen. Voor de samenstelling zijn de vereisten grofweg in twee categorieën onder te verdelen. In zes landen (6/10), moet de exacte samenstelling worden opgegeven, dus zowel de gevaarlijke als alle niet-gevaarlijke ingrediënten. In vier landen (4/10), worden additionele ondergrenzen voor bepaalde stoffen gebruikt, bijvoorbeeld voor niet-gevaarlijke ingrediënten en/of specifieke gevaarlijke ingrediënten.
Wat betreft de concentratie, wordt in vier landen (4/10) de exacte concentratie van de ingrediënten gevraagd en maakt één land gebruik van zelf-gedefinieerde concentratieranges. In vijf landen (5/10) is het een combinatie van deze twee, voor sommige of alle gevaarlijke ingrediënten moeten exacte concentraties worden opgegeven en voor de andere ingrediënten worden concentratieranges geaccepteerd.

In de meeste van deze landen (8/10) worden speciale formulieren gebruikt voor de aanmelding. In twee landen is het formaat vrij, als maar voldaan wordt aan de vereisten. Diverse manieren van elektronische aanmelding en verwerking zijn ontwikkeld.

**Discussie**

Aangezien de Europese Richtlijn Nr. 1999/45/EG niet aangeeft welke informatie moet worden aangeleverd en op welke manier, heeft dit in de verschillende landen geresulteerd in een grote variatie in gebruikte formulieren, methoden van aanlevering en vereisten wat betreft de op te geven samenstelling en concentratie van de ingrediënten. Bij de fabrikanten die producten op de ‘Europese markt’ brengen leidt dit tot onbegrip.

Het is de mening van het NVIC, dat zowel de Europese bevoegde instanties als de fabrikanten gebaat zijn bij Europese harmonisatie van de aanlevering van productinformatie.

De eerste stap in het proces van Europese harmonisatie is het bereiken van overeenstemming tussen de Europese vergiftigingencentra en (andere) bevoegde instanties over welke informatie over gevaarlijke preparaten essentieel is voor het uitvoeren van hun taak.
Een volgende stap is het ontwikkelen van een standaard (elektronisch) formaat voor aanlevering. De bereidwilligheid van leveranciers om adequate productinformatie aan te leveren zou kunnen verbeteren als het VIB als een uitgangspunt kan dienen en specifieke additionele informatie kan worden aangeleverd om aan de vereisten te voldoen.
Een derde stap is de implementatie van de vereisten en het formaat in Europese wetgeving, zoals ook is gedaan voor het VIB (Europese Richtlijn Nr. 2001/58/EG).

Opmerkelijk genoeg zijn richtlijnen over de vereisten wat betreft de samenstelling en concentratie in 1989 al opgesteld door een informele EAPCCT (European Association of Poisons Centres and Clinical Toxicologists) projectgroep en nogmaals gepubliceerd in de EAPCCT nieuwsbrief in 1996. Er werd voorgesteld dat de complete samenstelling, de exacte concentraties van (zeer) toxische en corrosieve ingrediënten en gedefinieerde concentratieranges voor de overige ingrediënten moeten worden opgegeven.
Wanneer deze richtlijnen worden vergeleken met de regels in de verschillende landen, lijkt dit voorstel een redelijk compromis. Het is de vraag of een revisie nodig is om consensus te bereiken. Aandachtspunt is het gebruik van (lage) concentratiegrenzen waarboven ingrediënten moeten worden opgegeven als alternatief voor een opgave van de exacte samenstelling. Daarnaast vraagt het gebruik van exacte concentraties of concentratieranges voor de opgegeven ingrediënten om aandacht.

Als er ooit een goed moment is om de discussie over harmonisatie van de aanlevering van productinformatie te starten en om de vereisten wettelijk vast te leggen op een Europees niveau, is het nu. Aangezien het EU-GHS-initiatief de huidige relevante Europese wetgeving gaat veranderen, moet duidelijk worden aangeven dat er een noodzaak is voor een adequate aanlevering van productinformatie voor de medische behandeling van personen die aan de gevaarlijke preparaten zijn blootgesteld.

# Summary

**Introduction**
Article 17 of the European Directive No. 1999/45/EC states that each EU Member State must appoint an authority where information regarding dangerous preparations must be notified. The appointed authority is responsible for supplying information exclusively for medical purposes when curative and preventive measures need to be taken in case of a threatening or actual exposure to these preparations. The Directive does not define which information should be notified and how. In the Netherlands, the Poisons Information Centre (PIC) was appointed for this task. Article 17 of the Directive was implemented in the national legislation, making the use of a special form and notification of the exact composition and concentration mandatory.

Ten years after implementation, the Dutch PIC still experiences problems with the notification of adequate product information. The suppliers have difficulties to provide more information than present on the MSDS and to use the special Dutch format because of the workload. For them it is most efficient to use the Material Safety Data Sheet (MSDS) for this purpose, a well-established format designed to inform professional users. As described in the European Directive No. 2001/88/EC, only dangerous substances above specified concentration thresholds have to be stated on the MSDS. The absence of guidelines for the required accuracy of the ingredient concentrations turns the use of wide concentration ranges into general practise. In the opinion of the Dutch PIC the MSDS does not provide sufficient detail to make a good risk assessment. Consequently it is more difficult to adequately inform healthcare personnel in case of acute intoxications.

A renewed discussion with industry and trade organisations representatives to improve notification was started in the Netherlands. In line with this project, the Ministry of Health, Welfare and Sport asked the Dutch PIC to conduct a survey in EU countries and make an overview of the various procedures and requirements. Before changing the Dutch situation only, it would be a good moment to evaluate whether there is basis for harmonisation on a European level, especially with the forthcoming EU-GHS regulation.

**Methods**
For this survey, the initial 15 European Union Member States (the EU15) were included, being Belgium, France, Spain, Portugal, Italy, Austria, Germany, Ireland, Denmark, Sweden, Finland, Luxembourg, Greece, the United Kingdom and the Netherlands. Norway was included to complete the group of Scandinavian countries with Product Registers. A questionnaire on three major topics, i.e. information on the competent authority, requirements on product composition and ingredient concentrations, and the notification procedures was sent to the competent authorities. When necessary, further questions were asked by e-mail,

telephone or through personal communication. Fourteen countries responded.

**Results**
In 6 countries it is the PIC that directly receives the information on dangerous products (6/14). In the other countries, a governmental authority is appointed. Most of them (6/8) make the information available to the PIC(s).

Just as in the Netherlands, in most countries (10/14) the competent authority requires more precise information on the composition of the product and concentration of its ingredients than present on a MSDS. Only 4 countries accept the MSDS for notification of product information. Various additional requirements are set to improve the quality above the MSDS level. For the composition, the additional requirements fall roughly into two categories. In 6/10 countries, the exact composition is required, i.e. all dangerous as well as non-dangerous substances have to be notified. In 4/10 countries, additional thresholds for substances are used, e.g. for non-dangerous substances and/or for specified dangerous substances.
For the concentration, 4/10 countries require the exact concentration of the ingredients, one country uses self-defined concentration ranges. In 5/10 countries it is a combination of these two, e.g. for some or all dangerous substances exact concentrations are required and for the other substances concentration ranges are allowed.

In most of these countries (8/10) special forms are used for notification. In two countries the format is free as long as the requirements are met. Various routes of electronic notification and processing have been developed.

**Discussion**
Because European Directive No. 1999/45/EC does not define which information should be notified and in what way, this has resulted in a considerable variety in methods of notification, used formats and country specific requirements regarding the composition and concentration of the ingredients. The lack of understanding by companies introducing products on the ‘European market’ can be imagined.

In the opinion of the Dutch PIC, the European competent authorities as well as the suppliers would benefit from European harmonisation of notification of product information.

A first step in the process of European harmonisation is to reach consensus between European PICs and (other) competent authorities on which additional information is essential to perform their task.
A next step would be a common (electronic) format for notification. The willingness of suppliers to fulfil the requirements could improve if the MSDS would serve as a basis and to provide them with harmonized guidelines on how the additional information should be delivered.

The third step is the legal implementation of the requirements and the format on a European level as is also done for the MSDS in European Directive No. 2001/58/EC.

Remarkably, guidelines on the requirements concerning the composition and concentration were already presented by an informal EAPCCT (European Association of Poisons Centres and Clinical Toxicologists) working group in 1989 and were again published in the EAPCCT newsletter in 1996. It was proposed that all ingredients, the actual concentrations on (very) toxic and corrosive ingredients and specified concentration ranges for the others should be mentioned. When comparing these guidelines with the various requirements of the responding countries, this proposal still seems a reasonable compromise. It should be evaluated if a revision of this document is necessary to reach consensus between the EU countries. One topic with special attention is the use of (low) threshold concentrations above which substances should be mentioned as an alternative for the exact composition. Another is the use of exact concentrations or concentration ranges for the mentioned substances.

It is now the right moment to reach harmonisation on product notification and to legally enforce the requirements on a European level. This could be initiated in the framework of EU-GHS activities changing the relevant European legislation.

# 1. Introduction

People come into contact with numerous preparations every day, from bleaches and caustic soda in household settings to solvents and industrial cleaners in occupational settings. Though expected to be safe with prescribed use, unintentional exposures can be caused by accidents or inappropriate use of products, e.g. by ingestion of the product, via inhalation or through skin contact. Also intentional exposures occur, often in an attempt to commit suicide. After such exposures an immediate risk assessment is necessary. Forthcoming intoxications must be treated properly.

Informing medical personnel (physicians, veterinarians, pharmacists) and/or the public about symptoms and treatment of acute intoxications is the main task of Poisons Information Centres. To fulfil this task adequately, information about the involved product(s) is crucial, especially information about the composition and the concentration of the ingredients. This can be achieved by notification of the product information to the Poisons Information Centres either directly or indirectly through a central governmental institute.

**Bodies responsible for receiving information relating to health**

Member States shall appoint the body or bodies responsible for receiving information, including chemical composition, relating to preparations placed on the market and considered dangerous on the basis of their health effects or on the basis of their physico-chemical effects.

Member States shall take the necessary steps to ensure that the appointed bodies provide all the requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used to meet any medical demand for formulating preventive and curative measures, in particular in case of emergency.

Member States shall ensure that the information is not used for other purposes.

Member States shall ensure that the appointed bodies have at their disposal all the information required from the manufacturers or persons responsible for marketing to carry out tasks for which they are responsible.

*(Article 17 of EU Directive No. 1999/45/EC)*

For the EU Member States the notification of the product information of dangerous products is mandatory. Article 17 of the European Directive No. 1999/45/EC (see complete text to the left) states that each EU Member State must appoint an authority where information regarding dangerous preparations (according to this directive) must be notified. The appointed authority is responsible for supplying information exclusively for medical purposes when curative and preventive measures need to be taken. (Note: Directive 1999/45/EC is the actualized version of Directive 88/379/EC)

It is not stated which authority should be appointed and whether this should be a Poisons Information Centre (PIC). The Directive also does not define which information should be notified and how this must be done, allowing countries to develop their own specific requirements and methods of notification.

In the Netherlands, Article 17 of the European Directive is implemented in national legislation and the PIC is appointed as the receiving authority. Additionally, the use of a special form and notification of the exact composition and concentration is mandatory. This special form, the Product Information Sheet, resembles the structure of a Material Safety Data Sheet (MSDS) but requires, amongst others, more specific information about the composition of the product. The Product Information Sheet can be submitted on paper or electronically. For electronic notification the Dutch PIC has developed the computer programme PINDA (Preparation INformation DAtabase).

Ten years after implementation, the Dutch PIC still experiences problems with the notification of adequate product information. For suppliers it is most efficient to use the MSDS for this purpose, a well-established format designed to inform professional users. In the opinion of the Dutch PIC the MSDS does not provide sufficient details to perform a good risk assessment. Consequently, informing healthcare personnel in case of acute intoxications is unnecessarily more difficult than needed.

A renewed discussion with industry and trade organisations representatives to improve notification has been started in the Netherlands. In line with this project, the Ministry of Health, Welfare and Sport asked the Dutch PIC to conduct a survey in present EU countries and make an overview of the various procedures and requirements. Before changing the Dutch situation only, it would be a good moment to evaluate whether there is basis for harmonisation on a European level, especially in the framework of the forthcoming EU-GHS (Globally Harmonised System of classification and labelling of chemicals) regulation.

In this report both the notification procedures and requirements in 13 responding EU countries and Norway are described and how the information is (made) available for medical purposes. The relevant similarities and differences are discussed, a comparison is made with the requirements for the Material Safety Data Sheet (MSDS) and suggestions are made for a possible uniform European notification procedure in the future.

# 2. Methods

The focus in this survey was on the notification procedures for dangerous preparations according to European Directive No. 1999/45/EC. Biocides are included in the scope of this survey because their notification to 'an appointed body' for medical purposes is also a legal obligation due to Article 23 of European Directive No. 98/8/EC, which strongly resembles Article 17 of European Directive No. 1999/45/EG.

For this survey, the initial 15 European Union Member States (the EU15) were included, being Belgium, France, Spain, Portugal, Italy, Austria, Germany, Ireland, Denmark, Sweden, Finland, Luxembourg, Greece, the United Kingdom and the Netherlands. These countries were selected because they were supposed to have the most experience with the implementation of this directive as compared to the later included EU countries. Additionally, Norway was included to complete the group of Scandinavian countries that are interesting for their 'Product Register Units'.

To collect the information on the notification procedures, a questionnaire (see Appendix 1) was sent to all relevant authorities and Poisons Information Centres of the 15 included EU Member States and Norway. In this questionnaire the following questions had to be answered, grouped in the three main issues that are addressed in this survey.

On the competent authority:

- **What is the appointed authority for notification of dangerous preparations?**
  Is this a Poisons Information Centre or another institute?
- **How is the information made available for medical purposes?**
  Especially when the competent authority is not the Poisons Information Centre.

On the requirements on product composition and ingredient concentration:

- **What are the requirements concerning the composition of a preparation and the ingredient concentration?**
  Is additional information necessary as compared to the Material Safety Data Sheet (MSDS)?

On the methods of notification:

- **Are there special forms used?**
  Can the MSDS be used or is a special form necessary?
- **Is electronic notification possible?**
  Is there a computer programme for electronic notification and processing of the data?
- **Are there costs involved for the supplier?**
  And if so, what are the costs?

The collected information was checked for completeness and clearness. When necessary, further questions were asked by e-mail, telephone or through personal communication (e.g. at international meetings). Information was also gathered through internet as some authorities make the notification forms and instructions available on their website. For each country a compact and comprehensive information sheet was created, containing the most essential information necessary for the comparison between the countries. The information sheets are presented in Appendix 2. The introductory page of this appendix gives more explanation on the information that is collected and how it is presented. The extent of detail in which the notification procedures are described reflects the quality of the responses and the available sources.

The collected information on electronic procedures, tools and/or initiatives for notification of preparation information is presented in Appendix 3.

In this report the requirements on product composition and ingredient concentration in the different responding EU countries are compared with the requirements for the Material Safety Data Sheet (MSDS), as described in the European Directive 2001/58/EC.

# 3. Results

Sufficient information was gathered from 14 of the 16 countries. Only Greece and Luxembourg did not respond to our enquiry. The results presented here are based on comparison of the country information sheets (present in Appendix 2) and the MSDS.

## 3.1 The competent authority

It was attempted to find out which authorities should receive information of dangerous preparations and how the information is (made) available for medical purposes.
The following division can be made (see also Table 1a):

- **PIC**
  The Poisons Information Centre is the (legal) authority to receive information of dangerous preparations in: Belgium, Portugal, United Kingdom, Sweden, Ireland, the Netherlands (6/14)
  In Sweden and Ireland, Article 17 is implemented but not yet legally enforced. In the UK, Article 17 is not implemented in National legislation and notification is voluntary.
- **GOV to PIC**
  A governmental authority (GOV) is the legal authority to receive information of dangerous preparations and makes the information available to the Poisons Information Centre(s) in: Germany, Austria, Italy, Finland, Norway, France (6/14)
  In France, notification of preparations classified as $T^+$, T and C is mandatory before placing the products on the market. Notification of all other preparations is mandatory on specific request of both the governmental authority and the French PICs.
- **GOV**
  A governmental authority is the legal authority to receive information of dangerous preparations but the information is not made available to the Poisons Information Centre(s) in: Denmark, Spain (2/14)
  In Denmark the PIC relies on voluntary notification. In Spain it is only obligatory to notify detergents, cleaning products and bleaches (as defined in National legislation) to the PIC. The Spanish PIC relies on voluntary notification of detailed information for dangerous preparations because the appointed authority only receives MSDS and the Spanish PIC does not regard this as sufficient.

In some countries notification of cosmetic products (according to European Directive 76/768/EC) and/or notification of dangerous substances (according to European Directive 67/548/EC) is obligatory due to national legislation. This additional information is presented in Table 1a but is not further discussed in this report.

*Table 1a: Competent authority and the legal obligation for notification*

| **Country** | **Notification a legal obligation?** | | |
|---|---|---|---|
| | **Dangerous preparations** | **Dangerous substances** | **Cosmetics** |
| **PIC -** The Poisons Information Centre (PIC) is the (legal) authority to receive information of dangerous preparations. | | | |
| **The Netherlands** | **Yes** | No | No |
| **Belgium** | **Yes** | Yes | Yes |
| **Portugal** | **Yes** | Yes | Yes |
| **Sweden** | **Not yet** | No | Yes |
| **UK** | **No** | No | No |
| **Ireland** | **Not yet** | No | No |
| **GOV to PIC**- A governmental authority (GOV) is the legal authority to receive information of dangerous preparations and makes it available to the Poisons Information Centre (PIC). | | | |
| **Germany** | **Yes** | No | Yes |
| **Italy** | **Yes** | No | No |
| **Norway** | **Yes** | Yes | No |
| **Finland** | **Yes** | Yes | No |
| **Austria** | **Yes** | No | No |
| **France** | **Yes** | *No info* | Yes |
| **GOV -** A governmental authority (GOV) is the legal authority to receive information of dangerous preparations but it is not made available to the Poisons Information Centre(s). The notification procedures to GOV are also described below because sharing the information would be a future option. | | | |
| **Denmark** (PIC) | **Only voluntary notification to PIC** | | |
| *Denmark (GOV)* | *Yes* | *Yes* | *No* |
| **Spain** (PIC) | **Notification mandatory for some product groups to PIC** | | |
| *Spain (GOV)* | *Yes* | *Yes* | *Yes* |

## 3.2 Requirements on product composition and ingredient concentration

The requirements on product composition and ingredient concentration in the different countries are compared with the requirements for the MSDS. Only in 4 out of 14 countries, the MSDS can be used for notification. In contrast, for most competent authorities (10 out of 14) notification of product information with a MSDS is not sufficient. Additional information on the composition of the preparation and/or the concentration of its ingredients is necessary. Additional requirements asked by the 10 countries are summarized below and presented in Table 1b.

In this section, for Denmark and Spain, only the requirements for notification of preparation information to the PIC(s) have been taken into account. It is this information that is actually used to inform healthcare personnel in case of acute intoxications and therefore is of most interest for the comparison made in this report.

*Composition*
For a MSDS, the following requirements with regard to the composition of a preparation are indicated (according to EU Directive 2001/58/EC):
- Dangerous substances have to be stated above specified concentration thresholds, and,
- Substances not classified as dangerous are not obligatory to provide (with a few exceptions).

For notification of preparation information to the competent authority, additional requirements fall roughly into two categories. In 6 out of 10 countries, the exact composition is required, i.e. all dangerous as well as non-dangerous substances have to be notified. In 4 out of 10 countries, additional thresholds for substances are used, e.g. for non-dangerous substances or for specified substances.

Exact composition: Belgium, Portugal, France, Spain, Norway and Sweden
Additional thresholds: Italy, Germany, Austria and the Netherlands
No additional info: Finland, Denmark, United Kingdom and Ireland

In Belgium, only for consumer products the exact composition has to be notified. In Austria, only for preparations classified as $T^+$, T and C additional thresholds are defined. For the other dangerous preparations a MSDS can be used for notification.

*Concentration*
For a MSDS, there are no guidelines on how the concentration of the ingredients of a preparation should be presented. In practice, suppliers choose for (self-defined) concentration ranges.

For notification of preparation information to the competent authority, these by the supplier defined concentration ranges are not sufficient.
In 4 out of 10 countries, the exact concentration of the ingredients is required. One country uses self-defined concentration ranges. In 5 out of 10 countries it is a combination of these two, e.g. for some or all dangerous substances exact concentrations are required and for other substances concentration ranges are allowed.

| | |
|---|---|
| Exact concentration: | Portugal, Norway, France and the Netherlands |
| Specified ranges: | Italy |
| Combination: | Belgium, Sweden, Spain, Germany and Austria |
| No additional info: | Finland, Denmark, United Kingdom and Ireland |

The appointed authorities in Germany and Austria (for $T^+$, T and C preparations) define the accuracy with which the exact concentrations must be notified (e.g. 10% or 20% relative).

## 3.3 Methods of notification

In most countries, arrangements are made to receive preparation information on paper or in digital form. Electronic notification and processing is not yet common practice.
In this section, for Denmark and Spain, only the requirements for notification of preparation information to the PIC(s) have been taken into account. The requirements are summarized below and presented in Table 1b.

*Notification forms*
The preparation information is received through special forms, MSDS, or free formats either on paper or in digital form, e.g. Word- or PDF-files. The notification of preparation information takes place by postal mail (both paper and digital carriers, like e.g. CD-ROM) or e-mail.
Most countries that require additional information with regard to the composition, use special forms (8 out of 10). In Belgium and Portugal (2 out of 10) the format is free as long as the requirements are met. In Finland, Denmark, Ireland and the United Kingdom, a MSDS can be used. In some countries an additional registration form is necessary to identify the notified preparations.

*Electronic notification and processing*
In 7 out of 14 countries, various routes of electronic notification and processing have been developed. These routes are described in Appendix 3.

*Costs of notification*
In most countries (11 out of 14) notification is (still) without costs for the supplier.

*Table 1b: Method of notification and requirements on product composition and ingredient concentration.*

| Country | Format | Additional requirements | Electronic notification possible? | Costs for the supplier? |
|---|---|---|---|---|
| **PIC** - The Poisons Information Centre (PIC) is the (legal) authority to receive information of dangerous preparations. | | | | |
| **The Netherlands** | **Special form** | **Yes** | **Yes** | **No** |
| **Belgium** | **Free format** | **Yes** | **Yes** | **Yes** |
| **Portugal** | **Free format** | **Yes** | **No** | **No** |
| **Sweden** | **Special form** | **Yes** | **No** | **No** |
| **UK** | **MSDS** | **No** | **Yes** | **No** |
| **Ireland** | **MSDS** | **No** | **No** | **No** |
| **GOV to PIC** - A governmental authority (GOV) is the legal authority to receive information of dangerous preparations and makes it available to the Poisons Information Centre (PIC). | | | | |
| **Germany** | **Special form** | **Yes** | **Yes** | **No** |
| **Italy** | **Special form** | **Yes** | **Yes** | **No** |
| **Norway** | **Special form** | **Yes** | **Yes** | **Yes** |
| **Finland** | **MSDS** | **No** | **No** | **Yes** |
| **Austria** | **Special form** | **Yes** | **Yes** | **No** |
| **France** | **Special form** | **Yes** | **No** | **No** |
| **GOV** - A governmental authority (GOV) is the legal authority to receive information of dangerous preparations but it is not made available to the Poisons Information Centre(s).<br>The PIC(s) rely on voluntary notification or partial National legislation. The notification procedures to GOV are also described below because sharing the information would be a future option. | | | | |
| **Denmark** (PIC) | **MSDS** | **No** | **No** | **No** |
| *Denmark (GOV)* | *Special form* | *Yes* | *Yes* | *No* |
| **Spain** (PIC) | **Special form** | **Yes** | **No** | **No** |
| *Spain (GOV)* | *MSDS* | *No* | *No* | *No info* |
| Note: it is not always clear whether the method of notification and the requirements are obligatory due to legislation. In the case of appointed authorities this can be seen as such. | | | | |

# 4. Discussion

The results of our survey are discussed in three major topics, i.e. aspects of the competent authority, requirements for the notification of product composition and ingredient concentrations and the notification procedures. The requirements for the notification of product composition and ingredient concentrations are compared with those for the MSDS and where relevant, a comparison with the Dutch situation is made. In the end, using the information available, suggestions are made on how the current situation on product notification can be improved in Europe.

## 4.1 The competent authority

Just like in the Netherlands, in 5 other countries (6/14) the Poisons Information Centre (PIC) is the competent authority to receive the information on dangerous preparations. However, this is not (yet) in all cases legally enforced (UK, Ireland and Sweden). Appointing the PIC as the competent authority seems a logical choice because informing medical personnel (physicians, veterinarians, pharmacists) about symptoms and treatment of acute intoxications with dangerous preparations is the main task of PICs.

In the other countries however (8/14), a governmental authority is appointed. This is often a governmental department involved in taking measures to protect public health, like a department on product safety or a health protection agency. In most cases the information is subsequently made available to the PIC for medical purposes. Appointing a governmental department as the competent authority might prove to be an advantageous strategy when a country has more than one PIC. Having one centralized authority that distributes the information or shares an accessible database with PICs significantly reduces the workload for manufacturers who can use one portal instead of numerous. Also, it is not necessary for every individual PIC to maintain a database and get involved in time-consuming interaction with manufacturers or trade associations.
In Germany, for instance, one governmental authority receives the information on dangerous preparations and distributes it to the 10 German PICs. In France, a governmental authority receives all information on preparations classified as very toxic, toxic and corrosive and has a legal obligation to transfer the information to one of the PICs making it available in a National database. This specific PIC should also receive all the information received on specific request by both the governmental authority and the other PICs.

Appointing a governmental department as the competent authority also proves useful in the Scandinavian countries were so called Product Registers already existed before the European Directive became effective. Implementing article 17 is most efficiently done by appointing

that authority and making the information available for the PIC, as is the situation in Finland and Norway. In Sweden however, the PIC is appointed as the receiving authority.
Other examples show that exchange of information on preparations between an appointed governmental department and the PIC is not always established. In Denmark and Spain, the information received by the governmental authority is not made available to the PIC. Therefore, these PICs have to rely on voluntary notification from manufacturers.
In Spain, there is a special situation because the appointed authority only receives MSDS and the Spanish PIC does not regard this as sufficient.

In summary, the PICs in most countries receive the notified information on dangerous preparations, either directly as being the competent authority themselves, or indirectly from the governmental competent authority. In some countries the PIC still rely on voluntary notification.

## 4.2 Requirements on product composition and ingredient concentration

The focus in this survey was on the requirements concerning the product composition and concentration of the ingredients. For the PIC this is the most important information. It is evident from the results that the requested information varies between countries.

Despite the variation in requested information by different authorities, one major conclusion can be drawn from the results: information provided via a Material Safety Data Sheet (MSDS) is generally not sufficient. In most countries (10/14), the PIC requires more precise information on the composition of the product and the concentration of its ingredients then is present on a MSDS. Even if a PIC accepts a MSDS, this is usually only because they have to rely on voluntary notification and (feel) they are not in the position to make demands (personal communication).

In this report, a comparison with a MSDS is made because this format is a widely accepted standard by the industry. The requirements are described in the ‘MSDS Directive’ 2001/58/EC and have been legally implemented in every EU country. For the industry, the MSDS represents an acceptable ‘preparation information standard’ to inform professional and industrial users on the risks of (the use of) a product. From the manufacturers point of view it would be most efficient to also provide the PICs with the MSDS to comply with Article 17 of directive 1999/45/EC.

The Dutch Poisons Information Centre shares the opinion of other EU PICs that the MSDS does not provide sufficient detail for performing adequate risk assessments. There are two important reasons to ask for the more extensive product information.

Firstly, the MSDS is only designed for the professional user. Most of the time only brief first aid measures are mentioned but no extensive information is provided on the toxicological properties of the product itself or its ingredients. Therefore, the PIC has to perform its own toxicological risk evaluation of the product. Detailed knowledge of the composition is essential to perform this task.

Secondly, no guidelines are given on how precise the concentration of an ingredient should be specified and in practise this often results in the use of (wide) concentration ranges. Accurate information for risk assessment is necessary because concentration ranges for an ingredient introduce unnecessary uncertainties in the case of acute intoxications. With precise concentrations the quality of the risk assessment can be significantly improved.

Improvement of the MSDS in this regard is not expected with the forthcoming REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) legislation that will also replace the MSDS Directive 2001/58/EC. The requirements for notification of ingredients on the MSDS will be basically the same. Thresholds will still be used above which classified substances must be mentioned and concentration ranges are still allowed.

This report shows that various additional requirements are set in the different EU countries to improve the preparation information quality compared to a MSDS. Some choose the most straightforward solution, i.e. they request the exact composition and exact concentrations. Others have alternatives for the exact composition e.g. by defining additional thresholds for certain substances (especially for substances not classified as dangerous) above which they have to be mentioned. Instead of requiring the precise concentrations for all substances, the use of precise concentrations for some or all dangerous substances combined with (specified) concentration ranges for the others can be a solution.

*To an improved European standard of product notification*
The Dutch PIC experiences problems with the notification of adequate product information. The suppliers have difficulties to provide more information than present on the MSDS and to use the special Dutch format because of the workload.
An extra complicating fact is that large companies working on a ‘European wide market’ are confronted with a considerable variety in requirements between countries.

In the opinion of the Dutch PIC, the European competent authorities as well as the suppliers would benefit from European harmonisation of notification of product information.

Three important steps have to be taken to establish European harmonisation. The first step is for European PICs and (other) competent authorities to reach consensus on the specific information that is essential to perform their task. With good arguments, the industry should be convinced of the needs, necessary to provide medical help in case of exposure to toxic ingredients.

The second step is the development of a common (electronic) format for notification suitable for the industry and the competent authority. The MSDS format can be used as a basis.
The third step is the legal implementation of the requirements and the format on a European level as is also done for the MSDS in European Directive No. 2001/58/EC.

The initiative to establish European harmonisation of product notification is in the hands of PICs and competent authorities. An initiative by the EAPCCT (European Association of Poisons Centres and Clinical Toxicologists) 18 years ago to establish the requirements on product composition and ingredient concentrations could be helpful to start with. An informal working group composed by representatives from European PICs and European household industry provided guidelines on the information that should be made available to the PICs together with a standardized form. This work started in 1986, finished in 1989 and was distributed among PICs and EAPCCT members at that time. As a reminder, the guideline was published again in the EAPCCT newsletter of April, 1996 (see Appendix 4).

In this EAPCCT guideline, the following minimal requirements concerning the composition and concentrations were proposed:

| *Composition:* | *Concentration:* |
|---|---|
| All constituents (whatever their toxicity) must be mentioned. | Actual concentrations on very toxic, toxic and corrosive constituents ($T^+$, T and C). |
| The use of group or class names is acceptable when all substances in the group have similar properties. | Specified concentration ranges for other constituents: 0-1%, 1-5%, 5-10%, 10-20%, 20-30%, 30-50%, 50-75%, >75%. |

When comparing these guidelines with the various requirements of the responding countries, this proposal seems a reasonable compromise. It should be discussed whether this proposal is suitable for the industry and the competent authorities.

The use of concentration thresholds needs to be discussed. In 4 out of 10 countries that require more information than present on a MSDS (low) thresholds are used for both dangerous substances (as on the MSDS) and substances not classified as dangerous (1% in Germany and Austria, 5% in the Netherlands and Italy). Furthermore, discussion is needed whether precise concentrations for some or all dangerous substances (Xn, Xi amongst others) are needed.

The EAPCCT could play a major role in guiding these discussions and act as a representative of the PICs viewpoint on a European level. With the forthcoming EU-GHS regulation, that will change relevant EU directives (most importantly the preparations Directive No. 1999/45/EC) the product notification requirements can be properly incorporated in EU legislation.

## 4.3 Methods of notification

In the early 90's the PICs and governmental departments probably received a stream of paper documents concerning preparation information and it was quite a task to handle and archive all these paper documents. Additionally, quite a lot of the data where manually entered into product databases to improve the accessibility.

However, at the end of the 90's the digital version of the paper form becomes more popular and this both reduces the handling time of a notification and makes stored information more readily accessible. Most competent authorities accept digital versions in PDF- or Word format that can be sent by postal mail on CD-ROM/Diskette or even more conveniently, by E-mail. The workload is significantly reduced but still, the files should be archived in a way to keep track of all relevant changes and the history of a product. Maintaining such a database is still a lot of work.

The next step is the development of electronic formats for notification, which can be easily imported into databases of the competent authorities. It makes the processing of the information less time consuming, lowers the costs, is less fault sensitive (no manual handling anymore) and gives more possibilities for the security of data. Almost half of the responding countries have already developed means of electronic notification and they all differ (see Appendix 3).

For manufacturers, especially those that operate on the European market, the situation is troublesome. First of all, the format is different in every EU country and to generate the format, different computer programmes have been developed (see Appendix 3). A typical programme requires that the preparation information is transferred manually after which the format is generated. Transfer of information between the manufacturers database or MSDS-software into the required specific programme is often not (yet) available.

An agreed common European electronic format would be a huge advantage. In an ideal situation this format should be a simple electronic data exchange format with specified data in a specified order, separated by symbols/punctuation marks (e.g. comma's or @ symbols) that can be read into present databases automatically. Very promising in this regard is the XML format, as this has become a general electronic standard for data exchange between existing information systems.

Data exchange with an agreed European electronic format becomes possible when both competent authorities and industry adapt their information systems. For the competent authorities it requires that their database can process the format. For the industry it will be a huge advantage if the MSDS-software manufacturers adapt their software so it will generate the format.

If there is a European format, then a single European portal for notification of product information of all (dangerous) products on the European market becomes possible. From this central database the information can be provided to the different PICs and competent authorities. Nevertheless, it should be realised, that interfaces need to be built before this is possible because many different databases are already in use or under construction at a national level. If European harmonisation will be achieved this will be a great advantage for industry, competent authorities and PICs.

## 4.4 Summary of measures to be taken

The following steps are necessary to improve the process of notification of dangerous products for the industry and the competent authorities:

1. Consensus should be reached on a European level on which information is essential for medical purposes. The previous EAPCCT proposal (1989) seems a reasonable compromise and can serve as a starting point for further discussion.
2. The development of a European electronic data exchange format.
   A common European electronic data exchange format that makes automatic processing possible, will be ideal.
3. The requirements should be legally enforced, preferably on a European level and subsequently adopted without changes into the National legislation of the European countries.
4. MSDS-software should be able to generate the agreed European format.
5. The competent authorities databases in different EU countries should be adapted to process the agreed format.

# Appendix 1. Questionnaire

Thank you very much for filling in this questionnaire about the notification procedures of preparation information in your country. Please mark your answers by replacing a box □ by an **X**. Please feel free to provide any additional information at 'Remarks' or in the 'Additional Information' box at the end.
You can send a filled in questionnaire by E-mail (nvic-apr@rivm.nl) or a printed version by post to:
NVIC/RIVM
T.a.v. Ronald de Groot
Postbus 1, 3720 BA Bilthoven
The Netherlands

**Which bodies have to receive the product information?**

□ (all) poison centre(s) but NO other institutes.
□ (all) poison centre(s) and the following institutes:

□ one central institute/poison centre that makes the information available, which is:
Name:
Street and no or P.O.B:
Postal code:
Residence:

How is the information made available for the poison centres?

Remarks:

□ all products on the market.
□ all dangerous products according to directive 1999/45/EC.
Exceptions? □ NO □ YES, the following (classes of) products:

□ dangerous products according to directive 1999/45/EC and in addition (due to National legislation) the following (classes of) products:

Remarks:

**Which data have to be submitted and in what form?**

 Special form/sheet for notification.
Also Material Safety Data Sheet necessary?  YES  NO
 Only Material Safety Data Sheet (MSDS).
 MSDS + additional information, which is:

Remarks:

***(If there are any special forms used, please sent them us)***

**When does the product information have to submitted?**

 before or  after marketing of the product on the market.
Deadline for notification:

Remarks:

**Is there an electronic way to register the product information?**

 YES  NO
If yes, in which way is this achieved?

(In the Netherlands a computer programme can be used to electronically deposit product information. The programme generates export files which can be sent by E-mail. These export files will be read into the NVIC database)

**How is the received information stored and how is it accessible?**

**Is notification free?**

 YES  NO, the costs are:

Remarks:

**Are there information sheets or tutorials available about the notification procedure?**

 NO  YES

Remarks:

***(If yes, please send them to us)***

Are there new developments in product notification to be expected in the near future, both nationally an internationally?

 NO  YES

If yes, can you please explain the developments:

ADDITIONAL INFORMATION

# Appendix 2. Overview of notification procedures in EU Member States

## Explanation

The notification procedures are summarized for every EU Member State from which sufficient information was received. Below are some general remarks that explain what information is presented in every topic.

**Legislation**
The aim of this survey is to make an overview of notification procedures for dangerous preparations according to Article 17 of European Directive No. 1999/45/EC. Although in this survey it was not directly asked how this article was implemented in National legislation, information was regularly received and presented here.

**Making the information available for healthcare personnel**
Ultimately the Poisons Information Centres (PIC) of a country should be able to inform medical personnel about exposures to preparations by having access to the preparation information. The PIC can receive the information either directly or, indirectly, through a central institute making the information available.

**Competent authority and contact information**
The focus is on authorities using or making the preparation information available for medical purposes. Additional authorities receiving information for other purposes are not mentioned.

In some countries the PIC does not receive information and relies on voluntary notification. If a governmental authority is the legal authority to receive information but the information is NOT made available, the authority is mentioned if sharing the information would be a future option.

**Requirements on product composition and ingredient concentrations**
A summary of the main requirements concerning the composition and the concentration in which the ingredients of the preparations must be notified is given. The emphasis lies on the differences with the requirements for a Material Safety Data Sheet (MSDS) if there are any. The competent authority should be contacted for specific guidelines.

For comparison, the requirements for the MSDS are summarized below. More specific guidelines are provided in European Directive 2001/58/EC.

| *Composition:* | *Concentration:* |
|---|---|
| Dangerous substances have to be stated if present in the preparation above specified concentration thresholds.<br>$T^+$, T substances ≥ 0,1%<br>C, Xn, Xi substances ≥ 1%<br>(thresholds for other substances are not presented here but are also either 0,1 or 1%)<br><br>Substances not classified as dangerous don't have to be mentioned (with a few exceptions). | No guidelines are given for the use of exact concentrations or concentration ranges.<br>The ranges are also not specified. In practice, ranges are often used on the MSDS. |

**Method of notification**

*Notification forms*
The form used for notification is described. This can be a MSDS, a special form or a free format.
Forms that are sent as PDF- or Word file have been named 'digital' notification to distinguish it from electronic notification described below.

*Electronic notification/processing*
Electronic notification is defined as a way of notification of information in a specific file format that makes automatic processing of the information into a database possible. Sending documents as, for example, PDF-files by E-mail is not counted as electronic notification.

*Costs of notification*
In some countries costs are involved for the supplier.

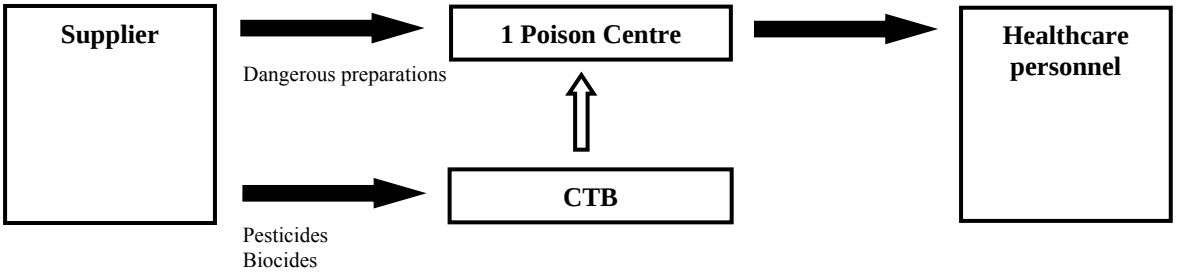
# The Netherlands

**Legislation**

The Food and Drug Act 'Notification of Product Information' (Staatsblad 1996, no. 38) implements the European Directive No. 1999/45/EC, effective as from 1 January 1997 (Staatsblad, no. 674).
In this Act the National Poisons Information Centre (part of the National Institute for Public Health and the Environment) is appointed as the authority where information regarding dangerous preparations can be registered in accordance with directive no. 1999/45/EC. Biocides and pesticides already have to be registered with the Board for the authorization of pesticides (CTB).

**Making the information available for healthcare personnel**

Exchange of preparation information between the CTB and the Dutch PIC has been legally arranged (Staatsblad 2004, no. 417). At this moment the exchange is not yet effective. The PIC and CTB are exploring the possibility of an electronic data transfer. Non-confidential information on active ingredients of biocides and pesticides is available through an internet website.




**Competent authority and contact information**

*Dangerous preparations:*
National Poisons Information Centre (NVIC).
P.O. Box 1
3720 BA Bilthoven
The Netherlands
Phone: +31 302508561
Fax: +31 302541511
E-mail: nvic-apr@rivm.nl
Website: www.vergiftigingeninformatie.nl

*Biocides and pesticides*:
Board for the authorization of pesticides (CTB)
P.O. Box 217
6700 AE Wageningen
The Netherlands
Phone: +31 317471810
Fax: +31 317471899
Website: www.ctb-wageningen.nl

**Note**: described below is the notification of dangerous preparations with the Dutch PIC. Information was not acquired about notification of pesticides and biocides with the CTB.

**Requirements on product composition and ingredient concentration** (legally defined)

| *Composition*: | *Concentration*: |
|---|---|
| In principle the full product composition must be stated. The rules are:<br>T, $T^+$ substances > 0,1%<br>C, Xn, Xi substances > 1%<br>Other substances > 5% | Exact concentration must be given but if the concentration in the product varies, specified ranges can be used. |
| The requirements are legally defined in the 'Food and Drug Act, Product Information Sheet' (Staatsblad 1996 no. 243). | |

**Method of notification**

*Notification forms*

The use of a Product Information Sheet (specified in the 'Food and Drug Act, Product Information Sheet') is a legal obligation. The special form and a tutorial are available from the website. The Product Information Sheet can be submitted on paper or digitally.

*Electronic notification/processing*

Electronic notification is possible. The NVIC has developed the computer programme PINDA (Preparation INformation DAtabase) (see Appendix 3). Electronic files are created by the programme and imported into a preparation database.

*Costs of notification*

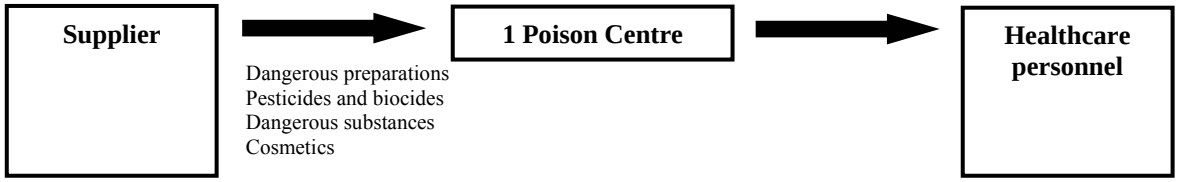
No costs are involved for the supplier.

# Belgium

### Legislation

The Centre National de Prévention et de Traitement des Intoxications (Belgium Poisons Information Centre) is appointed in national legislation as the authority where information on dangerous preparations according to 1999/45/EC (implemented by K.B. 11 January 1993/B.S. 17 may 1993), on pesticides (K.B. 28 February 1994/B.S. 11 May 1994) and on biocides (K.B. 5 September 2001/B.S. 12 October 2001) have to be notified.
Additional due to national legislation:
It is also obligatory to notify cosmetic products (K.B. 15 October 1997/ B.S. 16 January 1998) and dangerous substances (K.B. 13 November 1997/B.S. 26 March 1998) with the Centre National de Prévention et de Traitement des Intoxications.

### Making the information available for healthcare personnel




### Competent authority and contact information

Centre National de Prévention et de Traitement des Intoxications.
Rue Bruyn
1120 Bruxelles
Belgium
Phone: +32 22649640
Fax: +32 22649640
Website: www.poisoncentre.be

### Requirements on product composition and ingredient concentration

| *Composition:* | *Concentration:* |
|---|---|
| For consumer products: exact composition.<br><br>For industrial/professional products:<br>T, $T^+$ substances > 0,1%.<br>Xn, Xi substances > 1%.<br>In addition: 24 hour phone. no. must be noted where information about exact composition can be retrieved. If this is not possible then exact composition must be deposited (also for non hazardous substances). | For consumer products:<br>Exact concentration.<br>Only the concentration of non-hazardous substances can be stated in specified ranges: 2,5-10 %, 10-25%, 25-50%, 50-100%<br><br>For industrial/professional products:<br>Concentration ranges can be used (ranges not specified). |

Article 13 of K.B. 17 July 2002 (alteration of K.B. 11 January 1993) states that 'the chemical composition of the preparation and all information necessary to perform the task of abovementioned centre' must be notified. No specific guidelines are given in legislation but a refinement is given on the Poisons Information Centre website as summarized above.

**Method of notification**

*Notification forms*

The format is free. A Material Safety Data Sheet can be used. If the contents do not meet the requirements, a document with additional information may be necessary. The product information must be accompanied by a registration form ('EDF form'). The product information can be sent as Word or PDF-file together with the EDF form (available as Excel file). The special forms and the instructions are available from the website.

*Electronic notification/processing*

Electronic notification is possible. The MIS format (Access database) or the UDEPIC format can be used (see Appendix 3). For more information see the website.

*Costs of notification*

The costs for notification are 125 euro/product or product group.

# France

**Legislation**

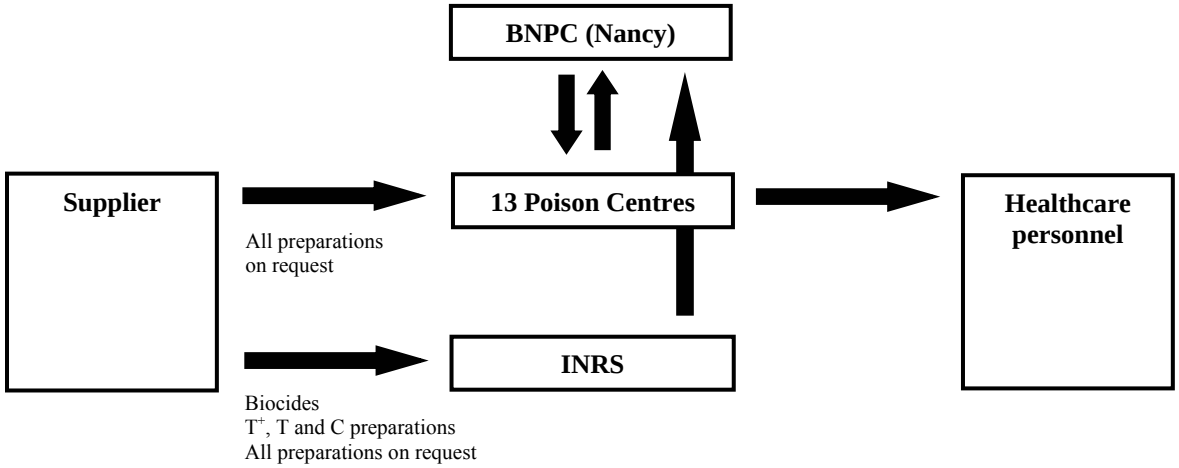
In France, the Institut National de Recherche et Sécurité (INRS) is appointed in National legislation (laws of 18-12-1996 and 16-12-2004) as the body to receive product information of dangerous preparations (including biocides) as mentioned in article 17 of Directive 1999/45/EC. For $T^+$, T and C preparations (including mutagenic cat. 1/2 (with R46), carcinogenic cat. 1/2 (with R45 or R49) and toxic for reproduction cat. 1/2 (with R60 or R61)) notification with the INRS is obligatory within 30 days after placing the products on the market. Biocidal products must be notified without delay. Other products must be registered on specific request of the INRS within 15 days.
Additionally, product information of any product on the French market (and not yet notified with the INRS) must also be made available in the shortest time possible to any Poisons Information Centre (PIC) on specific request of the PICs (so not necessarily before marketing). Exceptions are mentioned in National legislation (medicines a.o).
Additional due to national legislation:
Cosmetic products have to be notified to the PIC Paris, PIC Lyon and PIC Marseille, using a special form (the CERFA form or 'green card').

**Making the information available for healthcare personnel**

According to National legislation (law of 18-06-2002, J.O. Numéro 151 du 30 juin 2002 page 11301) the French PICs have a common information system called SICAP (Information System for Poisons Centres). It has two entities: the BNCI (National Database of Intoxication Cases) maintained by the Paris PIC and the BNPC (National Database of Composition and Products) maintained by the Nancy PIC. These two databases are linked, so an intoxication case (in the BNCI) is always linked to a product (in the BNPC).
Product information is gathered by individual PICs on request in order to answer clinical cases. It is a legal obligation to sent the information to the Nancy PIC for addition into the BNPC within 7 days after it is received.
The INRS also has a legal obligation to transfer all received preparation information to the Nancy PIC at least every three months, to make the information available to the French PICs.
The BNPC database is available for all French PICs through an Internet website with controlled access. A local update is made twice a year for all PICs.

From this survey it was not clear how the exchange of information between INRS/French PICs and the BNPC in Nancy is arranged and if all preparation information is effectively included in the BNPC database (as is described in legislation).

The INRS reports that the French PICs also have controlled access to the INRS database (ORFILA database) after a signed agreement. At least the Nancy PIC makes use of this.




**Competent authority and contact information**

Nancy Poisons Information Centre - Base Nationale Produit et Composition (BNPC)
Centre Hospitalier Universitaire
29 Avenue de Lattre de Tassigny
54037 Nancy
France
Phone: +33 383852192
Fax: +33 383852615
Website: www.centres-antipoison.net

Institut National de Recherche et Sécurité (INRS)
30 rue Olivier Noyer
F-75680 Paris Cedex
France
Phone : +33 140443000
Fax : +33 140443099
E-mail: info@inrs.fr
Website: www.inrs.fr

**Requirements on product composition and ingredient concentration** (legally defined)

| *Composition:* | *Concentration:* |
|---|---|
| Exact composition is requested. | Exact concentration is requested. |
| The requirements are legally defined in Art. R. 1341-2 of the Code de la santé publique. | |

**Method of notification**

*Notification forms*

The INRS recommends the use of two special forms, one for $T^+$, T and C preparations and one for biocidal products (available from the website). A MSDS, technical sheet and label must also be provided. By the French PICs, product information is received on paper or as a digital file (PDF, Word, etc.) on CD-ROM, diskette or by E-mail. From this survey it was not clear if the PICs use the same special forms as the INRS.

*Electronic notification/processing*

Electronic notification is NOT possible. The Nancy PIC is collaborating with the INRS to develop an Internet declaration route to both systems (probably finished in September 2007).

*Costs of notification:*

No costs are involved for the supplier.

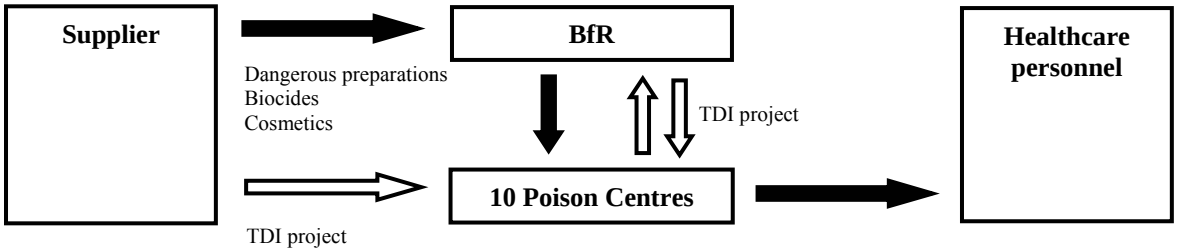
# Germany

### Legislation

Due to National legislation, dangerous preparations and biocides have to be notified with the Bundesinstitut für Risikobewertung (BfR) (§16e Abs.1 'Gefährliche Produkte' des Chemikalien-gesetzes). This will include most dangerous preparations according to Directive 1999/45/EC. Article 17 of this directive is not directly implemented in National legislation.
Exceptions: Notification with the BfR is not obligatory for non consumer products in hazard class explosive (E), highly flammable (F), extremely flammable ($F^+$), Oxidizing (O), Irritant (Xi), Harmful (Xn) and Dangerous for the Environment (N).
Additional due to national legislation:
It is also obligatory to notify cosmetic products with the BfR (Kosmetikverordnung § 5d).

### Making the information available for healthcare personnel

The information is made available to the 10 Poisons Information Centres (PICs) in Germany by the BfR via a monthly electronic data exchange by CD-ROM.
The TDI-project:
Although the notification of preparation information to the BfR is most the important route, notification to the individual German PICs is also a possibility, mainly for detergents using the EMIL programme (see Appendix 3 and below). Subsequently the product information is electronically distributed between all PICs and the BfR. This standardised procedure for product data exchange is part of the Research and Development project 'Toxikologischer Dokumentations- und Informationsverbund' (TDI).




### Competent authority and contact information

Bundesinstitut für Risikobewertung (BfR) (former BgVV)
Zentralstelle für Vergiftungen
Thielallee 88-92
14195 Berlin
Germany
Phone: +49 18884123460
Fax: +49 18884123929
Website: www.bfr.bund.de

**Requirements on product composition and ingredient concentration** (legally defined)

| *Composition:* | *Concentration:* |
|---|---|
| 1) Active ingredients of biocides.<br>2) $T/T^+$, carcinogenic, mutagenic, sensitizing substances and reproductive toxins ≥ 0,1%.<br>3) Strong corrosive acids and caustics, quaternary ammonium compounds and phenols ≥ 0,1% (if not under 1).<br>4) Corrosives and at room temperature volatile halogen hydrocarbons, petroleum distillates and glycols ≥ 1% (if not under 1 or 2).<br><br>All other ingredients if the concentration in the preparation is ≥ 1%. Under certain conditions these substances can be grouped. | Substances under 1-4:<br>The concentration must be given with an accuracy of 10% (relative). Specified ranges can be used for substances < 5% and if the exact concentration is not necessary for the classification of the product: 0-0,1%, 0,1-0,5%, 0,5-1%, 1-1,5%, 1,5-2%, 2-3%, 3-4%, 4-5%.<br><br>All other substances:<br>The concentration must be given with an accuracy of 20% (relative). Specified ranges can be used for substances < 10% and if the exact concentration is not necessary for the classification of the product:<br>1-2%, 2-4%, 4-7%, 7-10%. |
| The requirements are legally defined in Appendix 1 of the 'Giftinformationsverordnung' (BGB I.I.S. 2518) | |

**Method of notification**

*Notification forms*

A special form (with tutorial) is available for product information and one for company data.

*Electronic notification/processing*

Electronic notification is possible for detergents and biocides with the computer programme EMIL (Erfassings- und Meldeprogramm zur Informationsübermittlung für Pflege- und Reinigungsmittel). The programme was developed in the TDI project. (see Appendix 3)

*Costs of notification*

No costs are involved for the supplier.

**The EPECs project**

In Germany the 'Giftinformationszentrum-Nord' (PIC-Nord) receives MSDS for professionally used products, based on individual contracts with local companies. A recent initiative is to extend this database and start an European Poisoning Emergency Call Service for Safety Datasheets (EPECS). European PICs are asked to join and share MSDSs (for which they should contract manufacturers) via a secured internet database and participate in a multi-language emergency call service.

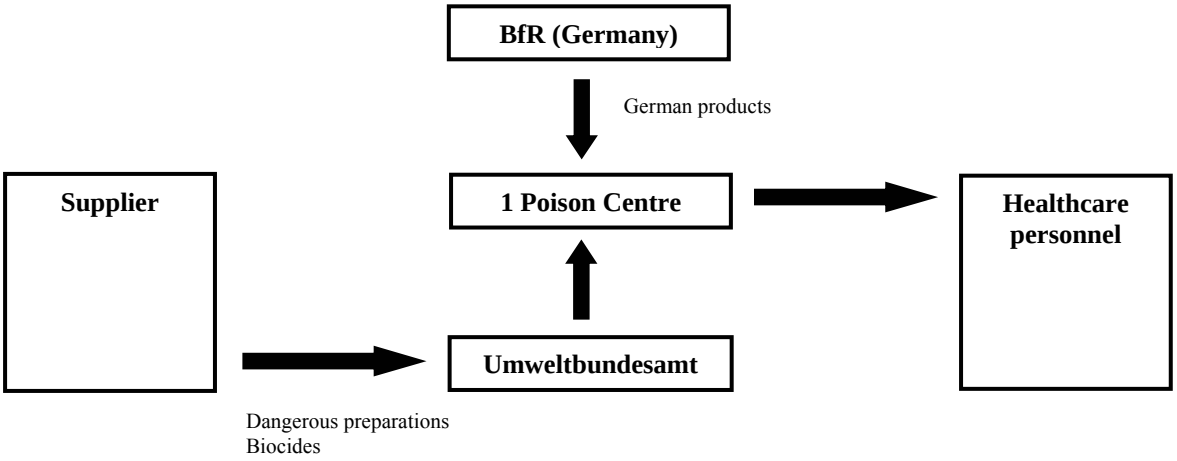
# Austria

## Legislation

Due to the 'Giftinformations-Verordnung 1999' (Bundesgesetzblatt II No. 137/1999) preparations classified as very toxic ($T^+$), toxic (T) and corrosive (C) must be notified to the Umweltbundesamt (Federal Environmental Agency). In addition, other dangerous preparations (and biocides) must also be registered to this agency due to the 'Chemikalienverordnung 1999' (§25 Abs. 8) (Bundesgesetzblatt II No. 81/2000).
Additional due to national legislation:
It is legally required to notify non dangerous preparations if they contain, in an individual concentration of ≥ 1% by weight for non-gaseous preparations or ≥ 0,2% by volume for gaseous preparations, at least one substance posing health or environmental hazards or one substance for which Community workplace exposure limits exist.

## Making the information available for healthcare personnel

The Umweltbundesamt provides the Austrian Poisons Information Centre (PIC) continuously with product information by CD-ROM (mandatory due to § 6 of the Giftinformations-Verordnung 1999). In addition, information on German products is received by the Austrian PIC from the Bundesinstitut für Risikobewertung (BfR) in Germany.
The Austrian PIC also receives MSDS directly from the industry on a voluntary basis.




## Competent authority and contact information

Umweltbundesamt (Abt. Chemikalien)
Spittelauer Laende 5
A-1090 Wien
Austria
Phone: +43 1313045633
Fax: +43 1313045660
E-mail: sdbreg@ubavie.gv.at
Website: www.umweltbundesamt.at

**Requirements on product composition and ingredient concentration** (legally defined)

| *Composition:* | *Concentration:* |
|---|---|
| For $T^+$,T and C preparations:<br>$T^+$, T ≥ 0,1%<br>C ≥ 1%<br>(except if there is a lower threshold mentioned in Directive 67/548/EC) | For $T^+$,T and C preparations:<br>The concentration must be given with an accuracy of 10% (relative). Specified ranges for substances < 5%: 0-0,1%, 0,1-0,5%, 0,5-1%, 1-1,5%, 1,5-2%, 2-3%, 3-4%, 4-5%. |
| All other ingredients if the concentration in the preparation is ≥ 1%. | For other substances:<br>The concentration must be given with an accuracy of 20% (relative) . Specified ranges for substances < 10%: 1-2%, 2-4%, 4-7%, 7-10%. |
| For other dangerous preparations:<br>MSDS. | For other dangerous preparations:<br>MSDS. |
| The requirements are legally defined in Appendix 1 of Giftinformations-Verordnung 1999 | |

**Method of notification**

*Notification forms*

The Material Safety Data Sheet (MSDS) is used as notification form and can be sent by diskette, CD-ROM or E-mail as .txt, .htm, .html, .doc, .rtf or .pdf file. When technically impossible, paper forms are excepted.

For very toxic, toxic and corrosive preparations an additional form is necessary besides the MSDS. The format is described in Appendix 1 of the Giftinformations-Verordnung 1999 and consists of company data and composition. There is also a special form to report changes in the preparation information.

*Electronic notification/processing*

Every MSDS must be accompanied by an electronic registration form (‘Schlüsseldatei’) (see Appendix 3). This is a ’.key’-file made by for example Windows Notepad, which will be used to identify the MSDS and to electronically process some important information in the database (like name and composition). The exact format is described in a document (‘SDB_meldeleitfaden.pdf’), which can be downloaded from the website.

No information was gathered on the possibility of electronic notification of the additional forms necessary for toxic, very toxic and corrosive preparations.

*Costs of notification*

No costs are involved for the supplier. Companies using the PIC emergency number on the MSDS are asked for a voluntary fee by the Federal Institute of Health.

# Spain

**Legislation**

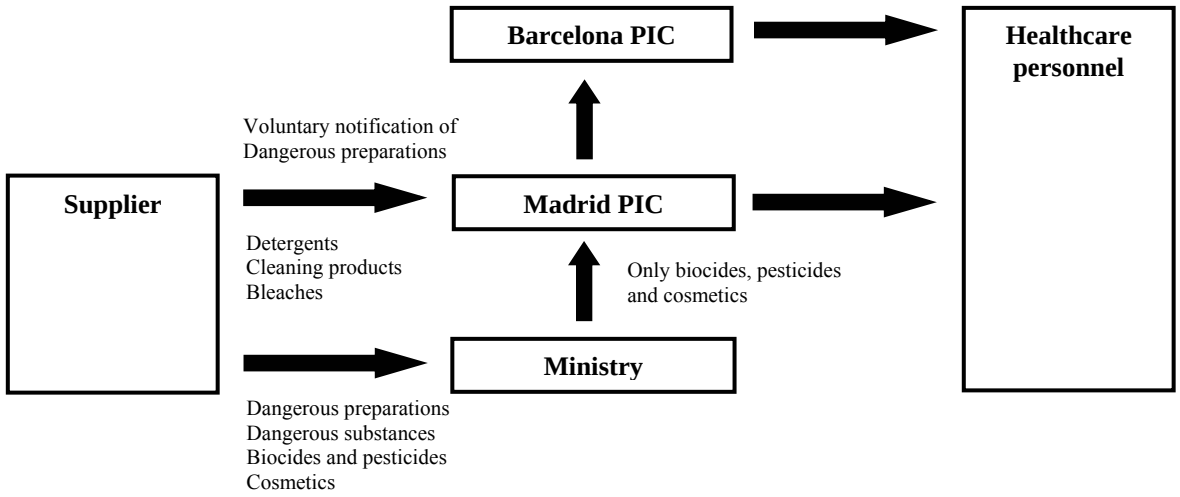
Article 17 of European Directive 1999/45/EC is implemented in National legislation. Dangerous preparations, biocides and pesticides have to be notified to the Ministerio de Sanidad y Consumo.

Additional due to national legislation:

Products in the scope of the Spanish Regulation on Detergents and Cleaning Products (R.D. 770/1999) have to be notified with the Servicio de Información Toxicológia (Madrid Poisons Information Centre) independent of hazard classification. It concerns both industrial and domestic products. Likewise, bleaches also have to be notified with the Madrid PIC according to the Spanish Regulation on Bleaches (R.D. 3360/83 and R.D. 349/93). Dangerous substances and cosmetic products on the other hand have to be registered with the Ministerio de Sanidad y Consumo.

**Making the information available for healthcare personnel**

For dangerous preparations the Madrid PIC relies on voluntary notification from the supplier. The information on dangerous preparations is not made available by the Ministry because they only receive MSDS which is not regarded as sufficient for the Madrid PIC. There is however some exchange of information: cosmetic frame formulations can be seen through an intranet connection and biocides and pesticides are received in paper form by Madrid PIC from the Ministry. The Barcelona PIC has an intranet connection with the Madrid PIC to make preparation information available.



**Competent authority and contact information**

*Detergents, cleaning products and bleaches:*
Servicio de Información Toxicológia (SIT)
Sección de Documentación
C/Luis Cabrera, 9
28002 Madrid
Spain
Phone: +34 915628585
Fax: +34 915636924

*Dangerous preparations and biocides:*
Ministerio de Sanidad y Consumo
Subdirección General de Farmacia y
Productos Sanitarios
Paseo del Prado 18-20
28014 Madrid
Spain
Phone: +34 915596100
Fax: +34 915964480
E-mail: oiac@msc.es

**Note**: described below is the notification of preparations with the Madrid PIC. Information about the method of notification with the Ministerio de Sanidad y Consumo was not acquired.

**Requirements on product composition and ingredient concentration**

| *Composition:* | *Concentration:* |
|---|---|
| All constituents, whatever their toxicity, must be mentioned. Constituents classified as $T^+$, T or C must be indicated with chemical name.<br>Under certain conditions name of the group or class can be used for the other ingredients. | For $T^+$, T and C substances real nominal percentages must be used.<br><br>For other constituents specified ranges can be used: 0-1%, 1-5%, 5-10%, 10-20%, 20-30%, 30-40%, 40-50%, 50-75%, >75%. |

**Method of notification**

*Notification forms*
A special Product Information Form must be used. Product labels or photocopy of product labels must also be sent. In addition there are two letters with predetermined layout, designed to communicate the list of notified products to the Madrid PIC. One for new entries and modification and one for withdrawals. Tutorial is available. Information must be sent by postal mail.

*Electronic notification/processing:*
Electronic notification is not possible.

*Costs of notification*:
No costs are involved for the supplier.

# Portugal

**Legislation**

Due to National legislation, product information of dangerous preparations (Decreto - Lei 82/2003), biocides (Decreto - Lei 121/2002) and pesticides (Decreto - Lei 94/98) must be notified with the Centro de Informação Antivenos (CIAV) (Portuguese Poisons Information Centre).

Additional due to national legislation:

The following products also have to be notified:

Dangerous substances (Decreto - Lei 82/95)

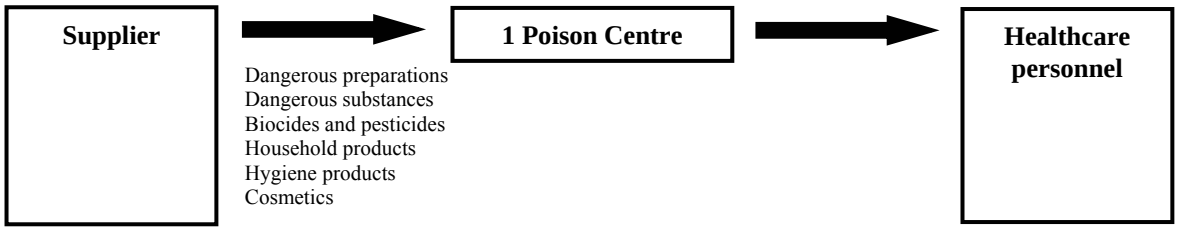
Household products (Decreto - Lei 397/86)

Cosmetic and personal hygiene products (Decreto - Lei 296/98)

There is a special arrangement for veterinarian products and food supplements.

**Making the information available for healthcare personnel**

The Poisons Information Centre informs healthcare personnel in case of acute intoxications.




**Competent authority and contact information**

Centro de Informação Antivenos (CIAV).

Rua Almirante Barroso, 36

1000-013 Lisboa

Portugal

Phone: +35 1213303284

Fax: +35 1213303275

Email: ciav.tox@inem.min-saude.pt

**Requirements on product composition and ingredient concentration**

The qualitative and quantitative formula must be notified.

No further specific requirements are given.

**Method of notification**

*Notification forms*

There is no obligatory form. There is a short list of requirements.
Product labels or photocopy of product labels must also be sent. A registration form (format not given) consisting of a list of notified products also has to be sent in twofold.

*Electronic notification/processing*

There is a computer programme available for the notification of pesticides and biocides.
No further information was gathered.

*Costs of notification*

No costs are involved for the supplier.

# Italy

**Legislation**

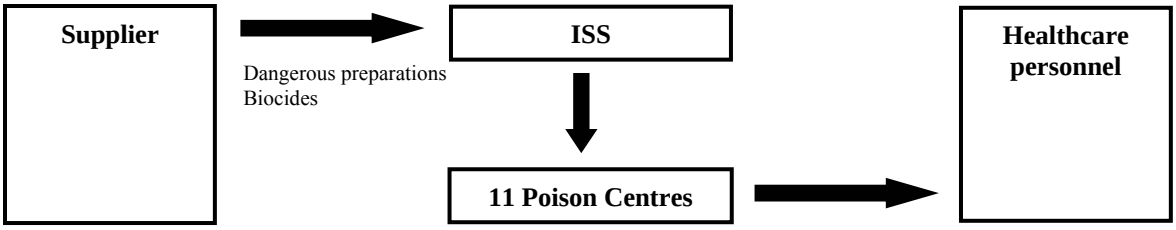
Due to National legislation (Legislative decree n. 65/2003, putting into effect 1999/45/EC and 2001/60/EC), product information of dangerous preparations and biocides must be notified with Instituto Superiore di Sanità (ISS).

Additional due to national legislation:

Medical devices also have to be registered according to the National Legislative Decree n.174/2000.

**Making the information available for healthcare personnel**

The Italian Poisons Information Centres have access to the ISS 'Data Bank on Dangerous Preparations'.




**Competent authority and contact information**

Instituto Superiore di Sanità (ISS)
Laboratoire di Tossicologia Applicata
Progretto Banca Dati Preparati Pericolosi
Viale Regina Elena 299
00161 Roma
Italy
ISS website: www.iss.it
Dangerous preparations website: www.preparatipericolosi.iss.it

**Requirements on product composition and ingredient concentration** (legally defined)

| *Composition*: | *Concentration:* |
|---|---|
| Dangerous substances:<br>Exact chemical name must be stated.<br>$T^+$, T, carcinogenic, mutagenic and substances toxic for the reproduction > 0,1%.<br>C, Xn, Xi and sensitizing substances > 1%.<br>Substances with physical risks (F, F, O, E) > 1%.<br>Non-dangerous substances:<br>Must be mentioned > 5%.<br>Family name can also be used. | Exact percentage is optional, otherwise specified ranges must be used:<br>0-1%, 1-5%, 5-10%, 10-20%, 20-30%, 30-50%, 50-75%, 75-100%. |

The requirements are legally defined in part B of Legislative decree n. 65/2003.

**Method of notification**

*Notification forms*

Electronic notification is obligatory. Notification by paper or digital files (PDF, Word etc.) is not allowed.

*Electronic notification/processing*

Electronic notification is obligatory. The computer programme 'ISS Formula' can be downloaded or obtained as CD-ROM from ISS (see Appendix 3). A tutorial is available. Export files in ZIP format can be sent by FTP (File Transfer Protocol) on the ISS website. Using E-mail or regular post (diskette, CD-ROM) is also possible. Each sending must be accompanied by a cover note with information on the company and contact person.

To transfer data included in internal companies databases to the ISS database, the generation of a compatible format without using the ISS Formula programme is also accepted. An example Export file is available on the ISS website or on the dangerous preparations website.

*Costs of notification*

No costs are involved for the supplier.

# Finland

**Legislation**

Due to National legislation, product information of dangerous preparations (according to 1999/45/EC) must be notified with the Product Register Unit of the Product Control Agency for Welfare and Health (Decree of the Ministry of Social Affairs and Health on submitting information on chemicals 374/2002).

Additional due to national legislation:

It is obligatory to notify non dangerous preparations if they contain one or more substances that are dangerous to health or the environment or a substance for which there is an occupational exposure limit, if the concentration of such a substance exceeds 1% by weight in solid or liquid preparations or 0,2% by volume in gaseous preparations.

Dangerous substances (according to 67/548/EC) also have to be notified. However, it is not necessary to provide information on chemicals which are used in industrial or scientific research and development and if the total amount of a hazardous substance annually manufactured/imported is so small that it cannot be considered as a risk.

**Making the information available for healthcare personnel**

The Finnish Poisons Information Centre has access to the product database through a direct internet connection.


**Competent authority and contact information**

Product Control Agency for Welfare and Health, Chemicals Department, Product Register Unit.
P.O. Box 686 (Uimalankatu 1)
FI-33101 Tampere
Finland
E-mail: tuote.rekisteri@sttv.fi
Phone: +35 832608200
Fax: +35 832608222
Website: www.sttv.fi

**Requirements on product composition and ingredient concentration**

| *Composition:* | *Concentration:* |
|---|---|
| MSDS. | MSDS. |

**Method of notification**

*Notification forms*

A Material Safety Data Sheet (MSDS) can be used. Codes for the use and industrial categories of the ingredients have to be noted. An adjusted MSDS form to include this information is available but the use is not obligatory. This form and instructions are available from the website. Forms can be sent as Word or PDF-file on diskette or CD-ROM. Paper forms are accepted as well.

*Electronic notification/processing*

Electronic notification is not possible.

*Costs of notification*

Costs of notification are 30 euro/product/year.

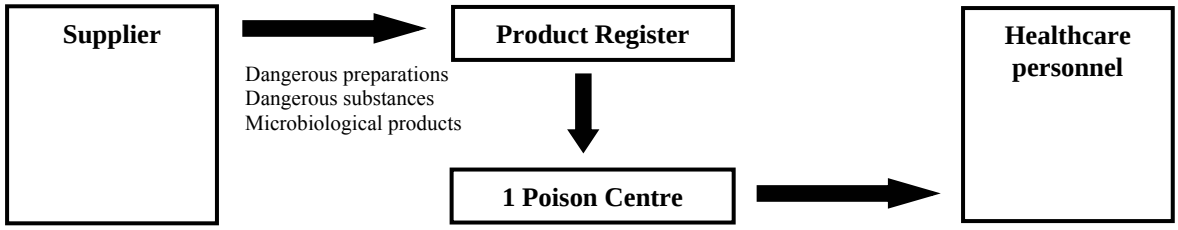
# Norway

## Legislation

The Norway Product Register requires information on all products that are classified in one of the danger categories in the Chemical Labeling Regulations section 6, or a chemical for which labeling is mandatory pursuant to section 16 (OAR labeling) if the quantity placed on the market each year is 100 kg or more (National legislation). It is assumed that this will include dangerous preparations according to 1999/45/EC and dangerous substances according to 67/548/EC above 100 kg manufactured/year.
Note that Norway is not an EU country so implementation of article 17 of directive 1999/45/EC is not mandatory.
Additional due to national legislation:
Microbiological products must be declared regardless of quantities.

## Making the information available for healthcare personnel

The Norway Poisons Information Centre has access through a secure, encrypted line.




## Competent authority and contact information

Produktregisteret
P.O. box 8180
Dep. N-0034 Oslo
Norway
Phone: +47 22054871
Fax: +47 22054899
E-mail: produktregisteret@produktregisteret.no
Website: www.produktregisteret.no

**Requirements on product composition and ingredient concentration**

| *Composition:* | *Concentration:* |
|---|---|
| Complete chemical formulation.<br><br>For biocides only 'active substances' have to be noted. | Exact weight percentage (not intervals) for each constituent up to 100%.<br><br>For products labeled with respect to fire or explosion hazard, all substances that gave rise to this classification must be listed with exact weight percentage. Other substances must be listed but information on percentages by weight is optional. |

**Method of notification**

*Notification forms*

A special form is available. Different forms are used for biocides/plant protection products and raw materials. Notification forms and instructions are available on website. Sending the preparation information by postal mail is preferred (if not using eDeclaration). Information sent by E-mail is printed and handled as ordinary mail.
The information is updated annually.

*Electronic notification/processing*

Electronic notification is possible. There is an electronic collection with XML-format and secure transfer ('eDeclaration'). At this moment, only for Norwegian companies, or companies with offices in Norway. (see Appendix 3).

*Costs of notification*

There are costs involved for the supplier. Information on the charge was not acquired in this survey.

# Sweden

## Legislation

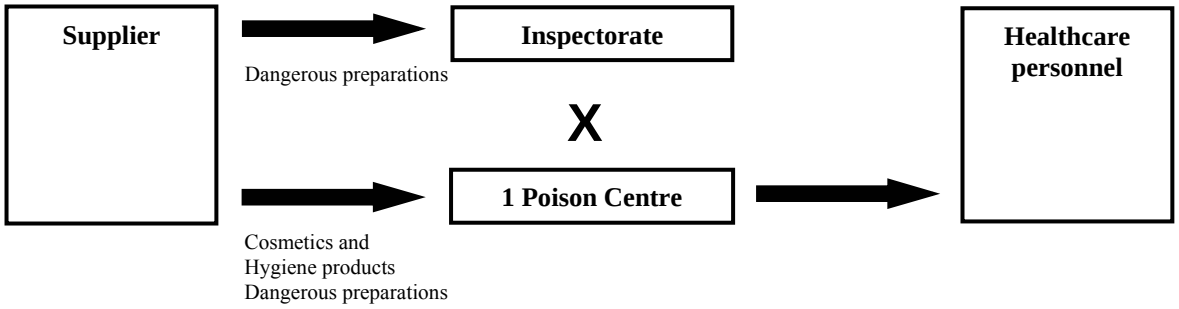
The Swedish Poisons Information Centre (PIC) is appointed as the competent authority responsible for receiving information about dangerous preparations, with reference to Article 17 of directive 1999/45/EC. The problem is that the directive has not been fully implemented into the Swedish legislation. The last paragraph (Member States shall ensure that the appointed bodies have at their disposal all the information required from the suppliers or persons responsible for marketing to carry out the tasks for which they are responsible) has not been implemented, meaning that it is not compulsory to provide the PIC with information about the composition of the products.

Additional due to national legislation:

Due to National legislation it is only compulsory to register cosmetics and hygiene products with the PIC. Products must also be registered with the National Chemicals Inspectorate if the product volume manufactured or imported reaches the minimum amount of 100 kg. This will probably include most dangerous preparations according to 1999/45/EC.

## Making the information available for healthcare personnel

Information is not shared between the Swedish Poisons Information Centre and the National Chemical Inspectorate, although at some times they may consult the Inspectorate (access on payment). Upcoming negotiations with the government will maybe make the information available in the near future.




## Competent authority and contact information

Swedish Poisons Information Centre.
Karolinska Hospital
SE-171 76 Stockholm
Sweden
Phone: +46 86100586
Fax: +46 8327584
Website: www.giftinformation.se

National Chemicals Inspectorate
P.O. Box 1384
SE - 171 27 SOLNA
Sweden
Phone: +46 87831100
Fax: +46 87357698
Email: kemi@kemi.se
Website:www.arbejdstilsynet.dk\Produktregisteret

**Note**: First, the (voluntary) notification of preparations with the Swedish PIC is described below. And then, after explaining the future possibilities, the notification of preparations with the Inspectorate is described.

**Requirements on product composition and ingredient concentration (PIC)**

| *Composition:* | *Concentration:* |
|---|---|
| All the ingredients in the product (except impurities less than 1%) should be declared. The use of group or class names is acceptable when all substances in the group have similar toxicological properties. | The concentration of $T^+$,T, C and Xn ingredients should be reported as exactly as possible.<br><br>For other ingredients specified concentration intervals are accepted: 0-1%, 1-5%, 5-10%, 10-20%, 20-30%, 30-50%, 50-75%, 75-100%. |

**Method of notification (PIC)**

*Notification forms*

A special form is used and available on the website. Extra information is necessary if only a Material Safety Data Sheet is sent. Product information can be sent in the following formats: ASCII Text (txt), GIF, JPG, Microsoft Rich Text Format (rtf), Microsoft Word, PDF, TIF or Html. One file for each product.
Information can be sent by CD-ROM, floppy disks or by E-mail (preferred). Paper copies are also accepted.

*Electronic notification/processing*

Electronic notification is not possible. A parameter file (txt file) is necessary to help the PIC attach each document file to the right product name and company. Instructions are given on the website.

*Costs of notification*:

No costs are involved for the supplier.

**Future possibilities**

Products must be registered with the National Chemicals Inspectorate if the product volume manufactured or imported reaches the minimum amount of 100 kg. This requirement applies to chemical products assignable to any of the product categories included in an Appendix of the Chemical Products and Biotechnical Organisms Ordinance (1998:941). Exceptions can be found on the website. The scope as defined in National legislation will probably include most dangerous preparations according to 1999/45/EC above 100 kg manufactured/year.

At the moment information is not shared between the Swedish Poisons Information Centre and the National Chemical Inspectorate and companies should notify with both authorities.

There are two reasons that lead to these circumstances. The Swedish PIC already collected product information before the Product Register started in 1976 and because in the beginning the importers/producers only had to declare the classified substances with the Product Register, the PIC continued in this way. Secondly, the notification of products with the Product Register takes place once a year, after the products have been manufactured or imported and the PIC needs the information as soon as the products are marketed.
Still, it would be useful for the Swedish PIC to have access to the Product Registers database and upcoming negotiations with the government will maybe make the information available in the near future.

Described below are the requirements and the method of notification with the Product Register to illustrate which additional information could be available.

**Requirements concerning the composition of the preparation (Inspectorate)**

| Composition: | Concentration: |
|---|---|
| Substances:<br>1) that give the product its properties dangerous to health or environment.<br>2) included as preservatives.<br>3) known to be toxic to reproduction, carcinogenic or sensitizing.<br>4) marked with * in App. 1 to KIFS 1998:8, irrespective of concentration.<br>5) not marked with * in App. 1 if they are included with at least 1%.<br>6) included in products with customs tariff Nos. 22, 28 or 29, including impurities with a concentration of > 1%.<br>7) included with > 5% by weight. | As accurately as possible and within the interval 0-1%, for substances under 1), 2) and 3).<br>Other concentrations may be rounded up or down to nearest whole percentage.<br>Some special rules for substances under 4), 5), 6) and for products under other customs tariff numbers.<br>For paint and lacquer products intervals can be used. |

**Method of notification (Inspectorate)**

*Notification forms*

Special forms, also for changes in product composition. Forms and tutorials are available on website.

*Electronic notification/processing*
Electronic registration is not possible at the moment.
The inspectorate is working on an electronic registration system (expected to be functional in 2007). Ordinary postal mail is preferred above E-mail because proper signature is necessary. Fax is an option.

*Costs of notification*
For the supplier there are cost involved in notification.
The charge is determined by product quantity and the number of products reported (only if quantities are above 1000 kg).

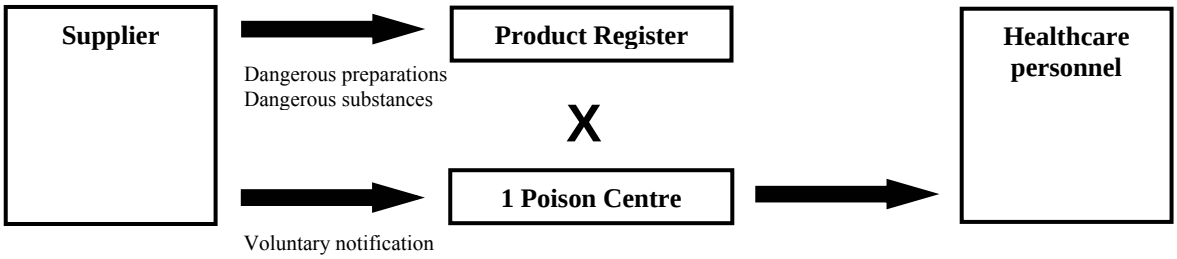
# Denmark

### Legislation

In summary, substances and materials that are classified as dangerous in accordance with the Danish Ministry of the Environment's regulations ('Products with danger symbol') have to be notified with the product register if the quantities produced or imported are above 100 kg. Exceptions can be found on the website. This will include dangerous preparations according to 1999/45/EC and dangerous substances according to 67/548/EC (see below), produced or imported above 100 kg/year. The Product Register is also appointed the legal authority to receive preparation information according to article 17 of directive 1999/45/EC.

### Making the information available for healthcare personnel

The product register does not share information with the Danish Poisons Information Centre. Making the information available is only possible after encrypted data transmission is established and the Danish PIC does not have the practical and financial means to realise this. However, the are legally entitled to access the registry. If necessary, information about a certain product can be received by telephone but the Product Register is only available during business hours.




### Competent authority and contact information

Product Register
Landskronagade 33
2100 Kobenhavn O
Denmark
Phone: +45 39152000
Fax: +45 39299712
E-mail: pd@arbejdstilsynet.dk
Website: www.arbejdstilsynet.dk

Danish Poison Information Centre
Clinic of Occupational Medicine
Bispebjerg Hospital
Bispebjerg Bakke 23
2400 Copenhagen NV
Denmark
Phone: +45 35316060
Fax: +45 35316070
Email: clintox@bbh.hosp.dk

**Note**: First, the voluntary notification of preparations with the Danish PIC is described below. And then, after explaining the future possibilities, the notification of preparations with the Product Register is described.

**Requirements on product composition and ingredient concentration (PIC)**

| *Composition:* | *Concentration:* |
|---|---|
| No special requirements. (MSDS is accepted) | No special requirements. (MSDS is accepted) |

The Danish PIC would like to receive the MSDS as a minimum although more specific information is wished for.

**Method of notification (PIC)**

*Notification forms*

Free format. Any product information form is accepted. In practice a MSDS will often be received but other forms are welcome. Information is received by CD-ROM or paper forms.

*Electronic notification/processing*

Electronic notification is NOT possible.

Costs of notification

No costs are involved for the supplier.

**Future possibilities**

In Denmark the Product Register is appointed the legal authority to receive preparation information according to article 17 of directive 1999/45/EC. However, this information is not made available to the Danish PIC at this moment. Sharing the information would be a future option to functionally implement the European legislation. Described below are the requirements and the method of notification with the Product Register to illustrate which information could be available.

**Main requirements concerning the composition of the preparation (Product Register)**

| *Composition:* | *Concentration:* |
|---|---|
| Exact information is required for:<br>- Substances > 1%<br>- $T^+$, T, carcinogenic, mutagenic or reprotoxic substances > 0,1%<br>- Substances included in the 'List of Dangerous Substances' or are subject to the special labelling rules and therefore have a lower percentage threshold.<br>- no minimum threshold for preservatives.<br>Other substances and materials can be declared by a general technical term, for example, perfume, filler, colouring. | Percentages in precise values.<br>Concentration intervals are not accepted. |

**Method of notification (Product Register)**

*Notification forms*

A special form is available. Not available on website.

*Electronic notification/processing*

Electronic notification is possible via the Product Registry's Internet notification system.

*Costs of notification*

No costs are involved for the supplier.

**The EPECs project**

The Danish PIC is exploring the possibility to join the EPECS project. In Germany the 'Giftinformationszentrum-Nord' (PIC-Nord) receives MSDS for professionally used products, based on individual contracts with local companies. A recent initiative is to extend this database and start an European Poisoning Emergency Call Service for Safety Datasheets (EPECS). European PICs are asked to join and share MSDSs (for which they should contract manufacturers) via a secured internet database and participate in a multi-language emergency call service.

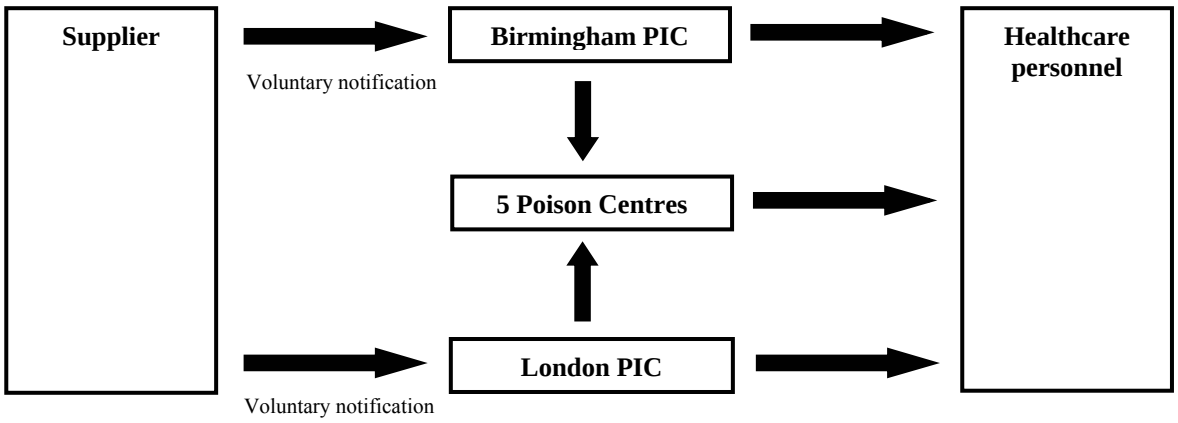
# United Kingdom

**Legislation**

Article 17 of European directive 1999/45/EC is not implemented in National legislation and notification of preparation information is not mandatory in the United Kingdom.
Manufacturers have a 'professional obligation' to provide the MSDS forms for all pesticide products, agrochemicals, veterinary medicines, soaps, detergents and related products to the Birmingham Poisons Information Centre (PIC). Agreements with trade associations are made. It is assumed that this will include dangerous preparations according to European directive 1999/45/EC.
All companies who place biocidal products on the market have the duty under the Biocidal Products Regulations (BPR, 2001, no. 880) to inform the Birmingham PIC.

**Making the information available for healthcare personnel**

The Birmingham PIC has a contractual responsibility to provide the received preparation information to the other UK PICs (together called the NPIS: National Poisons Information Service including the Belfast PIC in Northern Ireland). This was formerly done by the distribution of updated monthly CD-ROMs (NPIS Datasheet Compendium) but is recently possible by secure internet access to the Birmingham PIC database. The other UK PICs will direct the manufacturers to the Birmingham PIC for notification.
An exception is the London PIC which in addition, receives preparation information from manufacturers on a voluntary basis (see below). This information is also made available for other UK PICs via a controlled access internet website.



**Competent authority and contact information**

NPIS (Birmingham centre)
City Hospital
Dudley Road
Birmingham B18 7QH
United Kingdom
Phone: +44 1215074123
Fax: +44 1215074105
E-mail: msds@npis.org
Website: www.npis.org

NPIS (London centre)
Guy's & St. Thomas' Hospital Trust
Medical Toxicology Unit
Avonly road
London SE14 5ER
United Kingdom
Phone: +44 2077715310
Fax: 44 2077715309
E-mail: npis@gstt.sthames.nhs.uk
Website: www.medtox.org

**Requirements on product composition and ingredient concentration (Birmingham PIC)**

| *Composition:* | *Concentration:* |
|---|---|
| No special requirements. (MSDS accepted) | No special requirements. (MSDS accepted) |
| For biocidal products, schedule 8 of the BPR describes that: 'the identity of the ingredients of the biocidal product, and their concentration in metric units' must be notified. No further requirements on composition and concentration are given. | |

**Method of notification (Birmingham)**

*Notification forms*

MSDS is accepted plus any additionally required information for biocides. Information is received by E-mail or in paper forms.

*Electronic notification/processing*

Notification by the members of the UK Cleaning Products Industry Association (UKCPI) can be automatically entered into the NPIS database. A similar collaboration has taken place with the British Association for Chemical Specialties.

*Costs of notification*:

No costs are involved for the supplier.

**Notification of product information to the London PIC**
Besides receiving information from the Birmingham PIC, the London PIC has made agreements with the industry to receive product information on a voluntary basis. The other UK PICs have access to this database via internet (username and password necessary).

**Requirements on product composition and ingredient concentration (London PIC)**

| *Composition:* | *Concentration:* |
|---|---|
| No special requirements. (MSDS accepted) | No special requirements. (MSDS accepted) |
| The London PIC would like to receive the MSDS as a minimum although more specific information is wished for. | |

**Method of notification (London)**
*Notification forms*
The London PIC does not require a particular format, although they may ask for data in EAPCCT format when appropriate. A MSDS or a manufacturers own format are also accepted.
Information is received in paper forms or as digital files (Word- or PDF-files o.a.) by CD-ROM or e-mail and stored in a document management system. When possible the content is indexed to make them searchable.

*Electronic notification/processing*
Electronic notification is NOT possible.

*Costs of notification*
No costs are involved for the supplier.

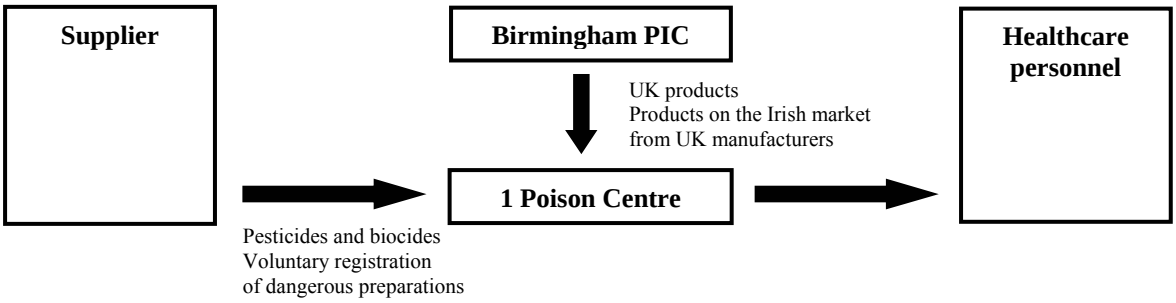
# Ireland

### Legislation

Article 17 of directive 1999/45/EG is currently not yet enforced in Ireland. The Irish Government has not yet appointed an authority as a 'Poisons Information Centre' to which information regarding dangerous preparations can be registered. It is stated that the 'poison centre' should receive the information in National legislation though. The Irish Statutory Instrument No 62 of 2004 implementing Directive 1999/45/EC in Ireland will be updated by March 2007. The Irish National Poisons Information Centre (PIC) will then be the legally appointed authority to receive product information on dangerous preparations. Until that moment the Ireland PIC relies on voluntary notification for dangerous preparations.
The Irish PIC is already designated the National authority to receive information on plant protection and biocidal products (Statutory Instrument no. 624, 2001 and no. 625, 2001).

### Making the information available for healthcare personnel

The Irish PIC receives information from the Birmingham PIC in the UK and can access their database. UK companies who supply products to the Irish market will notify with the Birmingham PIC. Irish manufacturers will notify the Irish PIC.




### Competent authority and contact information

National Poisons Information Centre
Beaumont Hospital
P.O. Box 1297
Beaumont Road
Dublin 9
Phone: +35 318379966
Fax: +35 318368476
Email: npicdublin@beaumont.ie
Website: www.beaumont.ie/public/npic

**Requirements on product composition and ingredient concentration**

| *Composition:* | *Concentration:* |
|---|---|
| No special requirements. (MSDS is accepted) (Notification of dangerous preparations is voluntary)<br><br>For biocides/pesticides:<br>Exact composition is required.<br>('Information on ingredients up to 100%') | No special requirements. (MSDS is accepted) (Notification of dangerous preparations is voluntary)<br><br>For biocides/pesticides:<br>Percentage is asked. No requirements specified. |

**Method of notification**

*Notification forms*

For pesticides and biocides a special form must be used, the 'National Poisons Information Centre Pesticide Safety Data' sheet. Information is received as PDF- or Word-file and stored in a document management system.
For all other voluntary notifications, so also for dangerous preparations, MSDS are accepted. These are preferably received in an electronic way (PDF) but paper forms are handled as well.

*Electronic notification/processing*

Electronic notification is NOT possible.

*Costs of notification*

No costs are involved for the supplier.

# Appendix 3. Electronic notification of product information

## PINDA (the Netherlands)

*Introduction*

The computer programme '***P**reparations **IN**formation **DA**tabase*' (PINDA) was developed bij the Dutch PIC and build by an ICT company using Visual Basic as a programming language and MS Access as the database. The tool was especially build to support electronic notification by small and medium sized Dutch companies, which do not have large numbers of dangerous preparations to notify. Larger companies are able to build their own electronic notification modules (as part of their own product information systems). The computer programme is handed out on request and (after registering) the company receives a 'personified' version of PINDA containing a unique company code. PINDA can be used on a stand alone PC or in a network. The programme allows product data entry and maintenance and allows the production of digital export files to notify the Dutch PIC, where electronic processing in a larger preparations database is performed.

*Functionality, Input*

The computer programme PINDA is essentially a digital version of the Product Information Sheet (that closely follows the structure of a MSDS). The same chapters of information have to be passed through. Three categories of information can be defined:

- Reason for notification (new product, change in composition, change of name, withdrawn from market).
- Company Information (company that has to notify, a contact with the product knowledge).
- Product Information (composition/concentrations, physical and chemical properties, first aid, packaging, toxicological properties, product labeling).

The computer programme and its database essentially support only data entry and maintenance for products of one company. However, one PINDA programme can be used (with some effort) with more than one database (each of them being company unique). The initial database contains only the unique company code and company name. ***All*** other data have to be entered by typing or by copy/paste from other computer programmes (e.g. Notepad, MS Word, MS Excel). PINDA does not support the import of other formats of product data and does not contain a substance list, from which substances can be chosen as ingredients of a product.

*Functionality, Output*
After finishing data entry and maintenance of the product information, digital export files can be made. All new and changed product data are with one click exported into ten digital export files. Single files do not represent a single product; of each product a part of the information is present in each of the ten export files. The files are of the *text* format. All ten export files need to be sent to the PIC and this is most commonly done as E-mail attachments; occasionally diskettes or CD-ROMs are sent.

*Electronic processing at the PIC*
At the Dutch PIC the ten export files are placed in a special directory for the preparations database. With one click the data from the export files is imported into the preparations database. With the import, all relevant checks are done to ensure correct data-entry in the preparations database.

## UDEPIC format (Belgium)

*Introduction*
(Information from the website: http://www.lisam.com)
The company Lisam Systems S.A. develops and markets the Lisam computer programme, in essence an extensive tool for the preparation of MSDS. It is developed for small to medium sized companies. The Lisam computer programme is modularly build, i.e. a company buys the basic module which contains 5000 substances, the calculation of Risk symbol and R- and S-phrases, and can produce most relevant documents as MSDS in a few languages. With additional modules, a company can create a complete tool for all his wishes. Some of these modules are branch and/or legislation specific modules.

The computer programme contains the Lisam Cosmetics module that produces an electronic PIC information sheet, called the UDEPIC format, specifically developed for the Belgian PIC. Likewise, there is a Lisam Detergents module, which was developed in collaboration with members of the NVZ, the Dutch organisation for the soap manufacturers.

*Functionality, Input*
No further information gathered.

*Functionality, Output*
No further information gathered.

*Electronic processing at the PIC*
No further information gathered.

# MIS format (Belgium)

*Introduction*
The MIS programme is a MS Access based small computer programme, developed by the Belgian PIC. In this programme all essential product information can be entered and the filled programme is send to the Belgian PIC.

*Functionality, Input*
The computer programme MIS contains mainly one category of information:

- Product Information (composition/concentrations, pH, names of digital documents).

The computer programme supports only data entry and maintenance for products. Per product the manufacturer and the importer-distributor can be specified. The initial computer programme contains no information. ***All*** data have to be entered by typing or by copy/paste from other computer programmes (e.g. Notepad, MS Word, MS Excel). The computer programme does not support import of other formats of product data. The computer programme contains no substance list, from which substances can be chosen as ingredients of a product.

*Functionality, Output*
The computer programme MIS does not produce export files. The computer programme itself is send to the Belgian PIC.

*Electronic processing at the PIC*
Nu further information gathered.

# EMIL (Germany)

*Introduction*
The computer programme '***E****rfassungs- und* ***M****eldeprogramm zur* ***I****nformationsubermittlung an Giftinformationszentren, BfR und UBA fur Wasch-, Pflege- und Reinigungdmitte****L***' (EMIL) was developed for the notification of washing and cleaning products to the following institutes (conform German legislation):

- IKW, Industrieverband für Körperpflege- und Waschmittel e.V. (the German Cosmetic, Toiletry, Perfumery and Detergent Association).
- BfR, Bundesinstitut für Risikobewertung (the German Federal Institute for Risk Assessment).
- The German PICs.

The computer programme was developed within the Research & Development project 'Toxikologischer Dokumentations- und Informationsverbund' (the TDI-project, see below) of the 'Bundesamt fur Umwelt, Naturschutz und Reaktorsicherheit' (BMU, the Federal Environment Ministry). Multiple products and multiple companies can be entered and maintained for notification to the abovementioned institutes, using different formats of digital export files for notification of the different institutes.

*Functionality, Input*
For the computer programme EMIL, three main categories of information can be defined:
- Reason for notification (first declaration, declarations of changes, declarations of corrections).
- Company Information (three companies have to be stated, the manufacturer, the supplier and the notifier; and also a contact with the product knowledge).
- Product Information (essentially composition/concentrations, the pH).

The computer programme and its database support data entry and maintenance of multiple products and for each product the manufacturer, supplier and notifier have to be stated. It is clearly specifically developed for product notification to various German institutes, based on the German legislation (interpretations of the EU legislation). The initial database contains no company information. Data can be entered by typing or by copy/paste from other computer programmes (e.g. Notepad, MS Word; the user manual does not report import possibilities). The computer programme contains an extensive substance list (relevant for the products to be notified), from which a selection can be made.

*Functionality, Output*
After finishing data entry and maintenance of the product information, different notification files can be created depending on what product data need to be notified to the different institutes (based on the different legislation acts). Notification files for legally required notification to the BfR make use of the Rosetta format (extension *.ROS). Notification files for free notification to the BfR and the German PICs, make use of the Rosetta or the Rosetta-XML format and have to be send as compressed files (extension *.ZIP). One notification file contains multiple products. The Rosetta(-XML) format is a modern type of data exchange format; XML is (becoming) the standard format for data exchange.
For the notification to UBA the product data are exported into five different digital export files. Single files do not represent a single product; of each product a part of the information is present in each of the five export files. The files are of the *text* format.
The notification files need to be sent to various institutes. Shipment is most commonly done as E-mail attachments or on diskettes.

*Electronic processing at the PIC*
The different institutes probably possess information systems with import modules for the notification files, as can be deducted from the TDI-project information. Also, the BfR has

indicated that all product information gathered by this institute can be electronically exchanged with the German and Austrian PICs.

# TDI (Germany)

*Introduction*
In the Research and Development project, *Toxikologischer Dokumentations- und Informationsverbund'* (TDI) the German PIC and BfR and the industry work together to establish a standardised procedure for product data exchange between themselves and with the industry. The project is funded by BMU, started in 1995 and seems to have ended. However, the websites on the TDI project are not up-to-date and more information gathering is necessary to get an actual picture (below is an overview of the activities within the project).

Nevertheless, from the information gathered, it is clear that there's electronic data exchange between the PIC and the BfR. All parties have the same software at their disposal. Product information has only to be notified to one of the PIC or the BfR. Subsequently the product information is electronically distributed between all PIC and BfR. For that purpose the Rosetta format for product data exchange is developed. It is also by the software programme EMIL that is used by companies for electronic notification of product information to PIC or BfR. How well the industry is using this tool is not clear. On the development of a harmonized category system for products was reported in an abstract published in scientific literature. So it seems that most of the project items (see below) have been tackled.

(Information from the website http://www.tdi-network.org)
**The Research Project (last update 18.09.2003)**
Project's History / Project Phases
1999 - 2002: 1st phase of the project:
- Development of concepts.
- Development of data acquisition programme EMIL.
- Development of data base software for participation poison centres and BgVV.

2002 - 2005: 2nd phase of the project:
- Start of product data acquisition / programme modifications.
- Start of product data transfer between industry and project centres / programme modifications.
- Start of European cooperation.
- Development of harmonized system of categorisation of products and biological causes of poisoning.

# Schlüsseldatei (Austria)

*Introduction*
The competent authority in Austria has to be notified with a MSDS as a digital file. However, together with the MSDS they would like to receive a *key file* (Schlusseldatei) that contains information on identification of the digital MSDS and some important product data. The key file is just a text file that needs to contain specific information, in a specific order, in a specific format. So, there is no computer programme to create the key file

*Functionality, Input*
The key file contains three main categories of information:
- Reason for notification (first declaration, declarations of changes, out of market).
- Company Information (only a number).
- Product Information (composition/concentrations, R/phrases, use, name of MSDS/document).

A guide indicates which information is necessary and how it should be ordered.

*Functionality, Output*
The key file accompanies the digital version of the MSDS and is send to the competent authority.

*Electronic processing*
No further information gathered.

# ISS Formula (Italy)

*Introduction*
The computer programme '*ISS Formula'* was developed by the Instituto Superiore di Sanità (ISS; National Institute of Health) for the notification of dangerous preparations in Italy. The computer programme can be downloaded from the ISS website. The company should use its VAT number as a unique company code for the notification. The computer programme allows product data entry and maintenance and allows the production of digital export files to notify the PIC, where electronic processing in a larger preparations database is performed.

*Functionality, Input*
For the computer programme ISS Formula, two main categories of information can be defined:
- Company Information (company that has to notify).
- Product Information (essentially composition/concentrations, few physical and chemical properties, product labeling, use).

The computer programme and its database essentially support only data entry and maintenance for products of one company. The computer programme contains an extensive substance list (based on the Annex I of the substances directive 67/548/EC), from which a selection can be made. Part of the information can be selected from predefined lists. Most information however has to be entered by typing or by copy/paste from other computer programmes (e.g. Notepad, MS Word, MS Excel). The computer programme does not support import of other formats of product data.

*Functionality, Output*
After finishing data entry and maintenance of the product information, a notification file (of the compression format: *.zip) can be generated. This file contains a few files of the CSV format. The zipped notification file contains all new or changed product information of only one company. The notification file can be uploaded to ISS through the website using the FTP protocol and encryption. Alternatively, shipment as E-mail attachments or on diskettes is also allowed.

*Electronic processing at the PIC*
The product information in the notification file is transferred to a computerized database at the ISS laboratory of Applied Toxicology.

## eDeclaration (Norway)

*Introduction*
(Information from the website: www.produktregisteret.no)
Since 2003 Norwegian companies, or companies with offices in Norway, can declare their products electronically, *eDeclaration*, to the Product Register. There are no changes or differences in the information which is to be declared to the Product Register as opposed to the paper based declaration. The Product Register's reasons for the development of electronic declaration

- Simplifies and saves time for the company and the Product Register.
- The company has all the information regarding declaration in one place (seems to indicate a safe secure environment where the company can enter and maintain their own product information).
- Fewer errors.
- Cheaper.

The requirements (e.g. internet access and MS Internet Explorer) indicate an internet solution.

This internet solution is provided through Altinn, a common internet portal for public reporting. Many public departments, including the Product Register, are participating. It resembles the eGovernment initiatives of the Dutch government. Altinn provides an open,

accessible and secure solution. In essence, a registered user of the portal makes use of predefined forms to register information with a specific governmental department. The users can either fill in the forms directly in the Internet portal or they can use their own IT systems to transfer pre-filled forms to the portal.

*Functionality, Input*
No further information gathered.

*Functionality, Output*
No further information gathered.

*Electronic processing at the PIC*
No further information gathered.

## SYSDECOS (Cosmetics in European countries)

*Introduction*
The computer programme '**SYS**tem for the **DE**claration of (Frame) Formulations of **COS**metic Products to European Poison Control Centres' (SYSDECOS) was initially developed for notification of cosmetic product (frame) formulations to the competent authority in Germany. However, the computer programme was well received in Germany and abroad, so that the European cosmetics industry invested in the further development of this tool, making it a general (trilingual, i.e. English, German and French) tool for notification of cosmetic products to most EU countries. Multiple products and multiple companies can be entered and maintained for notification to multiple countries, and digital export files for notification of the relevant countries can be created. Although there is no legal obligation for the notification of cosmetic products in the Netherlands, the Dutch Cosmetics Association supported the upgrade of SYSDECOS for Dutch notification and the development of an import module for the preparations database of the Dutch PIC.

*Functionality, Input*
For the computer programme SYSDECOS, three main categories of information can be defined:

- Reason for notification (first declaration, declarations of changes, declarations of corrections).
- Company Information (company that has to notify; a contact with the product knowledge).
- Product Information (essentially composition/concentrations based on frame formulations and/or the (sometimes obligatory) exact ingredient names, the pH).

The computer programme and its database support data entry and maintenance of multiple companies and multiple products per company. Per product multiple countries can be chosen, where the product is marketed.
The initial database contains no company information. Data can be entered by typing, by copy/paste from other computer programmes (e.g. Notepad, MS Word), or by import. SYSDECOS allows the import of data from other computer programmes (e.g. dBASE, MS Access, MS Excel) if the data have been saved by these other programmes in the CSV format, with the data in a specific order.
The computer programme contains both a cosmetic frame formulations list as well as a substance list, from which a selection can be made, which depends on the type of notification (there are three defined).

*Functionality, Output*
After finishing data entry and maintenance of the product information, a notification file, named a KOS-file, for e.g. the Netherlands can be generated. One notification file contains all new or changed product information of only one company and is restricted to the notification of one country. The notification file needs to be sent to the PIC and this is most commonly done as E-mail attachments or on diskettes.

*Electronic processing at the PIC*
At the Dutch PIC the export files are placed in a special directory for the preparations database. With one click the data from the export files is imported into the preparations database. With the import, all relevant checks are done to ensure correct data-entry in the preparations database.
In Sweden the information from the export file is stored in a MS Excel file. Information on how other National PICs handle the notification files and really process them like the Dutch PIC does, has not been gathered.

# Appendix 4, EAPCCT newsletter, April 1996 (p. 5-14)

ASSOCIATION EUROPÉENNE
DES CENTRES DE LUTTE
CONTRE LES POISONS

EUROPEAN ASSOCIATION
OF POISONS CONTROL
CENTRES

SIÈGE SOCIAL:
15, RUE JOSEPH STALLAERT
1060 BRUXELLES - BELGIQUE
TÉL.: 02/345.45.45

HEADQUARTERS:

President:
Dr. Hans Persson
Swedish Poison Information Centre
Karolinska Hospital
P.O.Box 60500
SE-104 01 Stockholm 60, Sweden

GENERAL SECRETARY
Elsa Wickstrøm
National Poison Information Centre
P.O.Box 8189 Dep.
0034 OSLO 1, Norway

Oslo, June 13th, 1989.

To the Poison Centres in Europe and members of the EAPCC.

Information on chemical products from the manufacturers to the Poison Centres.

Enclosed you will find the form for providing product information from industry to Poison Centres and guidelines for its use, together with a letter from the President of the EAPCC giving the background for this work.

The draft of the form etc. was mailed to Poison Centres last autumn and we have been discussing the matter with some Centres.

The following comments should be made at this time:

The information on the composition of the products is vital for the Posion Centres and must not be less detailed than it has been stated in the guidelines.

In many countries the manufacturers have to provide a Safety data sheet for industry using their products. These data sheets are designed for the employees working with the products. The sheets rarely give much information on the composition of the products and must not be confused with the form of information which should be sent to Poison Centres. Once the Poison Centre has received the information on the composition of the products, they will evaluate the product with regard to any toxicity or hazard and include it in their files.

The evaluation is made on the data the Centre already has on the constituents of the products and its own experiences.

On the form, however, there is an item named "Toxicology related to the Product (as available)". This means that if the manufacturer knows of any poisoning, hazard or damage caused by this particular product he should inform the Poison Centre about it under this item.

It should be emphasized that the Poison Centre needs information on all products on the market regardless of whether they are covered by the countrys regulations for classification and labeling of chemicals or not. The criteria for classification and labeling are often determined by an administrative need, not because there are strict borderlines between harmful and harmless chemicals and/or concentrations. The Poison Centres cannot evaluate a product unless it has sufficiently detailed information on the composition. This also includes products which are harmless.

As well as giving advice on toxic and hazardous products, it is important for the whole community that the Poison Centre is able to tell imidiately if a product is harmless. This avoids unnecessary anxiety, transport and hospitalization.

All manufacturers should always provide the Poison Centre with the necessary information on the composition of their products. Without that there may be doubt about the safety of even a harmless product in an emergency. Both physicians and the general public expect the Poison Centre to have the information and if the manufacturer has not provided it this may be bad publicity for the firm.

We hope the standardized form will benefit the Poison Centres as well as the industry.

Yours sincerely

Elsa Wickstrøm

Elsa Wickstrøm
General Secretary

Enc.

Association internationale de
'a Savonnene et de la Détergence

Federation
of European Aerosol Associations

édération
nternationale des Associations de
abricants de Produits
ntretien

Square Marie-Louise 49 - B-1040 Bruxelles ☎ 02/230 40 90 ⇀ fechim b 23 167

# EXCHANGE OF INFORMATION BETWEEN EUROPEAN POISON CONTROL CENTRES AND INDUSTRY (AIS:FIFE:FEA) REPRESENTING CLEANING, DISINFECTANT, AND MAINTENANCE PRODUCTS (INCLUDING AEROSOLS WHERE RELEVANT)

Contents



## I. BACKGROUND

Since they were first established, Poison Control Centres have regularly asked industry for product information in sufficient detail to maintain an up-to-date emergency data-base for the provision of:

- adequate medical advice in the case of poisonings

For practical reasons a standardised information form for manufacturers to use in different countries is highly desirable. Such a form is enclosed in this document which also contains guidelines for completion of the form. The information represents a minimum data set considered as essential for proper evaluation of the acute toxic effects, but it also allows for the provision of additional data when circumstances lead to the need of such data.

Accurate information enables the Poison Centre not only to recognise real risks but also to identify rapidly the cases where there is no risk.

In addition there may be, from time to time, a need for even more detailed information for the provision of

- more general, less urgent, information concerning the toxicity of the product, e.g. chronic effects, allergenic properties

- assessment of product safety and the possible need for preventive measures.

II. PRODUCT INFORMATION

1. General considerations

- The product information form should be completed and transmitted as soon as a new product is marketed (1), or an existing product is changed significantly (see guidelines on composition for details), or if any information in the previous form becomes invalid.

- Information is needed on all products including those considered innocuous.

- Information is needed on all constituents of the composition, with their quantities, including those considered inert or inactive.

- In some instances the Poison Centre may request, or the manufacturer may wish to give, additional information. The standardised request is not intended to inhibit such information exchange but rather to facilitate it by making the basic information exchange more straightforward.

2. Some Definitions

The following definitions may vary from one country to another but are recommended for more general use with a view to harmonising terminology.

(i) LEGAL DEFINITIONS

SUBSTANCES:
(cf Council Directive (79/831/EEC) of 18 September 1979 amending for the sixth time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJEC L 259/10 of 15.10.79)).

Chemical elements and their compounds as they occur in the natural state or as produced by industry. Such substances may contain additives indispensable to produce or maintain the substance in a particular physical or chemical state.

Note
A pure substance means a chemically defined entity which may have impuriti ) but not additives.

PREPARATIONS: (ibid)

Mixtures or solutions composed of two or more substances.

ARTICLE:
(cf Commission Document "How to report for EINECS")

An item which is formed to a specific shape, surface or design using manufacture, has end use function(s) dependent in whole or in part upon its shape or design and use, and 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.

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(1) In this context this includes free samples and products for consumer tests; if you have any problems of interpretation contact your Poison Centre for further information.

(ii) DEFINITIONS FOR USE IN CONTACT WITH POISON CENTRES

PRODUCTS:

The substances or preparations placed on the market, normally with a unique designation or brand name.

COMPOSITION:

The list of constituents and their proportions present in a product.

CONSTITUENTS:

The substances, class of substances, or preparations present in a product.

INGREDIENTS (OR RAW MATERIALS):

Substances and preparations used by the manufacturer to make a product. An ingredient is added during manufacturing but may not necessarily appear in the composition as a constituent (e.g. it may react *in situ* with another ingredient).

FORMULATION:

The proportion of each ingredient used by the manufacturer to make a product.

The formulation is the list of ingredients used in the manufacture whereas the composition is the list of constituents present in the final product.

Example demonstrating difference between ingredients and constituents:

| Product | Soap | | |
|---|---|---|---|
| Formulation Ingredients: | fatty acids<br>caustic soda | Composition Constituents: | soap<br>water |

3. CONFIDENTIALITY

Poison Centres guarantee that the confidentiality of information on the composition of products is secured. The information provided by industry is used only to evaluate the potential toxic risk and compile medical advice.

Poison Centres agree that they will not respond to any enquiries relating solely to the composition of any product without first obtaining the agreement of the manufacturer (or source of information) responsible for the product.

## III. GUIDELINES FOR COMPLETION OF A PRODUCT INFORMATION FORM

### IDENTITY

| | |
|---|---|
| Brand Name(s) | Complete and definitive<br>In all relevant languages<br>Give all alternative names<br><br>Where the same product is marketed under different names in the same country (e.g. different languages) or under different names in different countries, please list all these names on the same product information form. |
| Product Category | Describes intended use of product<br>Categories of products will be defined by industry (see attached list)<br>Mention alternative intended uses |
| Manufacturer/<br>Importer/Distributor | Name and address<br>telephone and telex/fax numbers |
| Contact Point(s) | For additional information Poison Centres need name of person or department (and address/telephone number) for rapid direct contact.<br>Companies should set up internal procedures to cope with contacts with Poison Centres which may be needed in emergency as well as non-emergency situations. |

### PACKAGING

| | |
|---|---|
| Type(s)<br>Size(s) | Type and size of packaging may influence toxic hazard. |
| Description | Colour, shape, any safety advice/phrases. Provide labels if possible but particularly if product is classified as very toxic, toxic, harmful, corrosive or irritant. |

### PHYSICAL CHARACTERISTICS

| | |
|---|---|
| solid, granules, powder<br>paste, gel<br>thin or viscous liquid<br>aerosol, gas,<br>highly volatile,<br>other | Knowledge of physical characteristics of product may aid identification and risk assessment. |
| Colour | |
| pH: as supplied, and<br>at dilution used | |

COMPOSITION

| | |
|---|---|
| Constituents | Qualitative and quantitative information needed. Mention all constituents (whatever their toxicity) by internationally accepted names.<br><br>The use of group or class names is acceptable when all substances in the group have similar toxicological properties (e.g. anionic surfactants, nonionic surfactants, (but not cationic surfactants), enzymes, (class of) polymers, perfumes, colours....<br><br>If the chemical name or the common name is not known by the notifier, the constituent may be designated by its trade name together with the name of its producer.<br><br>Give actual concentrations of any very toxic, toxic or corrosive constituents.<br><br>Give concentrations of all other constituents in % concentration bands:<br>0 to 1% 20 to 30%<br>1 to 5% 30 to 50%<br>5 to 10% 50 to 75%<br>10 to 20% over 75%<br><br>If product is reformulated but name is unchanged and no new constituents are added and concentrations of (same) constituents remain within same concentration bands, it is not necessary to resubmit the form to Poison Centres.<br><br>Give total reserve acidity/alkalinity(2) of product where relevant. |
| TOXICOLOGY | If easily accessible within the company, give relevant information on the toxicity of the product. |
| MANDATORY REQUIREMENTS RELATING TO SAFETY | e.g.<br>- mention if product is classified as Very Toxic, Toxic, Harmful, Corrosive, Irritant,<br><br>- mention if the product requires special packaging (e.g. Child Resistant Closures). |

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(2) acid/alkali reserve. For acidic preparations, this is the amount (g) of sodium hydroxide/100g of preparation required to produce a specified pH. For alkaline preparations, it is the amount (g) of sodium hydroxide equivalent to the g sulphuric acid/100g of preparation required to produce a specified pH.

Acid/alkali reserve measurement. For powders/solids and liquids the acid/alkali reserve is determined by titration (e.g. with 2 N-sodium hydroxide or 2 N-sulphuric acid) for acid substances/preparations up to a pH of 4 and for alkaline substances/preparations down to a pH of 10. Acid/alkali reserve is expressed as g sodium hydroxide (equivalent)/100g powder/solid or liquid required to adjust the pH to the appropriate value.

ENDORSEMENT

| | |
|---|---|
| by Company | Date product first marketed.<br>Date form completed and authorising signature.<br>Reference number of product.<br>Name of product replaced by this formulation (if applicable). |
| by Poisons Centre | Signature of person receiving form and responsible for its custody. |

# CONFIDENTIAL
# Product Information for Poison Centres

(Please refer to Guidelines)

## IDENTITY

**Brand name(s)**

**Product category** (intended use)

**Manufacturer** name: address: telephone: telex/fax:

**Distributor/ Importer** name: address: telephone: telex/fax:

**Contact point** department address: telephone: telex/fax:

## PACKAGING

**Type(s):**

**Size(s):**

**Description:**

Enclose sample labels when appropriate

## PHYSICAL CHARACTERISTICS

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| solid | ☐ | aerosol | ☐ | granules | ☐ | thin liquid | ☐ | as supplied | |
| | | | | | | | | pH: | |
| gel | ☐ | powder | ☐ | paste | ☐ | viscous liquid | ☐ | in dilution used | |
| highly volatile | ☐ | gas | ☐ | other: | | | | colour: | |

## COMPOSITION

### Constituents

## TOXICOLOGY related to the Product (as available)

## MANDATORY REQUIREMENTS RELATING TO SAFETY

## ENDORSEMENT

**Company**

date form completed:

name:

signature:

date on which this product was first marketed:

product reference number:

**Poisons Centre**

name:

signature:

this product replaces: