

EAPCCT

EUROPEAN ASSOCIATION OF POISONS CENTRES AND CLINICAL TOXICOLOGISTS

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General Secretary

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Newsletter

Meetings.

Experimental and Clinical Neurotoxicology, Oporto, Portugal, May 27-31, 1996.

Information: Dr. Ana Paula Augusto, Department of Nutrition Sciences, Oporto University,
Rua do Dr. Robert Frias, 4200 Porto, Portugal. Tel.: +351 550 2064. Fax: +351 550 4143

BIBRA

Toxicology Workshop.

Methodology and Principles of Toxicology 10-14 June 1996, London, UK.

Application forms and further particulars from Prof. K. R. Butterworth, BIBRA
International, Woodmansterne Road, Carshalton, Surrey SM5 4DS, Great Britain.
Tel.: +44 (0) 181-652 1000. Fax: +44 (0) 181-661 7029

BIBRA International.

Computer-Based Prediction of Toxicity and Metabolism. Wednesday June 19, 1996.

The Royal Society of Medicine, 1 Wimpole Street, London W1M 8AE. It is organized
by the Pharmaceuticals Group. For further information contact Carole Coyle, BIBRA
International, Woodmansterne Road, Carshalton, Surrey SM5 4DS, Great Britain.
Tel. + 44 181 652 1000, Fax +44 181 661 7029.

North American Congress of Clinical Toxicology

takes place in Portland, Oregon, USA, October 12-15, 1996.

For further information contact NACCT
P.O. Box 9130
Portland Oregon 97207-9130
USA

Activities in the EAPCCT.

As many of you will know there has been an EAPCCT Working Group having contact with branch organizations from industry. This work has been going on since 1986. In contact with the household industries the Working Group agreed with representatives from the industries on a form and guidelines for transmission of information on the composition of products from industry to poisons centres. This work was finished in 1989 and the form and guidelines distributed to poisons centres in Europe and the EAPCCT members. We know that manufacturers have started using this form in many countries. At a recent contact meeting between the Working Group and the household industries (A.I.S.E.) in Brussels it was agreed that the form and the guidelines should again be distributed to members to remind them of these useful tools to collect information on the composition of products. You will find them included in this Newsletter together with the letters which was distributed at the time.

From 1989-1990 there has also been special contact between the same EAPCCT Working Group and the European Cosmetic Industry through their organization COLIPA. Agreement has now been reached on transmission of information on the composition of cosmetic products and this document will be distributed to poisons centres in Europe. The system will be tested by some centres during the next six months. A report on the contact with COLIPA was distributed to the members of the Governing Body at their meeting in Oslo, March 31, 1995. To give you some information on the work with COLIPA this report is included in this Newsletter.

Greeting to all members.

Yours sincerely



Elsa Wickstrøm
General Secretary

ASSOCIATION EUROPÉENNE
DES CENTRES DE LUTTE
CONTRE LES POISONS

EUROPEAN ASSOCIATION
OF POISONS CONTROL
CENTRES

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GENERAL SECRETARY
Elsa Wickström
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To The European Poison Centres
and the Members of The European
Association of Poison Control Centres,

Enclosed you will find a standardized form for product information for poison centres and guidelines for its completion. A brief summary of the background is also given as well as some definitions.

The purpose of this document is to provide a form for conveyance of product information to poison centres, and the ambition has been to get an agreement between poison centres and industry in this context.

The form with accompanying text is the result of discussions in an informal working group composed by representatives from European poison centres and European household industry (Association internationale de la Détergence, Federation of European Aerosol Associations, Fédération Internationale des Associations de Fabricants de Produits Entretien). It is now distributed to poison centres in Europe for consideration and use, and it has also been sent to national representatives of the above associations.

On behalf of the working group I now would like to suggest that you make, if necessary, appropriate adaptation, translation etc of the document and then start to use it, at least for a test period. It could be a good ambition to discuss and try to evaluate the form during the EAPCC congress in Milano next year (25-29 September), and therefore any comments on the form and the guidelines are most welcome.

With kindest regards,

Yours sincerely



Hans Persson

ASSOCIATION EUROPÉENNE
DES CENTRES DE LUTTE
CONTRE LES POISONS

EUROPEAN ASSOCIATION
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GENERAL SECRETARY
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National Poison Information Centre
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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 Poison 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 country's 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 immediately 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
la Savonnerie et de la Détérgence



Fédération
of European Aerosol Associations



Fédération
internationale des Associations de
Fabricants de Produits
d'Entretien

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

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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 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 impurities 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.

(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	<u>Soap</u>
<u>Formulation</u> Ingredients:	fatty acids caustic soda
	<u>Composition</u> Constituents: soap 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
In all relevant languages
Give all alternative names

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
Categories of products will be defined by industry (see attached list)
Mention alternative intended uses

Manufacturer/)
Importer/Distributor)

Name and address
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.
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))
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
paste, gel
thin or viscous liquid
aerosol, gas,
highly volatile,
other

Knowledge of physical characteristics of product may aid identification and risk assessment.

Colour

pH: as supplied, and
at dilution used

Constituents

Qualitative and quantitative information needed. Mention all constituents (whatever their toxicity) by internationally accepted names.

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....

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.

Give actual concentrations of any very toxic, toxic or corrosive constituents.

Give concentrations of all other constituents in % concentration bands:

0 to 1%	20 to 30%
1 to 5%	30 to 50%
5 to 10%	50 to 75%
10 to 20%	over 75%

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.

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.

- mention if product is classified as Very Toxic, Toxic, Harmful, Corrosive, Irritant,
- mention if the product requires special packaging (e.g. Child Resistant Closures).

(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.
Date form completed and authorising signature.
Reference number of product.
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:

telephone:

telex/fax:

address:

Distributor/
Importer

name:

telephone:

telex/fax:

address:

Contact point

department

telephone:

telex/fax:

address:

PACKAGING

Type(s):

Size(s):

Description:

Enclose sample labels when appropriate

PHYSICAL CHARACTERISTICS

solid

aerosol

granules

thin liquid

as supplied

gel

powder

paste

viscous
liquid

in dilution used

highly
volatile

gas

other:

colour:

pH:

COMPOSITION

Constituents

TOXICOLOGY related to the Product (as available)

MANDATORY REQUIREMENTS RELATING TO SAFETY

ENDORSEMENT

Company

date form completed:

date on which this product
was first marketed:

name:

product reference number:

signature:

**Poisons
Centre**

name:

this product replaces:

signature:

Poisons Centres in Europe and EAPCCT

Information on the composition of cosmetic products

Introduction

Poisons Centres need to have information on the composition of all chemical products on the market in order to be able to give appropriate medical and toxicological advice. This information has to be collected, evaluated and prepared so that it is readily available when an enquiry is received. Both physicians and the general public are used to, and depend on, receiving reliable advice from Poisons Centres. They expect the Centre to have the necessary data on every product to be able to evaluate the toxicity.

Cosmetics

Cosmetic products are found commonly in most homes in Europe and Poisons Centres quite frequently receive enquiries about accidents or adverse effects from this kind of product.

Most cosmetics have little or no acute toxicity, though some will cause discomfort if ingested and a few may cause poisoning. Poisons Centres need to have information on the composition of all cosmetics to be able to firstly, reassure physicians and parents in cases where there is no danger and where unnecessary treatment and transport to hospital should be avoided, and secondly advise on the potential danger and the correct treatment in cases where poisoning may occur.

The Governing Body of the European Association of Poisons Centres and Clinical Toxicologists (EAPCCT) agrees that a «frame formulation» approach for transmission of data on the composition of some types of cosmetic products from the cosmetic industry to Poisons Centres is appropriate.

Representatives from the EAPCCT and the European Cosmetics Industries, through their organisation COLIPA, have formed a Working Group which has looked into the best way of transferring the necessary information on the composition of cosmetics from manufacturers to Poisons Centres. At an early stage the possibility of using «frame formulations», which have been evaluated in the United Kingdom, was considered. After discussion, the EAPCCT has agreed to the use of «frame formulations» as this will make communication with the cosmetic industry easier and quicker. However, some types of cosmetic products are not suitable for «frame formulations», mainly those where the composition is variable and one or more constituents are toxic and may cause poisoning. Examples of such products are nail varnish removers, artificial nail removers, nail strengtheners, hair straighteners, permanent wave neutralisers and cuticle removers.

For those cosmetics where «frame formulations» can be used, there must be agreed criteria for how the different constituents or groups of constituents should be described in the «frame formulations». Whenever possible, examples of the substances used under the description should be given in brackets. It may also be necessary to have a list of the various substances used for the different purposes in cosmetic products.

Chemically related substances which may lead to poisoning, but which differ in acute toxicity, should not be grouped together e.g. alcohols which could refer to ethanol, isopropanol or even higher alcohols. With regard to the percentage amount of each constituent this should be given in «intervals» rather than as maximum amounts. For some products it will be necessary to give the amount more exactly e.g. products containing corrosive substances, alcohols, vitamins A and D. One should also be aware that occasionally the Poisons Centres will need more precise and detailed information on the composition when dealing with special cases. The cosmetic industry must be prepared to communicate with Poisons Centres in such cases.

The manufacturer must send Poisons Centres a list of products with the exact name of the product and the «frame formulation» to which it corresponds together with any necessary additional information.

Conclusions

In the near future the EAPCCT - COLIPA Working group will have completed its work on the use of «frame formulations» for the majority of types of cosmetics. The criteria for use of «frame formulations» and the limitations for use will be included in the final document which will be discussed by the Governing Body of the EAPCCT and then distributed to its members for use in Poisons Centres in Europe.

Dr. Martine Mostin (Chairman)
Dr. Hans Persson
Dr. Elsa Wickstrøm