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**Guidance on the provision of confidentiality of chemical names**

 **1.0 Introduction**

**1.1** The European Communities (Classification, Packaging and Labelling of Dangerous Preparations) Regulation 2004, Statutory Instrument No 62 of 2004 is the legislation which implements the Dangerous Preparations Directive 1999/45/EC in Ireland. It is known as the ‘DPD’ and its purpose is to make sure that people are properly informed about the dangers of chemicals both at work and in the home. The DPD and thereby this Statutory Instrument are being phased out over the next five years by a direct acting CLP Regulation (EC) No 1272/2008 which entered into force in January 2009 and covers both substances and mixtures (formerly preparations). During a transitional period which runs up to 1st June 2015 both the DPD and CLP rules shall remain in place in Ireland.

**1.2**. The DPD places an obligation on suppliers to disclose the chemical identities of the hazardous substances on labels and/or packaging. This is to convey important information on the ingredients that contribute to the hazard(s) of the preparation. However, it has been acknowledged by the European Commission that such disclosure of constituents of preparations may put the confidential nature of a manufacturer's intellectual property at risk. To address this issue the DPD allows for confidentiality of chemical names, i.e. an alternative name may be used instead of the chemical name to preserve intellectual property. Regulation 19 of S.I No 62 of 2004 implements this provision in Ireland.

**1.3.** The Health and Safety Authority (HSA) as the Competent Authority for S.I No 62 of 2004, is responsible for administering the applications for confidentiality in Ireland. This document gives additional information on this and also provides guidance for companies wishing to submit applications for confidentiality to the HSA.

## 2.0 A brief description of the provision for confidentiality of chemical names

**2.1.**. The provision for confidentiality of chemical names is described in Regulation 19 of S.I No 62 of 2004 which also refers suppliers to Annex VI of the DPD. An introductory explanation is provided here.

**2.2** Regulation 19 of S.I No 62 of 2004 (implementing Article 15 of the DPD) defines the scope for confidentiality applications. Briefly, this only applies to chemicals that are classified as irritant (excluding chemicals that cause severe eye irritation) and/or acutely harmful. The chemical may additionally be classified for physical or environmental hazards. These classifications may be from those listed in Table 3.2 of Annex VI to CLP, or they may be self-classifications which have taken into account all available information. If a substance is classified for a health effect other than irritant or acutely harmful, or if it has a community occupational exposure limit, then confidentiality cannot be granted.

**2.3** The purpose of the provision of confidentiality is to protect intellectual property. Thus, the applicant must provide justification for the application and provide reasonable evidence that disclosure of the chemical name would put the confidential nature of their intellectual property at risk.

## 3.0 Applications for confidentiality

**3.1**The HSA will process applications for confidentiality of chemical names according to the criteria detailed in Regulation 19 of S.I No 62 of 2004 and of Article 15 of the DPD. The request must therefore conform to the scope defined and provide the information outlined in Part A of Annex VI of the DPD. The following sections provide additional information on how the requirements of the DPD and on the preferred format of applications.

## 4.0 Person responsible for granting confidentiality

**4.1**Confidentiality is available for preparations that are classified as dangerous for physical, health and/or environmental hazards. HSA approval is required for **classified** preparations only, applying the system described in this document. The person responsible for placing an **unclassified** preparation on the market may refer to a substance by an alternative name as long as it is done in accordance with the DPD. In the case of unclassified preparations, the person responsible applies the confidentiality system themselves.

## 5.0 Applications to the HSA

**5.1**. Applications prepared in accordance with Part A of Annex VI of the DPD may be submitted to the HSA in hard-copy or electronic form by post or e-mail to the address listed below. Electronic documents should be in Microsoft Word, RTF or PDF format.

**5.2** On receipt of the application, the HSA will confirm receipt, by e-mail (if available) or by letter, giving the name of the person responsible for processing the application and a reference number. This number should be quoted in any correspondence with the HSA regarding this application.

**5.3** The HSA will process applications within 4 weeks of receipt and inform the applicant of their decision by letter. (See Appendix 2) In some cases the HSA may request additional information if it is considered necessary in order to process the application. The HSA shall ensure that the information submitted in respect of the application remains confidential.

## 6.0 Format of the application

**6.1** To make the system as flexible as possible, the HSA envisages two types of application for confidentiality: full applications, which cover a single substance and a number of similar preparations containing that substance (see paragraphs 26-28), and include all the information required by the DPD Annex VI Part A. All substances for which confidentiality is claimed must have at least one full application. If a new preparation is produced that contains a substance for which confidentiality has already been granted and it is in the same group as the preparations listed in that agreement, then only a reduced application is required. This is called an update application.

**6.2** The information required for full and update applications are different and are described below.

### 7.0 Full applications

**7.1**. There is no formally agreed EU application form. However, the DPD Annex VI Part A provides convenient headings under which the required information can be presented and gives a description of what is required in each of these sections. Based on this, the HSA developed an application form (See Appendix 1)

**7.2**. Each application should cover a request for confidentiality for a single substance. Each substance for which confidentiality is being sought will require separate application of its own

**7.3** For successful applications, the HSA will issue a confirmation letter (See Appendix 2), outlining the key details of the application, including the substance and its alternative name and a list of the preparations for which the alternative name can be used. This letter can be copied and made available to the Competent Authorities of other Member States, where the preparation is placed on the market.

### 8.0 Update applications

**8.1**. An update application builds upon a previous full application and extends it to cover additional preparations within the same group. As such only a minimal amount of extra information is required.

**8.2** The update application should provide the HSA reference number for the previous full application, the name of the new preparations and a statement that the new preparations are in the same group (i.e. they have similar composition, the same classification and labelling and use) as those listed in the full Application. Provided that these conditions are met, then the update application should be successful.

**8.3** If the application is successful, an updated acceptance letter will be issued, extending the original letter to include a full list of preparations for which the confidential name may be used.

## 9.0 Providing bibliographical information

**9.1** No bibliography will be required when the classification of the substance has been taken from Table 3.2 of Annex VI to CLP

**9.2** When a substance is self-classified, a bibliography must be provided as evidence that the self-classification takes account of all existing pertinent information available on the properties of the substance. The purpose of the bibliography is to provide supporting evidence that the applicant has performed a diligent search of the scientific literature to assess the potential health hazards of the substance and to present sufficient information to allow HSA to check the classification, if necessary.

**9.3** The information presented will normally be limited to references to appropriate studies or information sources. In addition, for acute toxicity tests the LD50/LC50 values may be presented to allow a check that the substance is indeed harmful and in scope. Also, as the distinction between a mild and severe eye irritant (R36 and 41, respectively) is important, some indication of why the data meets the criteria for R36 could be included (for instance 'mild irritation was observed but was reversible within seven days'). It is also important to state clearly when no data for a particular end-point was found.

**9.4** In some cases applicants may not have access to information on studies conducted on the substance. In this case, the applicant should cite any appropriate information from the supplier's SDS and state clearly that he is using the supplier's self-classification and has not actually assessed the data underlying that position.

**9.5**. In some cases there will be no data available for a particular substance, but a ‘read-across’ analysis from another similar substance may be appropriate. The use of read-across can be acceptable, although a clear and scientifically robust argument supporting the read-across should be presented. The HSA may accept the application based on the classification information presented but this does not represent an endorsement by the HSA of this classification.

**9.6** Classification for physio-chemical or environmental hazards does not impact directly on the application for confidentiality and so a bibliography for these hazard end-points does not need to be supplied.

## 10.0 Grouping of preparations

**10.1** The introductory notes of Annex VI Part A of the DPD explain that to avoid multiple requests for confidentiality relating to the same substance used in different preparations, a single request for confidentiality may suffice if the preparations have:

* the same dangerous constituents present in the same concentration range;
* the same classification and labelling; and
* the same expected uses.

The HSA will accept such grouping of preparations in the same request provided it is in accordance with the criteria described above.

**10**.**2** When the preparations only contain one substance for which confidentiality is desired, the grouping is relatively easy. However, many preparations will be blends of several substances, each of which will require confidentiality. This may make appropriate grouping of preparations problematic. One possible approach is to group preparations that contain one or more of a number of substances together. By defining the concentration range of these substances as between 0 and X% the group can include preparations that contain a subset (i.e. one or more) of these substances, provided that the preparations all have the same classification and use.

**10.3**. Each constituent of a preparation may contribute to the overall classification of the preparation (using the conventional method defined in S.I No 62 of 2004). When the application covers a group of preparations that contain one or more constituents in a range of concentrations, then the applicant should take care to ensure that the classification of all the preparations in the group are the same.

### 11.0 Submission of application

**11.1** The completed applications, along with any supporting documentation, can be submitted to.

The Chemicals Helpdesk Team

Chemicals Policy and Services Division

Health and Safety Authority

Metropolitan Building

James Joyce Street

Dublin 1

### Alternatively, applications can be sent electronically via email to chemicals@hsa.ie. Any queries relating to the application can be also be submitted to chemicals@hsa.ie or by calling 1890 289 389

**Reference material:**

1. **CLP Regulation**: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>
2. **Dangerous Preparations Directive (DPD) 1999/45/EC**: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1999:200:0001:0001:EN:PDF>
3. **ECHA information on alternative name in mixtures** <http://echa.europa.eu/web/guest/alternative-chemical-name-in-mixtures>
4. **HSE Guidance on the provision of confidential of chemical names**: <http://www.hse.gov.uk/chip/appguide.htm>
5. **Statutory Instrument S.I No 62 of 2004**: <http://www.irishstatutebook.ie/2004/en/si/0062.html>

### Appendix 1

**APPLICATION FOR CONFIDENTIALITY OF A CHEMICAL NAME**[[1]](#footnote-1)

Applicant Reference Number:

Date of Application:

1. **Person responsible for placing the preparation on the market**

The contact details of the person with legal responsibility for placing the preparation on the market must be provided. If a second person is available who may be more able to deal with requests or questions from HSA in relation to a particular application, for instance a consultant, then their contact details may also be provided.

If the applicant allocates their own internal reference number to an application then this could usefully be included to help identify the application, for instance if the HSA needs to contact the applicant for more information.

1. **Precise identification of substance for which confidentiality is proposed and the alternative designation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **CAS No.** | **EINECS No.** | **Chemical name** | **Classification\*** | **Alternative designation** |
|  |  |  |  |  |

[\* Indicates if provisional classification]

If the CAS number is not available, the EINECS number alone will be sufficient

The chemical name should be given according to international nomenclature, such as IUPAC. This should be the exact name in CLP Annex VI, if listed; otherwise the EINECS name is preferred.

If the substance is in Annex VI to CLP then the classification presented should be the one listed. Otherwise, the self-classification should be provided and this should be indicated. When a substance is self-classified, a supporting bibliography of scientific evidence should be included (See Bibliographical information paragraph in Section 9). It is the duty of the company to keep informed of any classification changes for the substance (e.g. due to new data or a DSD change).

The alternative designation must provide enough information for health and safety precautions to be taken and to ensure that risks from handling the preparation can be minimised. This means that the most important functional groups should be identified in the alternative name. A lexicon for establishing alternative names is provided in Annex VI Part B of DPD and may be used. However, it is recognised that other nomenclature systems exist and may be more appropriate in some circumstances. These may be used, although it is recommended that alternative nomenclature systems are forwarded to the HSA for approval in advance of formal notifications being submitted. The nomenclature system used should be specified to allow the HSA to check if it agrees with the proposed name.

1. **Justification for confidentiality**

This section should provide the justification for the application for confidentiality, indicating clearly why disclosure of the chemical name will put at risk the confidential nature of intellectual property. This justification should be clear, transparent and persuasive. The text may include a brief description of the industry and product range and give an indication of the impact of disclosing the chemical name. For a company submitting numerous applications for different products, it is expected that some generic text would be applicable in most cases.

1. **Designation(s) or commercial name(s) of the preparation**

This should give the name of the preparation on the market. When an application covers several preparations in the same “group” only one “representative” preparation is expected to be listed here and described in detail in the sections below, with the other preparations listed in an Annex. See “Grouping of Preparations” in Section 10.

1. **Is the designation or commercial name the same for all the EU community?**

Yes  No 

If the designation is the same in all Member States then this section should be left blank. Otherwise specify the designation(s) or commercial name(s) used in the different Member States.

|  |  |
| --- | --- |
| **Member State** | **Designation or commercial name** |
| Belgium:Bulgaria:Czech Republic:Denmark:Germany:Estonia:Ireland:Greece:Spain:France:Italy:Cyprus:Latvia:Lithuania:Luxembourg:Hungary:Malta:Netherlands:Austria:Poland:Portugal:Romania:Slovenia:Slovakia:Finland:Sweden:United Kingdom |  |

**Composition of the preparation defined in point 2 of the Safety Data Sheet**

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **EINECS No.** | **Range** | **Classification** |
|  |  |  |  |

The composition of the preparation should be formally listed here. Which constituents must be listed is described in Point 2 of the SDS. The concentration of the substance in the preparation or the range of concentrations if it is present in a group of preparations should be specified. See “Grouping of Preparations” in Section 10

**6. Classification and labelling of the preparation**

This section should include the full classification and labelling of the preparation i.e. covering all hazard categories. See “Grouping of Preparations” in Section 10. The full text of the R- and S-phrases does not need to be given.

**7. Intended uses of the preparation(s)**

The use of the preparation should be specified. The terms to describe uses can be general within reason, for instance "Lubricant" or "Fuel additive". See “Grouping of Preparations” in Section 10.

**8. Safety Data Sheet**

A Safety Data Sheet for the preparation should be attached. It should conform to the latest version of the Safety Data Sheet Directive

When the application is for a group of preparations, only an SDS for the “representative” preparation in the group is expected to be included in the application. See “Grouping of Preparations” in Section 10.

This list provides the general headings under which all of the required information can be organised. However, the HSA may request additional information to supplement that already provided if considered necessary.

### Appendix 2:

### SAMPLE CONFIRMATION LETTER

Dr. John Smith

Company ABC

Alphabet Drive

Dublin

Ireland

 DD Month YYYY

Dear Dr. Smith

# Re: Application to use an alternative name

**HSA Reference Number:** 12345 (your reference: AB12)

**Substance:** Alphabet Acid

The Health and Safety Authority has considered the application to use an alternative designation for the chemical identity of a substance and, from the information presented therein, consider it to be in accordance with the provision for confidentiality of chemical names as defined in the Dangerous Preparations Directive 1999/45/EC, transposed through Regulation 19 of Statutory Instrument No 62 of 2004 in Ireland.

The HSA approval permits the substance **Barbituric Acid** to be referred to as **Amide derivative** when present in the following products only

Please contact us if you have any further questions relating to this application.

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Chemicals Business and Services Division

Health & Safety Authority

Metropolitan Building

James Joyce Street

Dublin 1

1. Based on Part A of Annex VI of the DPD [↑](#footnote-ref-1)