

The Labelling Handbook Volume 2

Requirements for Professional Product Labels

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1. INTRODUCTION TO PROFESSIONAL PRODUCT LABELS

- 1.1 Professional products are products for which users must be either certificated or, if the product does not require certification but is used as part of a business or employment, must receive training in its use. As such, certificated or trained users should be aware of their obligations in using pesticides and this impacts on the type of information that appears on the labels.
- 1.2 Volume 1 of this Handbook provides guidance on requirements for **all** product labels.
- 1.3 This Volume 2 sets out additional requirements on how text on a Professional Product Label must be presented. It is divided into several sections as follows:

Product Identity	Section 2	
Important Inform	Section 3	
Safety CHIP/CLP labelling		Section 4
Information	Safety Precautions	Section 5
	Medical Advice	Section 6
Directions for Use		Section 7
Company Advis	Section 8	

1.4 An example of a draft professional label including Product Identity, Important Information and Safety Information is given in Appendix 11. Examples of Directions for use are at Appendix 9.

Important note

The requirements and phrases listed below are the most up-to-date for a product authorised under Regulation 1107/2009. If your product was approved under COPR 1986 or PPPR 1995 on 14 June 2011 when the new Regulation came into force, then the previous labelling requirements will continue to apply unless we have issued an amendment authorisation until or we have reassessed your label in any future application.



2. PRODUCT IDENTITY

2.1 Introduction

Product Identity is not a specific discrete section on the label but consists of various information about the product and its use which will ensure that it is easy to identify what it is, what it contains and how it should be used.

The product identity includes the following information:

- (a) Product tradename
- (b) Product registration number
- (c) Authorisation holder and marketing company details
- (d) Formulation type
- (e) Amount and name of the active substance(s)
- (f) Net quantity of product
- (g) Product batch number/ date of manufacture
- (h) Product use-by date
- (i) Biological use phrase
- (j) The 'COSHH phrase'

Guidance on each item is set out below.

2.2 Location of Product Identity information on the label

The information included in the Product Identity must appear on the Container Label *and* on any separate Leaflet supplied with the product and must be formatted in line with the requirements detailed below *and* those set out in Volume 1.

2.3 **Product tradename**

The tradename is the product name as specified on the Notice of Authorisation. It must be formatted such that it is clear to the user what the correct full tradename is. Whilst use of different sized fonts and colours for different parts of the tradename is acceptable, you must ensure that this would not confuse a user.

We will not consider trademark or copyright issues with respect to tradenames. This is the responsibility of the applicant. However, we reserve the right to request a different tradename where:

- It is likely to cause confusion with another product or with non-pesticide products;
- It misrepresents the composition or intended use of the product;
- It makes claims that are not supported by data.



Further guidance on choosing an acceptable tradename is given in Volume 1/Appendix 1

2.4 **Product registration number**

This is the unique 5 digit identifying registration number given in the authorisation (currently prefixed with 'MAFF' or 'MAPP' depending on when we first allocated to a product) and this must appear in close proximity to the product tradename.

Where appropriate, this may appear on the back packaging label above the 'Safety Information' as an alternative to stating the product registration number on the front packaging label.

If your product registration number is currently prefixed with 'MAFF' this will be amended to 'MAPP' when the next authorisation for that product is issued.

2.5 Authorisation holder and marketing company details

The name and address of the authorisation holder, and if different, the name and address of the marketing company must appear.

A telephone number for the authorisation holder *and/or* the marketing company must also appear; *i.e.* if there are 2 different companies in these roles then you can choose to have both telephone numbers or just one. . However, in any case the number must be a suitable contact number for users to *e.g.* obtain advice on the use of the product or report adverse incidents.

2.6 Formulation type

The formulation type based on standard GCPC definitions as specified in the authorisation should preferably be given in full (*i.e.* suspension concentrate rather than SC) in a 'contents statement' with the amount and name of the active substance(s).- see 1.5 below

2.7 Amount and name of the active substance(s)

The name and content of each active substance, as specified on the Notice of Authorisation, must be given (usually included in a single 'contents statement' with the formulation type- see 1.4 above).



Important note

Labels for all organophosphorus and carbamate products require the following phrase to be included after the name of the active substance on the Main Area of the container label:

'[*active substance*] is an anticholinesterase organophosphate [or carbamate]. Handle with care'

2.8 Net quantity of product

The net quantity of the preparation in the container must appear (in accordance with the Weights and Measures Act). Where a number of smaller containers are packaged within a single outer, the outer should state how many, and what size, of the small packs are being supplied (this may be printed on the container itself rather than on the label area).

2.9 Product batch number/ date of manufacture

The formulation batch number (or some means of identifying it) plus the date of manufacture must appear (this may be printed on the container itself rather than on the affixed label area).

2.10 Product use-by date

An appropriate 'use-by date' must appear if the 2 year storage stability data evaluated for authorisation indicates an acceptable shelf-life of less than 2 years.

2.11 Biological use phrase

Brief statement on biological use (*e.g.* 'For the control of aphids and red spider mites on top fruit').

This statement may use descriptive terms such as kills, controls, repels and eradicates, but these terms must be supported by appropriate data.

2.12 The 'COSHH phrase'

Products for which the Control of Substances Hazardous to Health Regulations (COSHH) are applicable must carry the following phrase on the Container Label:

'The (COSHH) Control of Substances Hazardous to Health Regulations may apply to the use of this product at work'



Handy tip!

COSHH may be applicable if the formulation is classified Very Toxic, Toxic, Harmful, Irritant or Corrosive; includes a substance which has been given a Maximum Exposure Limit, (MEL) or Occupational Exposure Standard (OES) under the COSHH Regulations (details of substances with an MEL or OES are in the latest edition of <u>HSE Guidance Note EH40</u>); includes a micro-organism which may create a hazard to health; includes dust which may be present in substantial concentrate of air when the pesticide is used ('substantial concentration is explained the General Authorised Code of Practice on the COSHH Regulations, document L5 (formerly COP 29) available from HMSO); or includes any substance not mentioned above which creates a hazard to health which is comparable with the hazards listed above.



3. IMPORTANT INFORMATION BOX

3.1 Introduction

The Important Information is contained in a boxed area on the main part of the label. It communicates certain key information about the safe and effective use of the product. This will be information that appears in the 'Use' section of the product Notice of Authorisation

3.2 Location of Important Information on the label

The Important Information must appear on the Container Label *and* on any separate Leaflet supplied with the product and must be formatted in line with the requirements detailed below *and* those set out in Volume 1.

3.3 Information that must be included in Important Information

All of the following information must appear in a clearly legible format:

3.3.1 Heading

The boxed area must be labelled as 'Important Information',

3.3.2 Field of use

The 'field of use' phrase must read 'FOR USE ONLY AS A PROFESSIONAL...' followed by the appropriate entries from the choices below. The sub-heading 'Field of use' is not required).

Α.	В.
INSECTICIDE	IN OR NEAR WATER #
FUNGICIDE	IN INTERIOR LANDSCAPES#
HERBICIDE	IN FOOD STORAGE PRACTICE
PLANT GROWTH REGULATOR	BY COMPETENT PERSONS*
ACARICIDE	
NEMATICIDE	
ALGICIDE	
DESICCANT	
MOLLUSCICIDE	
SEED TREATMENT	
SOIL STERILANT	
RODENTICIDE	
BACTERICIDE	
[ANIMAL]/[BIRD] REPELLENT	
TURF TREATMENT	
WORM CONTROL AGENT	
SPROUT GROWTH INHIBITOR	
[MOLE]/[RABBIT]/[SQUIRREL] CONTROL	



You should use at least one term from column A (appropriate to the product uses) and possibly one from column B depending on if they apply to the specific product use.

These uses marked # require certification of the operator. The phrase marked * is required with any products which are used as a RODENTICIDE or for MOLE, RABBIT or SQUIRREL CONTROL as specified in column B.

3.3.3 Crops/situations

The authorised crop(s) or situation(s) of use for the product must always appear in the Important Information, under a sub-heading *e.g.* 'Crops:' and/or 'Situations'. Alternatively, the phrase 'For use on...' may be used. No specific formatting for the sub-heading is required.

The crops/situations listed must appear exactly as stated on the Notice of Authorisation. You should refer to the 'Crop Definitions List' guidance on our website for advice on the appropriate way of defining crops and situations of use.

3.3.4 Maximum individual dose

You must include the highest dose at which the product may be applied at any one treatment to a specific crop/situation. This must appear exactly as stated on the Notice of Authorisation. Depending on the product type, it will be stated as:

- (a) A maximum quantity of product to be used for a given area of land, a given volume of soil/other growing medium or a given volume or weight of seed/produce; or
- (b) A maximum concentration of product applied in water (*e.g.* if product is applied to 'run-off').

The units of quantity used must be appropriate to the formulation type (*e.g.* solid or liquid) and a sub-heading of 'Maximum individual dose' is required (no specific formatting for the sub-heading is necessary).

3.3.5 Maximum number of treatments or maximum total dose

You must include any restrictions on the total amount of product that may be applied to a specific crop/situation per crop/year/batch etc. This must appear exactly as stated on the Notice of Authorisation, either specified as :

a) Maximum number of treatments: The maximum number of applications that may be made within a given period (*i.e.* per crop or per year as appropriate) each application being at a dose up to the 'maximum individual dose'. It should be stated in terms of number of treatments/crop



or year (*e.g.* per crop for annual crops; per year for perennial crops; [per batch (of seed) for seed treatments).

(b) Maximum total dose: The maximum amount of product that may be applied within a given period (*i.e.* per crop or per year as appropriate), irrespective of the number of treatments made, as long as none of the treatments exceeds the 'maximum individual dose'. It should be stated in terms of the appropriate quantity of product/crop or year depending on the specific crop/situation (*e.g.* 'per crop' for annual crops; 'per year' for perennial crops).

A sub-heading reading 'Maximum number of treatments' or Maximum total dose' as appropriate is required (no specific formatting for the sub-heading is necessary).

3.3.6 Latest time of application

You must include any latest timings at which a product may be applied to a specific crop/situation exactly as stated on the Notice of Authorisation. A sub-heading 'Latest time of application' is required (no specific formatting for the sub-heading is necessary). The latest timing may be specified as:

- (a) A date- . this will usually specified as '....in the year of treatment' 'or '.....in the year of harvest').
- (b) A crop growth stage- this will not be as a numerical key and will usually be specified in terms of 'before...' a particular growth stage).
- (c) A number of days or weeks before harvest, or other as appropriate (*e.g.* before removal from store, before grazing,.

3.3.7 Other specific restrictions

Any other necessary restriction on the application of the product to a specific crop/situation must be specified *e.g.* minimum interval between applications; minimum concentration of product in the spray. These must be stated as given on the Notice of Authorisation. A sub-heading reading 'Other specific restrictions' is required (no specific formatting for the sub-heading is necessary).

3.3.8 Warning phrase

The following phrase must be included at the bottom of the Important Information area in bold text:

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS.



3.4 Option where label is too small to include all information

Where (due to space constraints) it is not possible to include the items in the in para. 3.3 in the Important Information section on the container label itself, the Field of use and Crops/situations MUST be included on the container label and the rest of the information relating to the use of the pesticide may be signposted to a separate leaflet. This leaflet MUST contain all of the information detailed above, including the Field of use and Crops/situations.

3.5 Examples of Important Information boxes

We have included four examples of acceptable formatting for the Important Information in Appendix 1 to this Volume.



4. CHIP/CLP CLASSIFICATION AND LABELLING

4.1 Introduction

CHIP/CLP classification is part of Safety Information and must appear on the Container Label *and* on any separate Leaflet supplied with the product formatted in line with the requirements detailed below and those set out in Volume 1. Only symbols and phrases which are appropriate to the product must be used. You should justify your choice of symbols and phrases when making an application.

Guidance on CHIP and CLP classification and labelling is in the <u>CHIP and CLP</u> <u>Guidance Document</u> on our website.

This section provides advice on how to format the required CHIP/CLP information on a PPP label.

4.2 Location of CHIP/CLP information on the label

- 4.2.1 CHIP/CLP have requirements on the information that must appear on classified products. However, they do not explicitly specify location and presentation (other than to define the size and colour of the hazard symbols/pictograms and that symbols/phrases must be in close proximity. The classification is a fundamental part of the Safety Information, so all information relating to CHIP/CLP should ideally appear on the Main Area of the label if space is available.
- 4.2.2 The basic information under CHIP/CLP that must appear on any classified product plus comments is detailed below. Note that in addition to the classification and labelling components not covered by the PPP Regulation 1107/2009, there is various other required information that duplicates that required by 1107/2009:



	CHIP	CLP	PPP requirements
1.	Tradename	Tradename	Tradename is already required on a PPP label
2.	Name, address and telephone number of the supplier	Name, address and telephone number of the supplier	Authorisation holder and marketing company if different are already required on a PPP label.
3.	Identification of the constituents of the preparation which result in it being classified as a dangerous preparation,	Identity of all substances in the mixture that contribute to the classificationthat contribute to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard.	The active substance must always appear on the PPP label.
4.	Hazard symbol(s) and Indication of Danger.	Hazard pictograms, signal words	-
5	Risk and Safety phrases.	Hazard precautionary statements, supplemental information	-
6.	For preparations intended for sale to the general public, the nominal quantity	For preparations intended for sale to the general public, the nominal quantity	The weight or volume of the PPP must always appear on the PP label.
7.	The general warning statement "To avoid risks to man and the environment, comply with the instructions for use."	EUH401 — 'To avoid risks to human health and the environment, comply with the instructions for use'	Either phrase must appear on all amateur products even if they are not subject to CHIP/CLP classification.

- 4.2.3 Most of the CHIP/CLP requirements must already appear on a PPP label and should continue to appear in the formats given elsewhere in this Handbook.
- 4.2.4 The phrases and symbols (4, 5 and 7 above) and the formulation constituents (3 above) are the additional CHIP/CLP information that must appear on the PPP label. We do not have a set format for presentation of this information but we suggest that it appear boxed and it must be on the Main Area of the label.
- 4.2.5 An example of such a 'CHIP and CLP box' is given below. You may utilise any other format as long as it complies with both the requirements of CHIP/CLP and the guidance on PPP labels in this Labelling Handbook.



(a) Example of a professional product 'CHIP Box'





Irritant Dangerous for the environment

Harmful if swallowed Irritating to eyes and skin Toxic to aquatic organisms. May cause long term adverse effects in the aquatic environment

Avoid contact with eyes In case of contact with eyes, rinse immediately with plenty of water and seek medical advice Wear suitable gloves If swallowed, seek medical advice immediately and show this container or label Keep out of reach of children This material and its container must be disposed of in a safe way Use appropriate containment to avoid environmental contamination

To avoid risks to man and the environment comply with the instructions for use

(b) Example of a professional product 'CLP Box'



Warning Suspected of causing cancer Harmful if swallowed Very toxic to aquatic life with long lasting effects.

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood Use personal protective equipment as required. If exposed or concerned: Get medical advice/attention. Dispose of contents/container Wash hands thoroughly after handling Do not eat, drink or smoke when using this product IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

To avoid risks to human health and the environment comply with the instructions for use



4.3 Options if CHIP/CLP phrases duplicate other phrases required on the label

- (a) Some phrases which were historically required on PPP labels in the 'Safety Precautions' are now also specified under CHIP/CLP (as safety or precautionary statements). Where these phrases must appear as CHIP/CLP requirements they need not be duplicated elsewhere on the label. For example the phrase KEEP OUT OF REACH OF CHILDREN may have been historically specified as a precautionary phrase on PPPs, but if it is also a requirement of CHIP/CLP (S2 or P102- and appears in the 'CHIP box'), then there is no need to repeat the phrase in the 'Safety Precautions'. section. You should note that if the phrases differ in any way it may *not* be appropriate to delete the phrase from the 'Safety Precautions' section. *e.g.* if the PPP authorisation requires the phrase 'KEEP OUT OF REACH OF CHILDREN *AND PETS*'.
- (b) Personal Protective Equipment (PPE) required by CHIP/CLP does not replace any specified under Regulation 1107/2009 in the SAFETY PRECAUTIONS. Those PPE will have been assessed according to *risks* inherent to use (*e.g.* during mixing, loading, application and handling treated/contaminated items), rather than the hazard presented. Operator protection requirements under CHIP/CLP and Regulation 1107/2009 must therefore always be specified separately.



5. SAFETY PRECAUTIONS

5.1 Introduction

- 5.1.1. In addition to the CHIP/CLP requirements, we may require a number of UK specific safety phrases to appear Safety Instructions section, to ensure safe storage, use and disposal of the product.
- 5.1.2 These may include phrases set out in Annex III to Regulation 1107/2009 (the 'Annex III phrases') if the risk assessment has been carried out that Regulation (see <u>Appendix 2</u>). Such additional phrases must be listed in the Safety Precautions section.

5.2 Location and format of Safety Precautions

- 5.2.1 The Safety Precautions represent key safety information and should appear on the Main Area of the label, and any separate leaflet supplied with the product.
- 5.2.2 In most cases, the Safety Precautions will appear after Product Identity, Important Information and CHIP/CLP box, but before the Directions For Use.
- 5.2.3 It must have a major heading **SAFETY PRECAUTIONS** in bold capitals with the following subheadings to appear in bold using upper and lower text as shown:
 - Operator protection
 - Consumer protection
 - Environmental protection
 - Storage and disposal

The precautionary phrases must appear under the appropriate subheading. Any sub-heading(s) need not appear if there no phrases are,.

- 5.2.4 The actual safety phrases must be presented as either:
 - upper and lower case (as specified in Appendices 2 to 6 to this Volume); or
 - the first parts of the phrases specified in upper case in this guidance may appear in **bold** (in place of upper case), but with upper/lower case as for normal text

We prefer that each phrase appears as a separate line of text. However, where space constraints dictate, they may follow on the same line as long as individual phrases are clearly differentiated from one another.

5.2.5 You must suggest appropriate phrases when submitting the draft label. these should be based on the assessment for the product/uses, and may take into account phrases used on similar products. We will clarify which phrases are needed after we have conducted our evaluation, specifying any changes required



via label amendments issued with the authorisation. To help you decide which phrases may be appropriate we have provided details of standard phrases and the situations where they might be used later in this Volume.

5.3 Operator Protection Safety Precautions

5.3.1 What are the operator protection phrases?

These reflect the precautions needed by the operator and others to be followed to ensure the safe use of the product. They include personal protective equipment (PPE) and engineering controls to be used during all stages of the application process. They are based on our operator **risk assessment** for the use of the product as proposed and apply to specific operations where PPE is required for safe use. They differ from the CHIP PPE requirements which are **hazard** based.

5.3.2 How do I write the PPE phrases?

The general format for PPE phrases is as follows:

WEAR SUITABLE [list PPE all in upper case] when [detail specific tasks in lower case].

The phrase should be written as concisely as possible and where necessary additional clarification of the phrase must appear directly below the main phrase.

Where several items of PPE are required, they should be listed in the following order:

CLOTHING \rightarrow GLOVES \rightarrow BOOTS \rightarrow EYE/FACE PROTECTION \rightarrow RESPIRATORY PROTECTIVE EQUIPMENT.

Where the PPE differs depending on the task, you should include separate phrases for each task. When many task/PPE combinations must be specified then it may be clearer to use a tabulated format. Some examples of PPE phrases (including an example of the tabulated form) are included in Appendix 3 to this Volume.

We have standardised the descriptions used for the various PPE options to allow the user as much flexibility in approach as possible (*e.g.* we would not specify trade names). You should use these terms in your PPE phrases unless we agree to something different.



5.3.3 Can the operator deviate from these PPE and how do I reflect this on the label?

If the operator conducts an appropriate COSHH assessment they may be able to make changes to the PPE they wear (*e.g.* use of engineering controls may negate the need for certain PPE). To reflect this, the following 'top and tail' phrases must also appear in the Safety Precautions directly above and below the PPE phrase(s):

Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:

[PPE phrase – see above]

However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.

Where specific engineering controls (*e.g.* a closed tractor cab) are required for the safe use of the product we will specify additional phrases that should appear above the PPE phrases along with a reworded version of the 'top and tail' phrases. An example is given in Appendix 3 to this Volume.

5.3.4 What if specific engineering controls are required for the safe use of the product?

Where specific engineering controls (*e.g.* a closed tractor cab) are required for the safe use of the product we will specify additional phrases that should appear above the PPE phrases along with a reworded version of the 'top and tail' phrases. An example is given in Appendix 3 to this Volume.

5.3.5 Are there any other operator protection phrases that must appear (including Annex III phrases)?

The following phrase is compulsory for products containing anticholinesterase organophosphate or carbamate active substances. If required this phrase must be the *first* phrase in the Operator Protection section:

This product contains an anticholinesterase organophosphate (or carbamate or carbomoyl triazole). DO NOT USE if under medical advice **not** to work with such compounds.

There are a number of other phrases that may be appropriate to appear in the Operator Protection section of the Safety Precautions (and may include Annex III phrases) and examples can be found in 3 to this Volume.



5.4 Consumer Protection Safety Precautions

These are the precautions to be followed to ensure the protection of persons likely to come into contact with treated material after application has occurred. Note they do not all relate to the consumption of the crop, but are included in this area for ease.

Examples of consumer protection phrases which may be required can be found in Appendix 4 to this Volume. There are no Annex III phrases that apply to the Consumer Protection section.

5.5 Environmental Protection Safety Precautions

5.5.1 What are the environmental protection phrases?

These are the precautions to be followed to ensure the protection of the environment (*i.e.* water, soil and air) and non-target organisms (*e.g.* fish and other aquatic life, bees, livestock and game) and examples can be found in Appendix 5 to this Volume. Several of the Annex III phrases fall into this category, and some have been tailored to reflect UK specific requirements and further guidance can be found on the <u>CRD website</u>.

5.5.2 Are there any environmental protection phrases that apply to all products?

The following environmental protection phrase is required for all professional authorised products (Annex III SP 1 phrase):

'Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads'.

If the product has authorised aquatic uses the phrase must be annotated as follows:

'Do not contaminate water with the product (except as directed for aquatic use) or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads'.

Important note

Prior to re-registration of products the COPR phrase 'DO NOT CONTAMINATE SURFACE WATER OR DITCHES with chemical or used container' may still be used.



5.5.3 Aquatic buffer zones

If the product is subject to an aquatic buffer zone, then this must be specified in the 'Environmental Protection' section of the Safety Precautions. The actual phrases used depend on whether the product falls into

- The original LERAP category A or B arrangements;
- The new interim buffer zone arrangements;
- The new 3 star Drift Reduction Technology buffer zone arrangements; and
- and whether application is by tractor mounted or broadcast air assisted sprayers

Full details of all phrases can be found in Appendix 5 to this Volume.

5.6 Storage And Disposal Safety Precautions

These are the precautions to be followed to ensure safety of product in storage and reflects good disposal practices – various examples can be found in Appendix 6 to this Volume.

5.7 Special requirements for seed treatment Safety Precautions

Whilst the use of the seed treatment product is covered under the pesticides legislation, the handling and sowing of seed and propagules *treated with that pesticide* are not authorised the COPR/PPPR. Treated material is therefore not covered by the labelling requirements. See Appendix 7 to this Volume for voluntary labelling guidelines.



6. MEDICAL ADVICE

- 6.1 Where the toxicity of the product justifies it, statements on First Aid and Guide to Doctor or Poisons Centre must appear. This Medical Advice must appear as appropriate in the Safety Precautions or as a separate section on the Container Label and any separate Leaflet.
- 6.2 Examples of standard statements for certain active substances (Organophosphate pesticides, Dinitro compounds, Anticoagulant rodenticides, Cyanides and Carbamates) are given in Appendix 8 to this Volume, along with details of the UK National Poisons Information Service (NPIS) Centres. For other products if it is considered that medical advice is appropriate, this will be required as part of the authorised text and requested as an amendment on the Notice of Authorisation. Other wording must not be used unless we have given prior agreement. Where Medical Advice is considered necessary, you should present this on the draft label for our consideration.



7. DIRECTIONS FOR USE

7.1 Introduction

The Directions For Use section contains all the remaining authorised text, required for the user to use the product properly. It contains information such as specific restrictions or warnings, crops and pests controlled, following crops, mixing and spraying advice, compatibility with other products and resistance information.

7.2 Location of Directions for Use

The Directions For Use should appear on the Container Label *and* on any separate Leaflet supplied with the product. However, where space constraints dictate, they may appear on the Leaflet only, providing a suitable phrase directs the user to where they may be found (full guidance on the definition and presentation of Container Labels and Leaflet is given in Volume 1).

7.3 Format of Directions for Use

7.3.1 The section must be headed with **DIRECTIONS FOR USE** in bold capitals and the heading must be followed with the following statement to highlight the status of the Directions For Use to make clear the user's responsibilities.

'IMPORTANT: This information is authorised as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product'.

- 7.3.2 The text under the major heading **DIRECTIONS FOR USE** should be set normally, *i.e.* in capitals and lower case as appropriate. All subheadings must be distinct from the main **DIRECTIONS FOR USE** heading.
- 7.3.3 We prefer standard formats for the Directions for Use, because this encourages familiarity with all labels. We have therefore provided some examples to use as a basis for your label. However we do allow some flexibility in format, as long as all of the information in the Directions for Use section is supported by appropriate data, and that you take into account our guidance on false and misleading information (see Volume 1). The content of the Directions for Use section must relate only to those uses 'summarised' in the Important Information box.
- 7.3.4 The structure of the Directions for Use section depends on the complexity of the label which is broadly dictated by the number of crop/pest combinations present. You may use sub-headings where this helps. The use of tabulated information usually improves clarity, so we encourage their use if appropriate. We prefer you to use a consistent format throughout the label (*e.g.* tabulate pests for each crop rather than use text for some and tables for others). If the label is very large



(perhaps in leaflet format), then we would encourage the use of an index to help the user.

7.3.5 Three different but acceptable formats are given in the examples in 9 to this Volume.

7.4 Information to be included in the Directions for Use

(a) Restrictions or Warnings

Most products have a restrictions or warnings section. This should be the first sub-section listing the restrictions for the product so the user can immediately see these without having to search through the rest of the section. (*e.g.* Do not use on sandy or very light soils; Do not use on frosted crops or during frosty weather; Do not use on crops suffering under stress, from drought or from pest/disease attack). It may be necessary to note in this section that where there are varietal restrictions or certain following crop restrictions etc, that further information on these is situated elsewhere on the label in more detail.

(b) Problem/pest controlled

This section should list the pests, weeds or diseases controlled with the susceptibilities and latest weed/pest growth stage or stage of the disease for effective control. This section should provide general advice on the effective use of the product and include resistance advice/management strategy and any positive tank mixture recommendations.

(c) Crop specific information

This section should provide specific information relating to each crop, *e.g.* dose, timings and varieties. This may be achieved with one simple section where there is only one crop or where all the crops may be treated the same or a number of sections covering the information for the range of crops. Alternatively a simple table may be used with general information following.

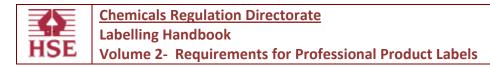
As a rule, the information for each crop should follow only one format to avoid confusion.

(d) Following crops

If required a detailed following crop section should then follow. However it may be appropriate for this section to appear in the crop specific information section if the specific crop sprayed (or its timing) would influence the succeeding crop. If there are no following crop restrictions this could simply be stated in the 'Restrictions' section.

(e) Mixing and Spraying

A section covering mixing and spraying instructions should appear next. This section would include information on water volumes (if not specified for each crop in the crop specific information section), application methods, spray quality (BCPC) and the method for cleaning application equipment.



This section must also include advice to use mechanical handling of the container if the pack size is greater than 20 litres or 25 kg.

(f) Compatibility

The compatibility section should list 'convenience' tank-mixes (*i.e.* those for which no specific recommendations and claims for use are made) and if required, 'positive' tank-mixes (for which specific claims and recommendations are made in the Directions For Use). Full details of the requirements for listing of both 'convenience' and 'positive' tank-mix recommendation are given in the 'tank-mix' section of the 'The Applicant Guide'.



8. COMPANY ADVISORY INFORMATION

8.1 Introduction

Whilst it is not considered to form part of the authorised text, you may wish to include a **Company Advisory Information (CAI)** section to provide additional information that you wish to appear on the label. The information in this section does not need to be supported by safety and efficacy data but MUST NOT contradict the 'Authorised Text' in any way'.

The CAI allows for the provision of additional information to the user without compromising the safety or efficacy of the use. Because the CAI is not checked by us, it allows you more scope in making changes to the label which are not subject to regulatory controls. You can make changes to the CAI section without applying for authorisation to do so.

8.2 Information included in the Company Advisory Information

The specific types of information that may appear are:

- Additional Health and Safety information.
- Additional information relating to the use of the product.
- Other information not directly related to the authorisation, *e.g.* company disclaimers.

Handy tip!

If you are not sure whether information should appear as authorised text or in the Company Advisory Information, you should contact us for advice before going to print.

8.3 Location of the Company Advisory Information

The CAI should appear as a separate section to the 'Authorised Text' on the Product Label (either Container Label or Leaflet); or as a completely separate Leaflet, which would be referenced from the 'Authorised Text' (this would make it easier to amend and update the information without the need to reprint the 'Authorised Text').

The inclusion of the CAI is not compulsory; however this information still forms part of the Product Label and its status as 'Other Text' must be made clear. The Company Advisory Information section should be clearly separated from the 'Authorised text' and must carry:

- A clear heading reading Company Advisory Information.
- A clear statement that this section is not part of the Product Label under the Control of Pesticides Regulations 1986 or the Plant Protection Products



Regulations 1995 (as appropriate) and that it provides additional advice on product use at the discretion of the applicant.

There are no other specific formatting requirements although CRD suggest that the section be structured for ease of use by the reader and further guidance is provided in Appendix 10 to this Volume.



9. LABELLING FOR EXTENSION OF AUTHORISATION FOR MINOR USE

- 9.1 Under Article 51 of Regulation (EC) 1107/2009 both authorisation holders and growers or grower organisations can apply for an 'extension of use. This is defined as an extension of authorisation for **minor uses** of existing authorised products. The extension can be given where the use is minor in nature, is in the public interest and all safety aspects of the risk assessment can be satisfied.
- 9.2 When an extension of use is given it can appear on the product label in a separate section titled 'Extension of Use' and with the following text:

This extension of the authorised use provides for the use of the [product name] in respect of crops and situations, other than those included on the product label [above]. No efficacy or phytotoxicity data have been assessed and as such the 'extension of use', is at all times done at the user's choosing, and the commercial risk is entirely theirs."



Appendix 1: Examples of Important Information sections

Example 1

This is the simplest format where the same restrictions apply to one or more crops and there is no need to differentiate between different restrictions for different crops.

IMPORTANT INFORMATION FOR USE ONLY AS A PROFESSIONAL HERBICIDE Crop: Winter wheat and winter barley Maximum individual dose: 2 litres product/ha Maximum number of treatments: 2 per crop Latest time of application: Before second node detectable stage Other specific restrictions: This product must not be used on durum wheat READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS



Example 2

This format may be used where different restrictions apply to different crops/situations and where there is a need to differentiate. Alternatively, the tabulated format in Example 3 may be used.

IMPORTANT INFORMATION

FOR USE ONLY AS A PROFESSIONAL HERBICIDE

Crops:	Winter wheat, winter barley and oilseed rape	
Maximum individual dose:	Winter wheat and barley: 2 litres product/ha Oilseed rape: 1 litre product/ha	
Maximum number of treatments:	Winter wheat and barley: 2 per crop	
Maximum total dose:	Oilseed rape: 3 litres product/ha/crop	
Latest time of application:	Winter wheat and barley: Before second node detectable stage Oilseed rape: 14 days before harvest	
Other specific restrictions:	This product must not be used on durum wheat	
READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS		



Example 3

As in Example 2 this format may be used where different restrictions apply to different crops/situations and where there is a need to differentiate. The use of the table presents the information in an easier to follow format than Example 2 and should be the standard where use on a number of crops/situations is authorised.

Note that the 'Other specific restriction' could appear in a headed column. However, in this case, due to space availability it has been included as a separate section below the table.

R USE ONLY AS	S A PROFESSIC	NAL HERBICIDE		
Crops:	Maximum individual dose	Maximum number of treatments	Maximum total dose	Latest time of application
Winter wheat and winter barley	2 litres product/ha	2 per crop	-	Before 2nd node detectable stage
Oilseed rape	1 litre product/ha	-	3 litres product/ha/crop	Before stem extension
Strawberry	1 litre product/ha	3 per year	-	14 days before harvest

Other specific restrictions:

A minimum interval of 7 days must be observed between applications to strawberry

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS



Example 4

CRD would prefer use of the Important Information formats in Examples 1 to 3 such that all required information appears on the Container Label. However the following format may be used to direct the user to any separate Leaflet is supplied with the product and in which the Important Information must appear in any case. Note that 'Crops/situations' must always appear on the Container Label and **may not** be 'signposted'.

IMPORTANT INFORMATION

FOR USE ONLY AS A PROFESSIONAL HERBICIDE

Crops:

Winter wheat, winter barley, oilseed rape, strawberry and land not intended to bear vegetation

Maximum individual dose: Maximum number of treatments: Maximum total dose: Latest time of application: Other specific restrictions:

Full details are on attached leaflet

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS

The Leaflet must then include the complete Important Information section:

}

	IMPORTANT INFORMATION					
F	FOR USE ONLY AS A PROFESSIONAL HERBICIDE					
	Crops/ situations	Maximum individual dose	Maximum number of treatments	Maximum total dose	Latest time of application	Other specific restrictions
	Winter wheat, winter barley	2 litres product/ha	2 per crop	-	Before 2 nd node detectable	This product must not be used on durum wheat
	Oilseed rape	1 litres product/ha	-	3 litres product/ha/ crop	Before stem extension	-
	Strawberry	1 litre product/ha	3 per year	-	14 days before harvest	Minimum interval between applications: 7 days
	Land not intended to bear vegetation	4 litres product/ha	1 per situation	-	-	-

READ THE LABEL BEFORE USE. USING THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH THE LABEL MAY BE AN OFFENCE. FOLLOW THE CODE OF PRACTICE FOR USING PLANT PROTECTION PRODUCTS



Appendix 2: Risk and Safety Precautions phrases in Annexes II and III of Commission Regulation (EU) No 547/2011 (previously Annexes IV and V of Directive 91/414/EEC

Code	Phrase			
Annex II –s	special risk phrases			
RSh1	Toxic by eye contact			
RSh2	May cause photosensitisation			
RSh3	Contact with vapour causes burns to skin and eyes and contact with liquid causes freezing			
	safety precaution phrases			
General pr				
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).			
Safety pree	cautions for operators			
SPo general provisions	Phrases relating to ppe, engineering controls and specific tasks when they should be used- See Volume 2/ Appendix 2			
SPo 1	After contact with skin, first remove product with a dry cloth and then wash the skin with plenty of water			
SPo 2	Wash all protective clothing after use			
SPo 3	After igniting the product, do not inhale smoke and leave the treated area immediately			
SPo 4	The container must be opened outdoors and in dry conditions			
SPo 5	Ventilate treated areas/greenhouses thoroughly/time to be specified/until spray had dried before re-entry			
Safety precautions related to the environment				
SPe 1	To protect groundwater/soil organisms do not apply this or any other product containing (<i>identify active substance or class of substance, as appropriate</i>) more than (<i>time period or frequency to be specified</i>)			
SPe 2	To protect groundwater/aquatic organisms do not apply to (soil type or situation to be specified) soils			
SPe 3	To protect aquatic organisms/non-target plants/non-target arthropods/insects respect an unsprayed buffer zone of (distance to be specified) to non-agricultural land/surface water bodies			



To protect aquatic organisms/non-target plants do not apply on
impermeable surfaces such as asphalt, concrete, cobblestones, railway
tracks and other situations with a high risk run-off
To protect birds/wild mammals the product must be entirely incorporated
in the soil; ensure that the product is also fully incorporated at the end of
rows
To protect birds/wild mammals remove spillages
Do not apply during the bird breeding period.
Dangerous to bees/To protect bees and other pollinating insects do not
apply to crop plants when in flower/Do not use where bees are actively
foraging/Remove or cover beehives during application and for (state time)
after treatment/Do not apply when flowering weeds are present/Remove
weeds before flowering/Do not apply before (state time)
ecautions related to good agricultural practice
To avoid the build-up of resistance do not apply this or any other product
containing (identify active substance or class of substances, as appropriate)
more than (number of applications or time period to be specified)
cautions for rodenticides
The baits must be securely deposited in a way so as to minimise the risk
of consumption by other animals. Secure bait blocks so that they cannot
be dragged away by rodents
Treatment area must be marked during the treatment period. The danger
from being poisoned (primary or secondary) by the anticoagulant and the
antidote against it should be mentioned.
Dead rodents must be removed from the treatment area each day during



Appendix 3: Safety Precautions phrases- Operator protection

1. Personal protective equipment and engineering control phrases

1.1 'Engineering control' phrases

(a) <u>Where any ppe are required, they must always appear between the following</u> standard phrases requiring the use of 'engineering controls'.

Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment:

[Insert PPE phrase(s) – see para. 1.2 below]

However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.

- (b) Where specific 'engineering controls' are required for the safe use of the product CRD will specify additional phrases that may need to appear prior to the PPE phrases above and a reworded version of the 'top and tail' phrases *e.g.*
 - (1) Vehicles fitted with a cab and forced air filtration unit plus a pesticide filter complying with HSE Guidance Note PM 74, or an equivalent or higher standard, must be used when making broadcast air assisted applications.
 - (2) Other engineering control of operator exposure must also be used where reasonably practicable in addition to the following personal protective equipment:

[Insert PPE phrase(s) – see para. 1.2 below]

(3) However, other engineering controls in additions to those specified in (1) above may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection.

1.2 'Personal protective equipment' (PPE) phrases

(a) <u>PPE phrases consist of a list of specific PPE to be worn when carrying out</u> <u>specific operations constructed from the following examples *i*</u>



i) <u>PPE</u>

Type of PPE	Terms to consider when constructing operator protection phrase- phrase to read as 'WEAR [<i>relevant ppe from list below</i>]'
Clothing	SUITABLE PROTECTIVE CLOTHING
	If applicable specify the type in brackets e.g.
	 SUITABLE PROTECTIVE CLOTHING (COVERALLS) SUITABLE PROTECTIVE CLOTHING (COVERALLS WITH HOOD) SUITABLE PROTECTIVE CLOTHING (APRON) SUITABLE PROTECTIVE CLOTHING (COVERALLS WORN BENEATH A SECOND DISPOSABLE COVERALL)
Gloves	SUITABLE PROTECTIVE GLOVES
	 If applicable specify the material of the gloves this in brackets in the body of the phrase e.g. SUITABLE PROTECTIVE GLOVES (BUTYL OR NITRILE) SUITABLE PROTECTIVE GLOVES (NEOPRENE OR NITRILE) SUITABLE PROTECTIVE GLOVES (NATURAL RUBBER OR POLYVINYL CHLORIDE (PVC))
	 If applicable additional information such as minimum glove thickness should appear after the main phrase (see examples below) e.g. SUITABLE PROTECTIVE GLOVES * At least 0.5 mm thick SUITABLE PROTECTIVE GLOVES * *At least elbow length
Footwear	RUBBER BOOTS
Eye or face protection	FACE PROTECTION (FACESHIELD) or EYE PROTECTION (GOGGLES)
Respiratory protective	SUITABLE RESPIRATORY PROTECTIVE EQUIPMENT *
equipment	* [specific type of RPE as recommended by CRD e.g Disposable filtering facepiece respirator to at least EN149 FFP2 or equivalent; Full facemask to at least EN 136 with a combination filter to at least EN141 A2P3, or equivalent.)



ii) <u>Operations</u>

Operation phrases- to be	added to the PPE from i) above.	
when handling	the concentrate	
	the product	
	water-soluble bags	
	contaminated surfaces	
	freshly treated material	
	treated seed.	
	treated material	
	treated crops	
	treated growing media	
	treated seed and contaminated seed sowing equipment	
when applying	the product	
	by vehicle-mounted or trailed equipment	
	by hand	
	by hand-held equipment	
	using pedestrian-controlled equipment	
	broadcast air-assisted equipment	
	the undiluted product	
	by soil injection equipment	
	as a space treatment	
	by paintbrush	
	by hand-held weedwiper	
	by hand-held controlled droplet application (CDA) equipment	
	by spot gun	
	the product indoors	
	the product where there is insufficient ventilation	
	as a structural treatment	
when treating	compost	
	compost by hand	
when making	cut stump treatments	
_	stem injection treatments	
when re-entering	treated areas	
C C	treated areas before adequate ventilation or removing	
	sheeting.	
when filling the planter		
when riding on the planter		
when igniting more than one smoke generator or in situations where it is not possible to		
vacate the treatment area immediately after ignition		
when bagging treated seed		
planting treated material		
acting as a groundmarker during aerial application,		



(b) <u>The following are examples of how to format PPE phrases</u>

i) Examples of standard text format::

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS, APRON), SUITABLE PROTECTIVE GLOVES, RUBBER BOOTS, AND FACE PROTECTION (FACESHIELD) when handling the concentrate.

WEAR SUITABLE PROTECTIVE GLOVES (NEOPRENE OR NITRILE*) AND EYE PROTECTION (GOGGLES) when handling contaminated surfaces, or applying by hand-held equipment * at least 0.5 mm thick.

WEAR SUITABLE PROTECTIVE GLOVES* applying by hand, * at least elbow length.

WEAR SUITABLE RESPIRATORY PROTECTIVE EQUIPMENT* when spraying.

*Disposable filtering facepiece respirator to at least EN149 FFP2 or equivalent

ii) Examples of tabulated format (used where there are extensive PPE)

WEAR SUITABLE PROTECTIVE CLOTHING for the operations listed as specified below:

When handling the concentrate	Suitable protective clothing (coveralls), suitable protective gloves, face protection (faceshield) and suitable respiratory protective equipment* *Disposable filtering facepiece respirator to at least EN149 FFP2 or equivalent.
When applying by hand-held equipment	Suitable protective clothing (coveralls) and suitable protective gloves
When applying by vehicle- mounted or trailed equipment	Suitable protective clothing (coveralls)

1.3 Specific 'personal protective equipment' (PPE) phrases for products containing micro-organisms

See <u>Regulatory Update 30/12</u> for full details. all such products should include the following phrase on the label:

'Micro-organisms may have the potential to provoke sensitising reactions'.



The minimum default levels of protective equipment for microbial based products are RPE meeting FFP3 standards. Such product labels must include one of the following PPE phrases in addition to the 'Engineering control' phrases:

i) For solid products

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS), SUITABLE PROTECTIVE GLOVES AND SUITABLE RESPIRATORY PROTECTIVE EQUIPMENT* when handling the product or applying the product. *Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

ii) For liquid products

WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS), SUITABLE PROTECTIVE GLOVES AND SUITABLE RESPIRATORY PROTECTIVE EQUIPMENT* when handling the concentrate or applying the product. *Disposable filtering facepiece respirator to at least EN149 FFP3 or equivalent.

2. Other operator protection phrases

Further examples of operator protection phrases which may be required (please note that for authorisations under Regulation 1107/2009 Annex III safety precaution phrases for operators may be applicable and these are listed in Appendix 2 of Volume 1):

- a) WASH ALL PROTECTIVE CLOTHING thoroughly after use, especially the insides of gloves.
- b) TAKE OFF IMMEDIATELY all contaminated clothing.
- c) HANDLE WITH CARE AND MIX ONLY IN A CLOSED CONTAINER.
- d) WASH SPLASHES/DUST/POWDER/CONCENTRATE/ANY CONTAMINATION from skin or eyes immediately.
- e) WASH HANDS/EXPOSED SKIN before eating and drinking/smoking/after work.
- f) TO BE USED ONLY BY OPERATORS INSTRUCTED OR TRAINED in the use of chemical/product/type of produce/and familiar with the precautionary measures to be observed.

2.1 May be appropriate where PPE is recommended:

WASH ALL PROTECTIVE CLOTHING thoroughly after use, especially the insides of gloves.



2.2 May be appropriate for classified products:

TAKE OFF IMMEDIATELY all contaminated clothing.

2.3 Required for pesticides classified as very toxic, toxic, harmful, corrosive or irritating:

WHEN USING DO NOT EAT, DRINK OR SMOKE

2.4 Required for pesticides classified as very toxic, toxic, or corrosive:

IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, seek medical advice immediately (show the label where possible).

2.5 Required for pesticides classified as harmful only:

IF YOU FEEL UNWELL, seek medical advice immediately (show the label where possible).

2.6 Compulsory for products which contain phosphoric acid esters or are classified as corrosive:

AFTER CONTACT WITH SKIN, WASH IMMEDIATELY with plenty of water [or other substance deemed appropriate for the specific situation - to be agreed with PSD].

2.7 May be required for certain pesticides which pose a hazard to eyes:

IN CASE OF CONTACT WITH EYES, RINSE IMMEDIATELY with plenty of water and seek medical advice.

2.8 May also be appropriate to specific products:

- a) DO NOT BREATHE DUST/GAS/FUMES/VAPOUR/SPRAY
- b) HANDLE WITH CARE AND MIX ONLY IN A CLOSED CONTAINER
- a) WASH SPLASHES/DUST/POWDER/CONCENTRATE/ANY CONTAMINATION from skin or eyes immediately.
- b) AVOID ALL CONTACT/BY MOUTH/WITH SKIN/EYES
- c) WASH HANDS/EXPOSED SKIN before eating and drinking/smoking/after work.
- d) TO BE USED ONLY BY OPERATORS INSTRUCTED OR TRAINED in the use of chemical/product/type of produce/and familiar with the precautionary measures to be observed.



2.9 May be appropriate for storage practice products:

- a) ENSURE ADEQUATE VENTILATION IN CONFINED SPACES
- b) APPLY SOLUTIONS from unbreakable containers carrying a pouring tube or similar device.
- c) EXTINGUISH ALL NAKED FLAMES INCLUDING PILOT LIGHTS, WHEN APPLYING THE FUMIGANT/DUST/LIQUID/PRODUCT
- d) DO NOT BREATHE DUST/ GAS/ FUMES/ VAPOUR/ SPRAY/ FOG/ MIST/ SMOKE.

or

DO NOT WORK IN CONFINED SPACES OR ENTER SPACES IN WHICH HIGH CONCENTRATIONS OF VAPOUR ARE PRESENT. Where this precaution cannot be observed distance breathing or self-contained breathing apparatus must be worn, and the work should be done by trained operators.



Appendix 4: Safety Precautions phrases- Consumer protection

- 1. May be appropriate to Agricultural, Horticultural and Forestry products:
 - a) DO NOT USE ON FOOD CROPS
 - b) KEEP UNPROTECTED PERSONS OUT OF TREATED AREAS for at least (appropriate interval to be specified).

2. May be appropriate to food storage practice products:

- a) DO NOT APPLY TO SURFACES on which food/feed is stored, prepared or eaten.
- b) DO NOT APPLY TO CLOTHING
- c) REMOVE/COVER ALL FOODSTUFFS BEFORE APPLICATION
- d) Protect food preparing equipment and eating utensils from contamination during application.
- e) USE ONLY ON (appropriate foodstuff to be specified).
- f) REMOVE ALL PETS/ LIVESTOCK BEFORE TREATMENT
- g) KEEP/APPLY/SUSPEND ONLY in positions inaccessible to children and pets.
- h) REMOVE EXCESS DUST AND AIR TREATED FABRICS THOROUGHLY BEFORE USE
- i) DO NOT USE IN OCCUPIED DWELLING HOUSES

3. May be appropriate to fumigant products:

- a) Fumigate only under conditions which allow no leakage of gas to adjacent occupied premises.
- b) VENTILATE TREATED AREAS thoroughly when gas/smoke has cleared.
- c) KEEP ANIMALS/BIRDS OUT of premises where grain is under fumigation or being aired following fumigation.



Appendix 5: Safety Precautions phrases- Safety Precautions phrases- Environmental Protection

- 1. The following are examples of environmental protection safety precautions which may be appropriate. Please note that products currently authorised may carry older phrases that pre-date phrases a) to h) which are the agreed Regulation 1107/2009 Annex III environmental phrases (tailored to reflect UK requirements). The old phrases will be replaced by the latter for individual authorisations as and when we process relevant applications (e.g.re-registration) Further guidance on their use can be found on the <u>CRD website</u>:
 - a) Do not contaminate water with the product or its container [except as directed for aquatic use*]. Do not clean application equipment near surface water / Avoid contamination via drains from farmyards and roads.

(* if appropriate)

- b) Do not contaminate water with the product or its container except as directed for aquatic use. Do not clean application equipment near surface water / Avoid contamination via drains from farmyards and roads.
- c) To protect non target insects/arthropods respect an unsprayed buffer zone of *(distance to be specified in metres)* to non-crop land.
- d) RISK TO NON-TARGET INSECTS OR OTHER ARTHROPODS. See Directions for use.

The following associated advisory buffer zone phrase should then appear in the 'Directions for use' section of the label:

Avoid [spraying/application*] within 5 m of the field boundary to reduce effects on non-target insects or other arthropods.

(* 'application' is intended for use with solid products).

- e) To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is also fully incorporated at the end of rows.
- f) To protect birds/wild mammals remove spillages.
- g) To protect birds/wild mammals the product must be entirely incorporated in the soil; ensure that the product is fully incorporated at the end of rows. Remove spillages.



- h) Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower *[except as directed on specify crop as required]*. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.
- i) DO NOT USE OUTDOORS
- j) DANGEROUS/HARMFUL TO LIVESTOCK. Keep all livestock out of treated areas/away from treated water for at least (appropriate interval required)/for at least 2 weeks and until foliage of any poisonous weeds such as ragwort has died and become unpalatable. Bury or remove spillages.

2. For products classified as 'Category B' for Local Environment Risk Assessment For Pesticides (LERAPS) the following apply:

a) If application is via horizontal boom sprayers [and hand-held sprayers if appropriate], the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body]*. Aim spray away from water.

* delete if hand-held use not recommended

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a horizontal boom sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.

b) If application is via horizontal boom sprayers [and hand-held sprayers if appropriate] <u>and</u> broadcast air assisted sprayers, the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from broadcast air-assisted sprayers to fall within 'X m' of the top of the bank of a static or flowing waterbody, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a



narrower buffer zone, or within 5m of the top of a ditch which is dry at the time of application. Aim spray away from water.

[Where distance 'X' is determined through an appropriate assessment of the risks to aquatic life.]

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body.]* Aim spray away from water.

3. For products classified 'Category A' for Local Environment Risk Assessment For Pesticides (LERAPS):

a) If application is via by horizontal boom sprayers [and hand-held sprayers if appropriate], the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body.]* Aim spray away from water. THIS PRODUCT IS NOT ELIGIBLE FOR BUFFER ZONE REDUCTION UNDER THE LERAP HORIZONTAL BOOM SPRAYERS SCHEME

* delete if hand-held use not recommended

b) If application is via horizontal boom sprayers [and hand-held sprayers if appropriate] <u>and</u> broadcast air assisted sprayers, the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from broadcast air-assisted sprayers to fall within 'X m' of the top of the bank of a static or flowing waterbody, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 5m of the top of a ditch which is dry at the time of application. Aim spray away from water.



[Where distance 'X' is determined through an appropriate assessment of the risks to aquatic life.]

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body.]* Aim spray away from water. THIS PRODUCT IS NOT ELIGIBLE FOR BUFFER ZONE REDUCTION UNDER THE LERAP HORIZONTAL BOOM SPRAYERS SCHEME

* delete if hand-held use not recommended

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme for BROADCAST AIR-ASSISTED SPRAYERS ONLY. Before each spraying operation from a broadcast air-assisted sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.

4. For products that require a buffer zone and <u>are not</u> classified as 'Category A' or 'Category B' for Local Environment Risk Assessment For Pesticides (LERAPS) but which may be applied via broadcast air-assisted sprayers to orchard crops (inc. bush, cane and top fruit), the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from broadcast air-assisted sprayers to fall within 'X m' of the top of the bank of a static or flowing waterbody, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 5m of the top of a ditch which is dry at the time of application. Aim spray away from water.

[Where distance 'X' is determined through an appropriate assessment of the risks to aquatic life.]

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a broadcast air-assisted sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.



- 5. For products that have been assessed under the 'interim buffer zone arrangements' and which may include buffer zones > 5m the following apply:
 - a) For products with multiple buffer zones the crop table in 'IMPORTANT INFORMATION' must detail the buffer zone distance for each crop in an additional column and the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within the distance specified for the crop to the top of the bank of a static or flowing water body, or within 1 m of the top of a ditch which is dry at the time of application. [For crops with 5m buffer zone only: DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body].* Aim spray away from water. ALL CROPS WITH A BUFFER ZONE GREATER THAN 5M ARE NOT ELIGIBLE FOR BUFFER ZONE REDUCTION UNDER THE LERAP HORIZONTAL BOOM SPRAYERS SCHEME.

* if hand held use is permitted

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a horizontal boom sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone as appropriate to the crop must be maintained. NOTE ALL BUFFER ZONES OF MORE THAN 5M ARE NOT REDUCIBLE. The results of the LERAP must be recorded and kept available for three years.

b) For products with a single > 5m buffer zone: the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within X* metres of the top of the bank of a static or flowing water body, or within 1 m of the top of a ditch which is dry at the time of application. Aim spray away from water. THIS PRODUCT IS NOT ELIGIBLE FOR BUFFER ZONE REDUCTION UNDER THE LERAP HORIZONTAL BOOM SPRAYERS SCHEME

* Where X is the buffer zone distance e.g. any number from 6 to 20m

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. The statutory buffer zone must



be maintained and the distance recorded in the LERAP record form. The LERAP record form must be kept available for three years.

c) For products with a 5m buffer zone the following phrases must appear:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies in line with LERAP requirements.

DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within 5 m of the top of the bank of a static or flowing water body, unless a Local Environment Risk Assessment for Pesticides (LERAP) permits a narrower buffer zone, or within 1 m of the top of a ditch which is dry at the time of application. [DO NOT ALLOW DIRECT SPRAY from hand-held sprayers to fall within 1 m of the top of the bank of a static or flowing water body]*. Aim spray away from water.

* if hand-held uses are permitted

This product qualifies for inclusion within the Local Environment Risk Assessment for Pesticides (LERAP) scheme. Before each spraying operation from a horizontal boom sprayer, either a LERAP must be carried out in accordance with CRD's published guidance or the statutory buffer zone must be maintained. The results of the LERAP must be recorded and kept available for three years.

6. For products with buffer zone under the 3 star Drift Reduction Technology scheme:

- a) Under 'IMPORANT INFORMATION' the crop table must detail the buffer zone for each crop in an additional column
- b) Under 'IMPORANT INFORMATION a restriction to prevent hand-held use for any crop with a >5m buffer zone via horizontal boom sprayer must be included e.g.

'Do not apply via hand-held equipment'.

c) The following phrases must appear in the 'Safety Precautions' section:

To protect aquatic organisms respect an unsprayed buffer zone to surface water bodies as specified for the crop. HORIZONTAL BOOM SPRAYERS MUST BE FITTED WITH THREE STAR DRIFT REDUCTION TECHNOLOGY. Low drift spraying equipment must be operated according to the specific conditions stated in the official three star rating for that equipment as published on HSE Chemicals Regulation Directorate's website. Maintain three star operating conditions until 30 m from the top of the bank of any surface water bodies.



DO NOT ALLOW DIRECT SPRAY from horizontal boom sprayers to fall within the distance specified for the crop to the top of the bank of a static or flowing water body, or within 1 m of the top of a ditch which is dry at the time of application. Aim spray away from water. NOTE: BUFFER ZONES OF MORE THAN 5 M CANNOT BE REDUCED UNDER THE LOCAL ENVIRONMENT RISK ASSESSMENT FOR PESTICIDES (LERAP) SCHEME.

The statutory buffer zone must be maintained and the distance recorded in Section A of the LERAP record form. The LERAP record form must be kept available for three years.

d) 'In the Directions for Use' the following phrase must appear

'Effectiveness using three star drift reduction technology may be reduced."

7. For products applied by aircraft, the following phrase must appear:

Since there is a risk to aquatic life from use, spraying from the air must not take place within 250 m horizontal distance of surface waters or ditches.

8. The following phrases may be appropriate to products used in aquatic situations:

- a) The maximum concentration of active ingredient in treated water must not exceed [x] ppm or such lower concentration as the appropriate water regulatory body may require.
- b) Users must consult the appropriate water regulatory body (Environment Agency/Scottish Environment Protection Agency) before using the product near water and must obtain their agreement before using this product to control aquatic weeds.



Appendix 6: Safety Precautions phrases- Storage and Disposal

1. Required for products classified as very toxic, toxic, harmful, corrosive or irritant:

- a) KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS
- b) KEEP OUT OF REACH OF CHILDREN

2. Required for products supplied in standard containers:

KEEP IN ORIGINAL CONTAINER, tightly closed, in a safe place/under lock and key/ away from damp/sources of heat.

[This phrase is a statutory condition of storage if required to be kept 'under lock and key']

3. Required for products supplied in sachets:

STORE UNUSED SACHETS in a safe place. DO NOT STORE half-used sachets.

4. Required for products supplied in washable containers:

WASH OUT CONTAINER THOROUGHLY [empty washings into the spray tank*] and dispose of container safely. [* insert if appropriate]

or

RINSE CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of container safely/dispose of container as follows [appropriate advice]:

5. Required for products supplied in non-washable containers:

EMPTY CONTAINER COMPLETELY and dispose of safely.

6. Required for products that are harmful, toxic or very toxic and have nonreturnable/non refillable containers:

DO NOT RE-USE CONTAINER for any purpose.

- 7. Required for products that are supplied in returnable/refillable containers:
 - a) DO NOT RE-USE CONTAINER FOR ANY OTHER PURPOSE



- b) RETURN EMPTY CONTAINER TO THE SUPPLIER
- c) DO NOT RINSE OUT THE CONTAINER
- d) OPEN THE CONTAINER ONLY AS DIRECTED



Appendix 7: Safety Precautions phrases- Treated seed bags agreement

The 'Treated Seed Bag Agreement' requires that the name of the seed treatment product and active substance(s) contained therein should appear on the treated seed label in addition to the safety phrases as detailed below.

1. The following phrase must appear if required by CRD:

WEAR SUITABLE PROTECTIVE GLOVES when handling treated seed.

2. The following phrases should appear on all sack labels:

- a) DO NOT HANDLE seed unnecessarily.
- b) DO NOT USE TREATED SEED as food or feed.
- c) DO NOT RE-USE SACKS OR CONTAINERS THAT HAVE BEEN USED FOR TREATED SEED for food or feed.
- d) KEEP TREATED SEED SECURE from people, domestic stock/pets and wildlife at all times during storage and use.
- e) WASH HANDS AND EXPOSED SKIN before meals and after work.
- f) BURY OR REMOVE SPILLAGES
- g) TO PROTECT BIRDS/WILD MAMMALS, treated seed should not be left on the soil surface. Bury or remove spillages'.
- b) DO NOT APPLY TREATED SEED FROM THE AIR. (applies to authorised seed treatments on grains only and where aerial application will be made).

3. If the TERa or TERst is less than 100 then the seed bag label must carry the following advisory phrases:

- a) Treated seed must be drilled Treated seed must be drilled
- b) Cereal Seed should be drilled to a depth of 40 mm into a well prepared and firm seed bed
- c) If cereal seed is present on the soil surface, or if spills have occurred, then, if conditions are appropriate, the field should be harrowed then rolled to ensure good incorporation.



d) In addition to the above, the treated seed label may also carry advisory information for the end user on such issues as seed storage, drilling directions etc., as appropriate.



Appendix 8 Examples of medical advice

1. Organophosphate compounds with anticholinesterase activity

SYMPTOMS OF POISONING

These may include excessive sweating, headache, weakness, faintness and giddiness, nausea, stomach pains, vomiting, small pupils, blurred vision, muscle twitching, tightness of the chest. Note that the onset of symptoms may be delayed by several hours after exposure.

FIRST AID

If any of the above symptoms occur, particularly if there is known contamination:

STOP WORK

Remove contaminated clothing. Wash exposed skin and hair.

Prevent all exertion.

Call doctor AT ONCE and show this label.

GUIDE TO DOCTOR

This product contains an anticholinesterase organophosphorus compound.

Specific Treatment

- 1. IN CASES OF MODERATE POISONING AND SEVERE POISONING AND AS EARLY AS POSSIBLE inject atropine sulphate 2 mg or pro rata for children and repeat (if necessary) to maintain full atropinisation
- *2. IF AVAILABLE administer pralidoxime 30mg/kg body weight by intra-muscular injection. Repeat after 4-6 hours for as long as atropine is required.

[* Note for marketing company. Omit for compounds for which pralidoxime is not an effective antidote]

Other measures

- 1. Keep airway clear.
- 2. Watch respiration intubation with endotracheal tube, or tracheotomy may be necessary in conjunction with artificial ventilation.
- 3. Put patient at complete rest in hospital for 24 hours at least.

Confirmation of Diagnosis

By estimating cholinesterase activity in plasma and red blood cells.

Further advice from:

Name, address, telephone number of marketing company/authorisation holder

or



2. Dinitro compounds

SYMPTOMS OF POISONING

These may include fatigue, excessive and unusual sweating and thirst, with sleeplessness and loss of weight in protracted cases. In severe cases there may be rapidly increasing anxiety and restlessness with an increase in respiration and heart rate.

FIRST AID

If any of the symptoms occur, particularly if there is known contamination (*i.e.* yellow staining of the skin):

STOP WORK Remove contaminated clothing. Wash exposed skin and hair thoroughly. Keep person at rest in the coolest available place. Sponge skin with cold water and give cold water to drink. Call doctor AT ONCE and show this label.

GUIDE TO DOCTOR

This product contains a DINITRO compound that can uncouple oxidative phosphorylation.

<u>Treatment</u>

- 1. Treat suspected cases of poisoning by vigorous cooling, giving abundant fluids and oxygen for dyspnoea.
- 2. DO NOT GIVE morphine or barbiturates.
- 3. If swallowed, wash out the stomach and give activated charcoal.

Diagnosis

By estimating blood [active substance] concentration.

Further advice from:

Name, address, telephone number of marketing company/authorisation holder

or



3. Anticoagulant rodenticides

SYMPTOMS OF POISONING

Spontaneous haemorrhage from the nose, into the skin or into internal organs. Onset may be delayed.

FIRST AID

If any of the above symptoms occur, particularly if there is known contamination (including on previous occasions):

Stop work. Remove contaminated clothing wash exposed skin and hair. **Prevent all exertion** Call doctor AT ONCE and show label

GUIDE TO DOCTOR

This product contains [active substance name] an anticoagulant.

<u>Treatment</u>

- 1. Vitamin K₁ (phytomenadione) 10-20 mg orally (pro-rata for children). Repeat daily until prothrombin time returns to normal.
- 2. In severe cases, transfusion of fresh frozen plasma or blood may be indicated together with vitamin K_1 .
- 3. In some cases, symptoms may reappear if treatment is stopped prematurely. Prothrombin time should be monitored for 2 weeks after stopping vitamin K.

Confirmation of diagnosis

By estimating prothrombin time.

Further advice from:

Name, address, telephone number of marketing company/authorisation holder

or



4. Cyanides

SYMPTOMS OF POISONING

Anxiety, headache, nausea, confusion, rapid breathing followed by laboured breathing and turning blue. In severe cases, impaired consciousness and convulsions.

FIRST AID

Stop work and leave the contaminated area. Remove contaminated clothing. Wash clothes, exposed skin and hair. Prevent exertion. Call doctor AT ONCE and show this label. DO NOT GIVE MOUTH TO MOUTH resuscitation in cases of ingestion

GUIDE TO DOCTOR

This compound contains or can generate cyanides.

Treatment

- 1. If antidotes (see below) are available they should be administered if poisoning is moderate or severe.
- 2. If antidotes are not available administer oxygen, maintain respiration and control convulsions.
- 3. Supportive therapy, including 100% oxygen may be necessary to complement antidote therapy.

Antidotes

Regime 1 (preferred)

Adult

- 300 mg dicobalt edetate (20 millilitres of 1.5% solution) intravenously over one minute followed by
- dextrose (50 millilitres of 5-% solution) followed by
- 12.5 mg sodium thiosulphate (50 millilitres of 25% solution) intravenously over 10 minutes

Children

• There is no information on the use of dicobalt edetate in children.

Regime 2

Adult

- 300 mg sodium nitrite (10 millilitres of 3% solution) intravenously over 5-20 minutes followed by
- 12.5 mg sodium thiosulphate (50 millilitres of 25% solution) intravenously over 10 minutes

Children

- 4 mg/kg body weight sodium nitrite (0.13 millilitres of 3% solution) intravenously over 5-20 minutes immediately and a further dose of 2 mg/kg body weight 30 minutes after the first only if the methaemoglobin concentrations achieved are not excessive and a satisfactory clinical response has not been attained.
- 400 mg/kg body weight sodium thiosulphate (1.6 millilitres/kg of 25% solution) intravenously over 10 minutes.

Further advice from:

Name, address, telephone number of marketing company/authorisation holder

•



5. Carbamate compounds with anticholinesterase activity

SYMPTOMS OF POISONING

These may include excessive sweating, headache, weakness, faintness and giddiness, nausea, stomach pains, vomiting, small pupils, blurred vision, muscle twitching, tightness of the chest.

FIRST AID

If any of the above symptoms occur, particularly if there is known contamination:

STOP WORK. Remove contaminated clothing. Wash exposed skin and hair. Prevent all exertion. Call doctor AT ONCE show this label.

GUIDE TO DOCTOR

This product contains an anticholinesterase carbamate compound.

Specific Treatment

- 1. IN CASES OF MODERATE AND SEVERE POISONING AND AS EARLY AS POSSIBLE inject atropine sulphate 2 mg or pro rata for children and repeat if necessary to maintain full atropinisation.
- 2. DO NOT USE pralidoxime.

Other measures

- 1. Keep airway clear.
- 2. Watch respiration intubation with endotracheal tube or tracheotomy may be necessary in conjunction with artificial ventilation.
- 3. Put patient at complete rest in hospital for 24 hours at least.

Confirmation of diagnosis

Estimation of cholinesterase activity may be misleading unless special procedures are used to prevent reactivation.

Further advice from:

Name, address, telephone number of marketing company/authorisation holder

or



6 List of the UK National Poisons Information Service (NPIS) Centres

NPIS BELFAST	Royal Victoria Hospital Grosvenor Road Belfast BT12 6BB
NPIS BIRMINGHAM	City Hospital Dudley Road Birmingham B18 7QH
NPIS CARDIFF	Llandough Hospital Penarth Cardiff CF64 2XX
NPIS EDINBURGH	The Royal Infirmary 1 Lauriston Place Edinburgh EH3 9YW
NPIS LONDON	Medical Toxicology Unit Avonley Road London SE14 5ER
NPIS NEWCASTLE	Wolfson Unit Claremont Place Newcastle-upon-Tyne NE2 4HH



Appendix 9: Examples of Directions For Use formats

Applicants are encouraged to present the Directions For Use section in one of the following formats (specified headings do not need to appear if no relevant information is being presented).

Format 1

DIRECTIONS FOR USE

'IMPORTANT: This information is authorised as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product'.

RESTRICTIONS

Weedkiller X must not be applied to any crop suffering from stress as a result of drought, waterlogging, low temperatures, pest or disease attack, nutrient or lime deficiency or other factors reducing crop growth.

Do not use on under sown crops.

Do not use on broadcast sown crops

Do not spray if frost is expected

Certain following crop restrictions apply; these are detailed under 'Crop Specific Information'

WEEDS CONTROLLED

Weedkiller X is a herbicide with foliar and root activity against a broad range of weeds. Good spray cover of the weeds is essential. Weedkiller X is most effective against small actively growing weeds.

Weed species	Susceptibility	Growth stage
Cleavers	S	Up to 6 whorls
Chickweed	MS	Up to 3 true leaves
Charlock	MR	Up to 2 true leaves
Poppy, common	S	Up to flower bud visible

Weed resistance

Where resistance to Weedkiller X is known or suspected within a population of chickweed Weedkiller X should be used in sequence or tank mixture with a herbicide with a different mode of action.

Recommendations for improved weed control with tank-mixtures

If black-grass is present Weedkiller X may be mixed with Weedkiller Z; this mixture will also improve control of chickweed and charlock.

Products should only be tank-mixed if each product can be applied within the label recommendations for its use.



CROP SPECIFIC INFORMATION

Winter and spring wheat, winter and spring barley, winter and spring oats and rye.

Apply Weedkiller X at a dose of 5 litres product/ha to healthy, actively growing crops from when the crop has two true leaves until before the flag leaf just visible stage.

All varieties of wheat (except varieties of durum wheat), barley, oats and rye may be treated.

Do not apply Weedkiller X more than once to any cereal crop.

Apply in 100-200 litres of water per hectare. Where crop growth is thick or weed growth dense up to 400 litres per hectare may be used.

Spray quality: MEDIUM (BCPC)

Only cereals, field beans or grass may be sown in the same calendar year as an application of Weedkiller X is made.

Carrots and Parsnips

Weedkiller X may be applied once the crop has three true leaves up to and including 28 days before harvest. Apply in spray volume of 100-200 l/ha water using conventional ground vehicle mounted/drawn equipment. Use the higher volume where crop growth is thick or weed growth dense.

Spray quality: MEDIUM (BCPC)

All commercial varieties may be treated.

Crops should be actively growing.

Only cereals, field beans or grass may be sown in the same calendar year as an application of Weedkiller X is made.

MIXING

Before use ensure that all spraying equipment is clean. Add half the required volume of water and start agitation, add the required quantity of Weedkiller X. Fill the tank to the required volume whilst maintaining agitation. Continuous agitation must be maintained until spraying is complete.

All application equipment must be thoroughly cleaned with water prior to storage or use on another crop.

COMPATIBILITY

Weedkiller X may be tank mixed with any of the following products. Weedkiller X should be added to the spray tank before the other product, always ensure Weedkiller X is fully dispersed before adding the second product. Maintain agitation throughout mixing and spraying.



Weedkiller Z Pestkiller A Weedkiller ZX Pestkiller B



Format 2

This is a variation on Example 1 with the simple instructions for use on each crop presented in a tabular format.

DIRECTIONS FOR USE

'IMPORTANT: This information is authorised as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product'.

RESTRICTIONS

Weedkiller X must not be applied to any crop suffering from stress as a result of drought, waterlogging, low temperatures, pest or disease attack, nutrient or lime deficiency or other factors reducing crop growth.

Do not use on under sown crops.

Do not use on broadcast sown crops

Do not spray if frost is expected

Certain following crop restrictions apply; these are detailed under 'Crop Specific Information'

WEEDS CONTROLLED

Weedkiller X is a herbicide with foliar and root activity against a broad range of weeds. Good spray cover of the weeds is essential. Weedkiller X is most effective against small actively growing weeds.

Weed species	Susceptibility	Growth stage
Cleavers	S	Up to 6 whorls
Chickweed	MS	Up to 3 true leaves
Charlock	MR	Up to 2 true leaves
Poppy, common	S	Up to flower bud visible

CROP-SPECIFIC INFORMATION

Crop	Dose	Earliest timing	Latest timing
Winter and spring varieties of wheat*, barley, oats and rye.	5 litres product/ha	Three true leaves	Before the flag leaf just visible stage
Carrots	5 litres product/ha	Three true leaves	Before 30 % of the expected root diameter is reached
Parsnips	5 litres product/ha	Four true leaves	Before 30 % of the expected root diameter is reached

*excluding varieties of durum wheat.



All crops should be actively growing.

Do not apply Weedkiller X to any crop more than once.

Apply in 100-200 litres of water per hectare using conventional ground vehicle mounted/drawn equipment. Where crop growth is thick or weed growth dense up to 400 litres per hectare may be used.

Spray quality: MEDIUM (BCPC)

FOLLOWING CROPS

Only cereals, field beans or grass may be sown in the same calendar year as an application of Weedkiller X. is made.

MIXING

Before use ensure that all application equipment is clean. Add half the required volume of water and start agitation, add the required quantity of Weedkiller X. Fill the tank to the required volume whilst maintaining agitation. Continuous agitation must be maintained until spraying is complete.

All application equipment must be thoroughly cleaned with water prior to storage or use on another crop.

COMPATIBILITY

Weedkiller X may be tank mixed with any of the following products. Weedkiller X should be added to the spray tank before the other product, always ensure Weedkiller X is fully dispersed before adding the second product. Maintain agitation throughout mixing and spraying.

Weedkiller Z Weedkiller ZX Pestkiller A Pestkiller B



Format 3

For some products with more complex labels, the layout described in Examples 1 and 2 above would make the label difficult to write or understand (e.g. an insecticide used on many crops, for the control of many different pests with several different crop/pest combinations each with specific recommended application regimes). In such cases, the following is suggested:

DIRECTIONS FOR USE

'IMPORTANT: This information is authorised as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product'.

RESTRICTIONS

X Pest must not be applied to any crop suffering from stress as a result of drought, waterlogging, low temperatures, nutrient or lime deficiency or other factors reducing crop growth.

Do not spray if frost is expected.

Avoid spraying crops under conditions of high temperature and sun light as this may lead to transient crop effects.

FOLLOWING CROPS

Any crop may be sown after a crop treated with X Pest.

MIXING

Apply using conventional ground vehicle mounted/drawn equipment. Before use ensure that all application equipment is clean. Add half the required volume of water and start agitation, add the required quantity of X Pest. Fill the tank to the required volume whilst maintaining agitation. Continuous agitation must be maintained until spraying is complete.

All application equipment must be thoroughly cleaned with water prior to storage or use on another crop.

CROP SPECIFIC INFORMATION Wheat, barley and oats

For the control of cereal aphids (Barley Yellow Dwarf Virus vectors) in autumn sown crops. Apply a single application as a routine in the period mid-late October if BYDV is commonly a problem on the farm or locality. Spray immediately if aphids are found in the crop earlier. Further treatments may be required in high risk areas especially during mild winters.

Winter and spring crops: Grain aphid and Rose-grain aphid applications should be made once official threshold have been reached.



Dose: 1 I/ha. A maximum of three applications may be made to any one crop Latest time of application: 3 days before harvest

Water volume: 200-300 l/ha Spray quality: MEDIUM (BCPC)

Peas (All varieties)

For the control of pea aphids and pea moth. Apply to flowering crops according to specialist advice or once thresholds have been reached. Repeat as necessary.

Dose: 1 I/ha. A maximum of two applications may be made to any one crop Latest time of application: 5 days before harvest

Water volume: 100-300 l/ha Spray quality: MEDIUM (BCPC)

Winter and spring oilseed rape

For the control of pollen beetle and flea beetle

Pollen beetle: Apply at the green/yellow bud stage according to specialist advice or if official thresholds have been reached.

Flea beetle: Apply at first signs of attack. Repeat 10-14 days later if necessary.

If aphid vectors of Beet Western Yellow Virus are present at application then X Pest should be co-applied with 100ml of X Pest Z in a minimum spray volume of 300 l/ha.

Dose: 1.25 l/ha. A maximum of three applications to any one crop, including only one after yellow bud stage.

Latest time of application: 5 days before harvest.

Water volume: 200-400 l/ha Spray quality: MEDIUM (BCPC)

Brassicas: Cabbage, Brussels sprouts, Cauliflower, Broccoli and Calabrese

For the control of flea beetle, caterpillars and mealy cabbage aphid. Apply at first signs of attack. Repeat if necessary.

If infestations of mealy cabbage aphid are high at application then X Pest should be coapplied with Pest Control Extra at a dose of 500 ml in a spray volume of 400 l/ha.

Dose: 1 I/ha. A maximum of two application per crop Latest time of application: 3 days before harvest

Water volume: 200-400 l/ha Spray quality: MEDIUM or COURSE (BCPC)



COMPATIBILITY

X Pest may be tank mixed with any of the following products.X Pest should be added tothe spray tank before the other product, always ensure X Pest is fully dispersed beforeadding the second product.Maintain agitation throughout mixing and spraying.Weedkiller ZX Pest Z (winter and spring oilseed rape only)Weedkiller ZXPest Control Extra (Listed brassicas only)



Appendix 10: Examples of Company Advisory Information (CAI)

1. Additional Health and Safety Information

In addition to the CHIP/CLP classification and labelling and the Safety Precautions which form part of the 'Authorised Text' on the product label the CAI could be used to provide additional Health and Safety information where they are not specifically required by other Government Departments or other legislation. This may include further advice relating to disposal of product/container and spray washings (applicants should ensure that any additional advice on disposal which is not required on the Product Label is acceptable under any other UK legislation *e.g.* Environment Agency may be able to advise), fire precautions and first aid/medical treatment.

2. Guidance relating to the use of the product

In addition to The Directions For Use section which forms part of the 'Authorised Text' and provides sufficient information for the end user to be able to apply the product safely and effectively the CAI could be used to provide additional advice that is not required as part of the 'Authorised Text'. This need not be supported by safety/efficacy data on, *e.g.* application equipment and on factors relating to general crop agronomy and it should consist of specific information relating to good practice, which applicants would want to highlight to ensure that the product is used efficaciously. For example machinery calibration information which could include conversion tables (*e.g.* for metric to imperial) and calibration charts (*e.g.* for relating nozzle output to forward speed, and for showing what areas will be treated by different amounts of product), nozzle selection information in addition to the BCPC classification of spray quality (fine, medium, coarse) which must appear in the 'Directions for use', where relevant (*e.g.* this would not be necessary for a pre-emergence herbicide) and factors relating to product/crop agronomy.

Examples of the types of phrases relating to the use of the product which would *generally* be considered to be Company Advisory Information are given below. The acceptability of a phrase (without data) will depend upon the context in which it is to be used (*i.e.* the type of product/active substance, target pest and target crop). This list is not designed to be exhaustive. There may be certain circumstances where some of the phrases listed below would need to be accompanied by supporting data and so would belong in the Directions For Use. Some of the phrases listed below are only relevant to certain products therefore would not be permitted if they were irrelevant to the product in question (*e.g.* instructions to 'Mix well' would not be applicable to products applied as granules, except those applied by admixture).



3. Application equipment (use and calibration of equipment, nozzle selection, etc).

- (a) Application should be carried out with [application machinery] operating according to the manufacturer's instructions
- (b) The table below gives the amount of [product] required per 50 kg of seed to obtain the correct dosage per hectare at differing seeding rates.
- (c) When the seed treatment machine throughput capacity has been determined, select the appropriate vibrator and rheostat settings from the graphs below to admix the recommended proportion of [product]
- (d) It is essential that safety guards are fixed to all potentially dangerous moving parts and exposed chains
- (e) Unless otherwise specified, recommended nozzles are for use at 0.5m nozzle spacing. For other nozzle spacings check manufacturer's output charts for suitability
- (f) Use high clearance tractors with narrow wheels and crop dividers
- (g) Ensure that the sprayer is in good working order by paying particular attention to the condition of the pump, hoses, nozzles or disc assemblies and pressure gauge. Replace damaged, worn or malfunctioning parts. Calibrate sprayer accurately.
- (h) Adjust the boom height to give the correct height above target; alternate spray fans or cones should meet just above the top of the crop. Even cover with a well mixed spray is essential for good results

4. General agronomic advice (advice on pest and crop biology, threshold levels, mode of action and pesticidal effect.

- (a) [*Product*] is a useful input for high yield wheat and winter barley growing systems. The influence of [product] on growth will vary according to the crop and its stage of growth at the time of application.
- (b) For severe infestations use a recommended pesticide
- (c) [*Product*] is a foliar acting herbicide. Leaf symptoms, being a reddening then yellowing of foliage, are first seen on grass weeds but take longer to appear on broad-leaved weeds.



- (d) In common with all protectant fungicides it is necessary to spray [product] before blight appears in the crop. For this reason a regular spraying programme should be carried out
- (e) Root development and tiller production for autumn sown barley is largely determined in the autumn of sowing
- (f) For information on threshold levels for treatment contact [your adviser]
- (g) Frit fly: Winter wheat crops following grass and late sown spring oats may be attacked. Larvae damage the shoots causing the centre leaf to become yellow and die resulting in plant death or very weak growth
- (h) Leatherjackets: Roots and stems are attacked at or below ground level and plants die-off rapidly. Damage usually occurs between March and May but earlier attacks can be seen in some seasons
- (i) Wheat bulb fly: Crops are usually attacked from mid-January to March. Centre leaves of damaged plants turn yellow and die.
- (j) Eyespot is associated with second or subsequent winter cereal crops, but can be a problem even after a one year break. Susceptible varieties, wet autumns, mild winters and early drilling all increase the risk of infection
- (k) Diseases of oilseed rape can develop and spread very rapidly. It is therefore important that crops are regularly inspected so as to detect sudden increases in disease levels.
- (I) *Alternaria brassicae* mainly develops through the spring and summer, especially following hot humid weather
- (m) *Phoma* leaf spot is spread by rain and can be found from October onwards.
- (n) The spread of *Sclerotinia* is favoured by wet weather during flowering.
- (o) The purpose of spraying is to delay the 75% foliage blight development stage until after the full weight of tubers has been formed. With main crop varieties, bulking comes to an end in late September, so there is no point in preserving the haulm after this stage
- (p) [*Product*] is a protectant fungicide and will not control established disease

5. 'Good Agricultural Practice'

- (a) Maximum benefit will be obtained where crop development is not restricted by inadequate nutrition or by attack from pests and diseases
- (b) Clean application machinery before use



- (c) Ensure that the boom height is correctly adjusted
- (d) Do not apply to crops suffering from stress
- (e) Spray cones should overlap just above the top of the crop
- (f) Water volume should be maintained to ensure good coverage and contact with the pest
- (g) Good spray cover is essential to achieve optimum control.
- (h) Good spray coverage of soil and weeds is essential
- (i) The soil type should be accurately diagnosed as this determines the recommended rate
- (j) Allow foliage to dry before applying [product] after rainfall or irrigation
- (k) Avoid spraying during periods of drought/extreme temperatures/freezing conditions/rain or if rain is imminent/low relative humidity
- (I) Ensure good coverage and penetration of the crop
- (m) Ensure that spray swaths do not overlap
- (n) Ears not emerged at the time of treatment will not be protected
- (o) [*Product*] should be applied to crops during good growing conditions at the correct timing
- (p) Where the soil is cloddy it is advisable to increase the volume of water
- (q) Weeds become less susceptible to [product] when their growth is restricted by natural senescence or by drought, frost, high temperature, a covering of dust or flooding. Reduced control will occur if such conditions occur at, or immediately after, spraying

6. Resistance issues

(a) 'In order to reduce the risk of resistance developing, consider using products of different mode of action when carrying out repeat treatments'

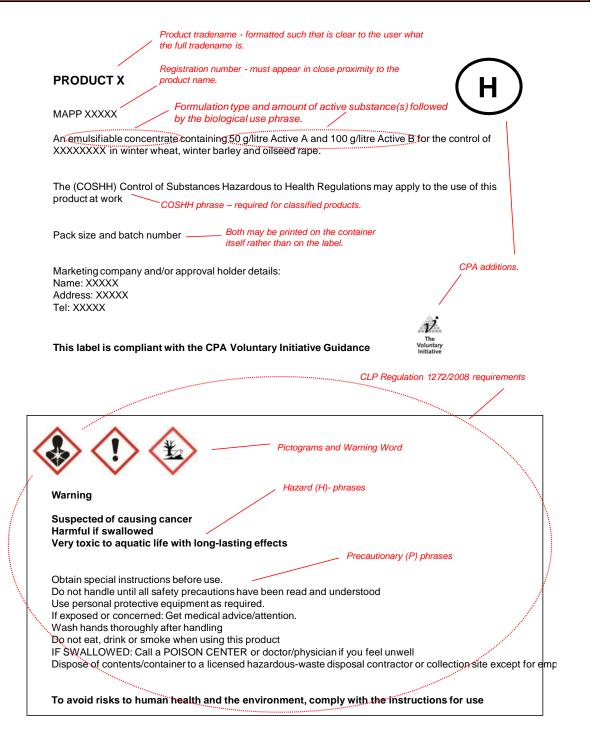
It would be impossible to provide a fully comprehensive list of the information that may be used on a label without supporting data. This is because the acceptability of a phrase will depend on the context in which it is to be used (*i.e.* the type of product/active substance, target pest and target crop). Additionally, a particular phrase may be used on the label without supporting data but might still be a condition of the authorisation, in which case the phrase would belong in the Directions For Use.



This consideration of label phrases in context rather than isolation forms the basis for decision making in CRD and is the reason why devising a set of standard label phrases could be unnecessarily restrictive. In drawing up labels applicants are encouraged to adopt a similar approach by first considering the basis for each label phrase used (*e.g.* it may be based on general knowledge for spray applications or based on data previously submitted for the active substance).



Appendix 11 – Draft professional label example





	IMPORTANT INFORMATION -	or words of the same meaning e.g. Key information	
	FOR USE ONLY AS AN AGRICULTURAL HERBICIDE		
	Crops:	Winter wheat, winter barley and oilseed rape	
	Maximum individual dose:	Winter wheat and barley: 2 litres product/ha Oilseed rape: 1 litre product/ha	
	Maximum number of treatments:	Winter wheat and barley: 2 per crop	
	Maximum total dose:	Oilseed rape: 3 litres product/ha/crop	
	Latest time of application:	Winter wheat and barley: Before second node detectable stage Oilseed rape: 14 days before harvest	
	Other specific restrictions:	This product must not be used on durum wheat	
REA	THE LABEL MAY BE AN OFFENCE	THIS PRODUCT IN A MANNER THAT IS INCONSISTENT WITH . FOLLOW THE CODE OF PRACTICE FOR USING PLANT ROTECTION PRODUCTS	

Standard headings and subheadings must appear

Key information about the the safe and effective use of the product. Where space is limited the field of use and crops/situations must appear and the rest of the information may be signposted to a separate leaflet.

SAFETY PRECAUTIONS Operator protection

Engineering control of operator exposure must be used where reasonably practicable in addition to the following personal protective equipment: WEAR SUITABLE PROTECTIVE CLOTHING (COVERALLS) AND SUITABLE PROTECTIVE GLOVES when handling the concentrate. WEAR SUITABLE PROTECTIVE GLOVES when handling contaminated surfaces. However, engineering controls may replace personal protective equipment if a COSHH assessment shows they provide an equal or higher standard of protection. WASH CONCENTRATE from skin or eyes immediately. WASH HANDS AND EXPOSED SKIN before meals and after work. WHEN USING DO NOT EAT, DRINK OR SMOKE.

IF YOU FEEL UNWELL, seek medical advice immediately (show the label where possible).

Environmental protection

Do not contaminate water with the product or its container. Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads.

Storage and disposal

KEEP IN ORIGINAL CONTAINER, tightly closed in a safe place. Keep dry and frostproof in a suitable pesticide store. RINSE CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer at time of filling and dispose of safely. KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDING STUFFS. KEEP OUT OF REACH OF CHILDREN.

The standard heading and phrase must appear

DIRECTIONS FOR USE

IMPORTANT: This information is approved as part of the Product Label. All instructions within this section must be read carefully in order to obtain safe and successful use of this product'.