

Guidance on environmental risk mitigation/precaution labelling for UK authorised plant protection products

Including 'safety precautions' required under
Assimilated Regulation No 547/2011 regards
labelling requirements for plant protection
products and UK specific labelling

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Introduction

This paper gives guidance on how the various types of environmental risk labelling are used on plant protection products (PPPs) in the UK. Risk labelling is used to identify where risk management or mitigation measures/restrictions should be employed to minimise particular risks occurring through the intended use of a product. The principles of risk labelling are described below, with regards to Assimilated Regulation No. 547/2011.

Guidance for hazard classification and labelling requirements are not considered in detail in this document; sources of additional information are indicated where appropriate.

The difference between hazard and risk labelling

Hazard classification and labelling is also required for products authorised in the UK.

Hazard classifications are based on the intrinsic toxicity or other properties of a substance or preparation, whereas a true determination of risk also takes into account the likelihood of that hazard occurring (for example in relation to exposure through normal use).

Hazard labelling is normally used to identify harm that might occur through, for example:

- accidental spills
- washing of equipment
- disposal of a product or its container

Environmental classification and labelling is required to follow the 'CLP regulation' (Assimilated Regulation No 1272/2008). The only wildlife group for which a hazard classification is currently undertaken under CLP regulation is aquatic life.

Further [UK guidance for CLP labelling with regards to the environment](#) is available on HSE's website.

For all other wildlife groups, for example birds, bees, non-target arthropods, HSE has implemented an entirely risk-based approach to labelling. It should be noted that there is currently no risk mitigation available for soil organisms.

Environmental ‘safety precautions’ (risk labelling) required under Assimilated Regulation No 547/2011

The labelling requirements, under Assimilated Regulation No 547/2011, are equivalent to those previously required under Annex V to Directive 91/414 and apply to all UK plant protection products with a post-Annex I approval (or its equivalent authorisation under Assimilated Regulation No 1107/2009). All products authorised under Assimilated Regulation No 1107/2009 that require labelling to ensure safe use, based on an assessment according to uniform principles, should apply the labelling phrases included in Tables 1 to 7.

Where ‘safety precautions’ phrases are included as ‘Environmental Protection Restrictions’ in the Notice of Authorisation, they should be included or flagged as such on the authorised label in any ‘Important Information’ area or ‘Safety Precautions’. Although there is a requirement for users to observe any such precautions or directions wherever they occur on product labels, some environmental phrases have previously been considered to be advisory in nature.

Specific details in relation to possible risk mitigation/precautionary labelling to protect non-target terrestrial vertebrates, aquatic life, groundwater, bees and other pollinators, terrestrial arthropods, soil organisms, and terrestrial plants are detailed in turn in the following tables.

Table 1: Risk mitigation phrases to protect terrestrial vertebrates: granules, pellets and baits

Current UK phrase ¹	Criteria for use of UK ‘safety precaution’ phrase
(required text in bold within single quotation marks, select appropriate term between square brackets)	
SPe 5: ‘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.’	The phrase shall be assigned to plant protection products such as granules or pellets which must be incorporated to protect birds or mammals from harm. Various UK phrases have been devised in order to manage risks from solid formulations by ensuring that they are not accessible to birds or mammals. All have a similar meaning to the example quoted here. The current SPe 5 phrase states clearly what is required and will be used where a risk assessment indicates that incorporation is required to manage a risk to birds or mammals from consumption of the plant protection product. SPe 5 phrase would not be applied to products such as slug pellets which are intended to be left on the surface.

¹ The SPe 7 phrase ‘Do not apply during the bird breeding period’ was presented in the previous version of this document, but this phrase is not relevant for use in the UK.

Current UK phrase ¹	Criteria for use of UK 'safety precaution' phrase
(required text in bold within single quotation marks, select appropriate term between square brackets)	
SPe 6: 'To protect [birds/wild mammals] remove spillages.'	The phrase shall be assigned to plant protection products such as granules or pellets to avoid uptake by birds or wild mammals. The SPe 6 criteria indicate that it is to be used for all solid formulations which are used undiluted. SPe 6 phrase is relevant for products such as slug pellets which may be left on the surface, as well as granules and pellets intended for incorporation.
SPe 5 and SPe 6: '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.'	Where both SPe 5 and SPe 6 are required as a result of a risk assessment, they will be combined (as shown) on labels for solid formulations which are incorporated into soil.

Table 2: Risk mitigation phrases to protect terrestrial vertebrates: seed treatments

Labelling required by HSE for seed treatments and treated seed sack labels will continue to be used in the UK where a risk has been identified which requires mitigation. Current UK wording is included in the table below.

Current UK phrase² (required text in bold within single quotation marks, select appropriate term between square brackets)	Criteria for use of UK ‘safety precaution’ phrase
‘To protect [birds/wild mammals], treated seed must not be left on the soil surface. Bury or remove spillages.’ ‘Treated seed must not be broadcast.’	Where an assessment indicates that without risk mitigation measures consumption of treated seed may pose a risk to birds or mammals, the UK phrase will be used on seed sack labels provided that such management practices are considered to adequately minimise the risk. In some cases, the amount of seed left in a spill may pose a risk whilst the small amount available from seed accidentally unincorporated might not. However, both ‘... not be left on soil surface...’ and ‘Bury...’ are usually used. As with other solid formulations (see SPe 6 above), removing spillages of treated seed may be more appropriate than burying them. The two phrases have therefore been combined.
‘Seed must be drilled to a depth of 40 mm into a well-prepared seed bed.’ ‘If seed is present on the soil surface, or if spills have occurred, then, if conditions are appropriate, the field	This phrase only applies to cereal seeds and where mitigation is required to reduce the availability of treated seed. The UK phrase should be used if the risk management method(s) are sufficient to reduce risk to an acceptable level. Other factors may need consideration, for example drilling depth may have

² The phrase ‘DO NOT APPLY TREATED SEED FROM THE AIR’ was presented in the previous version of this document, but this is not relevant for use in the UK.

Current UK phrase ²	Criteria for use of UK ‘safety precaution’ phrase
(required text in bold within single quotation marks, select appropriate term between square brackets)	
must be harrowed and then rolled to ensure good incorporation.’	efficacy implications (supporting data demonstrating effectiveness with 40 mm incorporation would be required as part of the efficacy data package).

Table 3: Risk mitigation phrases to protect aquatic organisms

Current UK phrase ³ (select appropriate value between square brackets)	Criteria for use of UK 'safety precaution' phrase
SP 1 Professional use 'Do not contaminate water with the product or its container. <i>Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.</i>' Amateur use † 'Do not contaminate water with the product or its container.' 'Do not empty into drains.'	All plant protection products should be labelled with 'Do not ...or its container.' The text in single quotation marks should be used as appropriate (see below) In line with previous requirements, all product labels should carry the SP 1 phrase. The words 'except as directed for aquatic use' may be added when use of the product in-or-near water is authorised. The operations indicated in italics in SP 1 are standard good practice for all spray operators in the UK. Operators are legally required to be trained to handle, apply and dispose of plant protection products appropriately and this includes taking action to avoid contamination of water. These parts of SP 1 should however, be included unless they are inappropriate for a particular product's use situation. Where use is horticultural rather than agricultural, substitution of 'farmyards' by other terms, for example simply 'yards', is considered appropriate.

³ The SPe 2 phrase '**To protect** [groundwater/aquatic organisms] **do not apply to** (soil type or situation to be specified) **soils**' and the SPe 4 phrase '**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 of run-off**' was presented in the previous version of this document, but these phrases are not relevant for use in the UK.

Current UK phrase³ (select appropriate value between square brackets)	Criteria for use of UK 'safety precaution' phrase
	For all amateur use plant protection products, the amateur use phrase should be applied (†), with the additional phrase 'Do not empty into drains'.
'To protect aquatic organisms, respect an unsprayed buffer zone distance to surface water bodies in line with LERAP requirements.'	The phrase shall be assigned to protect aquatic organisms if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk mitigation measures are necessary to avoid unacceptable effects. Until further notice, the UK will continue to use existing Local Environment Risk Assessment for Pesticides (LERAP) phrases in addition to SPe 3 where a risk to aquatic life from spray use has been identified. The SPe 3 phrase has been modified slightly to read as follows: 'To protect aquatic organisms, respect an unsprayed buffer zone distance to surface water bodies in line with LERAP requirements'. The appropriate existing LERAP phraseology would then follow this phrase. The associated LERAP phrases based on the application method and buffer distance can be found in the Labelling Handbook Volume 2.

Current UK phrase³ (select appropriate value between square brackets)	Criteria for use of UK 'safety precaution' phrase
	Further advice related to aquatic buffer zones (BZs) is as follows for: LERAP – Horizontal Boom Sprayers LERAP – Broadcast Air Assisted Sprayers October 2011: Interim Scheme update to aquatic BZs Local Environment Risk Assessment for Pesticides (LERAPs) - HSE Although aerial application is now uncommon in the UK, risk management may occasionally still be required. Products must undergo a specific risk assessment and be authorised for application from the air. Where appropriate the SPe 3 phrase should be modified slightly to read as follows: 'To protect aquatic organisms, respect an unsprayed horizontal buffer zone distance to surface water bodies of X m when spraying from aircraft' (where X is usually 250m). Amateur uses: For UK amateur use products. Exposure is assumed to be managed through appropriate labelling. Most spray home garden products should have the following phrase:

Current UK phrase ³	Criteria for use of UK 'safety precaution' phrase
(select appropriate value between square brackets)	
	'Direct spray away from ponds and other surface water bodies'
For products recommending use in or near water a) 'The maximum concentration of active ingredient in treated water must not exceed [X] ppm or such lower concentration as the appropriate water regulatory authority may require.' b) 'Users must consult the appropriate water regulatory body (Environment Agency/Scottish Environment Protection Agency/Natural Resources Wales/Department of Agriculture, Environment and Rural Affairs in Northern Ireland) before using the product near water and must obtain their agreement before using this product to control aquatic weeds.'	The two existing UK phrases regarding the maximum water concentration and consultation of appropriate authorities will still be used as appropriate on all products recommended for use in or near water (a and b in the 'Current UK phrase' column). X ppm is the concentration at which it is determined through a suitable risk assessment, no unacceptable effects on aquatic organisms other than the target organism will occur.

Table 4: Risk mitigation phrases for protection of groundwater

Current UK phrase	HSE's Comments
See comments	The phrase shall be assigned to plant protection products for which an evaluation according to the uniform principles shows that for one or more of the labelled uses, risk mitigation measures are necessary to avoid contamination of groundwater If the GAP for a product cannot be adjusted sufficiently, the SPe 1 phrase 'To protect [groundwater/soil organisms] do not apply this or any other product containing (identify active substance or class of substance, as appropriate) more than (time period or frequency to be specified)'. might be used to minimise exposure of groundwater. That is unless crop rotation patterns in the UK, combined with recommendations for use of the product (and active substance) would mean that, in practice, the re-use interval would be longer than identified in the regulatory assessment as being 'necessary' to cause pollution of groundwater. Any case to support this would need to be corroborated by relevant information on use and cropping patterns. Since authorisations are given on a product by product rather than active substance basis, enforcement of the '...or any other product...' part of the phrase might also prove

	unrealistic, in which case use of the SPe 1 phrase may not be considered appropriate.
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Table 5: Risk mitigation phrases to protect bees and other pollinating insects

Current UK phrase (required text in bold within single quotation marks, select appropriate term between square brackets)	Criteria for use of UK ‘safety precaution’ phrase
When required for all crops SPe 8: ‘Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.’ When only required for some crops † SPe 8: ‘Dangerous to bees. To protect bees and pollinating insects do not apply to crop plants when in flower, except as directed on [crop]. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.’	The phrase shall be assigned to plant protection products when an evaluation according to the uniform principles shows, for one or more of the labelled uses, that risk mitigation measures must be applied to protect bees or other pollinating insects. The SPe 8 phrase includes reference to ‘pollinating insects’. Currently there are no agreed guidelines on how to assess the risk to insect pollinators other than bees. However, unless specific cases are highlighted which require a novel assessment the standard bee risk assessment is currently considered to cover other pollinators. Risk management to protect bees, for example not applying to flowering crops or when flowering weeds are present, should also reduce any risk posed to other pollinators. The UK wording ‘...except as directed on [crop]’ may be added to the new SPe 8 phrase following ‘...crop plants when in flower,’ where the authorisation is for use on several crops - but where only some of these uses pose a risk to bees (†).

Current UK phrase	Criteria for use of UK 'safety precaution' phrase
(required text in bold within single quotation marks, select appropriate term between square brackets) Amateur use SPe 8: 'Dangerous to bees. To protect bees and pollinating insects do not apply to plants when in flower. Do not use where bees are actively foraging. Do not apply when flowering weeds are present.'	Amateur uses: For amateur use products the SPe 8 phrase as included in the 'Current UK phrase' column may be required to mitigate the risk to foraging bees. This will be required where assessment to uniform principles indicates mitigation is required to protect foraging bees/pollinating insects.

Table 6: Risk mitigation phrases to protect other non-target terrestrial arthropods

The statutory labelling is only expected to apply to horizontal boom sprayer applicators. For application via broadcast air-assisted applicators (for example orchard sprayers) advisory labelling would normally be applied. See the relevant phrase detailed below.

Current UK phrase (required text in bold within single quotation marks, select appropriate term between square brackets)	Criteria for use of UK ‘safety precaution’ phrase
Field crop application using horizontal boom sprayers: SPe 3: To protect non-target insects/arthropods respect an untreated buffer zone of [5m/10m] to non-crop land.’	The phrase shall be assigned to protect non-target arthropods, if an evaluation according to the uniform principles shows that, for one or more of the labelled uses, risk mitigation measures are necessary to avoid unacceptable effects.
Field crop application using horizontal boom sprayers fitted with 3* drift reduction technology (DRT): SPe 3: ‘To protect non-target insects/arthropods respect an untreated buffer zone of [5m/10m] to non-crop land.’ 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	The phrase shall be assigned to protect non-target arthropods, if an evaluation according to the uniform principles shows that, for one or more of the labelled uses, risk mitigation measures including drift reduction technology are necessary to avoid unacceptable effects. The drift values to use for the risk assessment with 3* DRT are: • At 5m = 0.17%

Current UK phrase	Criteria for use of UK 'safety precaution' phrase
(required text in bold within single quotation marks, select appropriate term between square brackets)	
Division's website. Maintain three star operating conditions until 30 m from non-crop land.	At 10m = 0.08%
Broadcast air-assisted spray application - ADVISORY PHRASE a) must appear in the 'Safety Precautions' section of the product label 'RISK TO NON-TARGET INSECTS OR OTHER ARTHROPODS. See Directions for use.' b) must appear in the 'Directions for use' section of the product label 'The best available application technique, which minimises off-target drift should be used to reduce effects on non-target insects or other arthropods.'	Advisory label phrase for broadcast air-assisted spray application (for example to orchards, hops, vines and other soft fruits). Buffer zones are not expected to be practical restrictions for broadcast air-assisted uses. The labelling phrases included in the column 'current UK phrase' are normally expected to be used where mitigation is required to protect non-target arthropods. The two sections of text should be included in the 'Precautions' and 'Directions for use' sections of the product label respectively.

Table 7: Risk mitigation phrases to protect non-target terrestrial plants

Current UK phrase⁴ (required text in bold within single quotation marks, select appropriate term between square brackets)	Criteria for use of UK 'safety precaution' phrase
Field crop application using horizontal boom sprayers: SPe 3: 'To protect non-target plants respect an unsprayed buffer zone of [5m/10m] to non-crop land.'	The phrase shall be assigned to protect non-target plants, if an evaluation according to the uniform principles shows that, for one or more of the labelled uses, risk mitigation measures are necessary to avoid unacceptable effects.
Field crop application using horizontal boom sprayers fitted with 3* drift reduction technology (DRT): SPe 3: 'To protect non-target plants respect an untreated buffer zone of [5m/10m] to non-crop land.' 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	The phrase shall be assigned to protect non-target plants, if an evaluation according to the uniform principles shows that, for one or more of the labelled uses, risk mitigation measures including drift reduction technology are necessary to avoid unacceptable effects. The drift values to use for the risk assessment with 3* DRT are: • At 5m = 0.17% • At 10m = 0.08%

⁴ The SPe 4 phrase **'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 of run-off'** was presented in the previous version of this document, but this phrase is not relevant for use in the UK.

Current UK phrase ⁴	Criteria for use of UK 'safety precaution' phrase
(required text in bold within single quotation marks, select appropriate term between square brackets)	
on HSE Chemicals Regulation Division's website. Maintain three star operating conditions until 30 m from non-crop land.	
For any clomazone products unless there is an acceptable wind tunnel study that demonstrates a different or no buffer zone is required, mitigation is applied in the form of a 10-metre buffer zone. In addition to this, an appropriate stewardship programme⁵ needs to be in place. The following phrase must appear on the label: To appear in the Safety Precautions: 'To protect non-target plants respect an untreated buffer zone of 10 metres to non-crop land.' To appear in the Directions for Use: 'There is a risk to adjacent crops and non-crop vegetation from the volatilisation of [product name]. This may result in damage/bleaching to neighbouring vegetation. If effects are seen they must be reported	HSE received reports of damage to non-target plants such as hedgerows from the use of a clomazone product in the field they surround. It was determined that this is due to a mixture of spray drift and volatilisation. HSE considered new data which showed that effects for example bleaching due to volatilisation can be seen up to 10m from target plants treated with a clomazone product. On this basis it has been concluded that all clomazone containing products must carry a safety precaution to protect non-target plants. This is to ensure compliance with the requirement of Art. 4(3)(e) that a PPP should have no unacceptable effects on the environment. The mitigation was included in accordance with Art. 31(2), which provides that, 'The authorisation shall set out the requirements relating to the ... use of the plant protection product ...'. HSE will apply this mitigation (10-metre buffer zone) to all clomazone containing products unless suitable evidence is

⁵ The Stewardship programme must be clearly and easily accessible via a direct link from the label, in British English and sufficiently detailed so the notifier, the crop advisor and the applicant stewardship coordinator are clear on the process to follow, and the details required.

Current UK phrase ⁴	Criteria for use of UK 'safety precaution' phrase
(required text in bold within single quotation marks, select appropriate term between square brackets) via the stewardship program (see [add website address] or contact your crop protection distributor or adviser).'	provided to demonstrate 'acceptable' levels (10 % trigger used by HSE) of bleaching to non-target plants at a different distance. HSE advice to remove restriction: To remove this restriction, data such as a wind tunnel study must be submitted, an example is a published EPA method: https://www.epa.gov/reducing-pesticide-drift/generic-verification-protocol-testing-pesticide-application-spray-drift, to demonstrate that it is not required. The most sensitive plant based on laboratory data for clomazone is chickweed that should be exposed concurrently in the wind tunnel study to assess phytotoxicity at various distances. This should be submitted to support an application to amend an authorisation. HSE would be happy to consider protocols for such a study via our study protocol consideration service please see this link for guidance: Pesticide products: consideration of study protocols by HSE - Pesticides - HSE.

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit [the HSE website](#).

This publication is available on the HSE website at www.hse.gov.uk/pesticides/assets/docs/ecotox-risk-mitigation-labelling.pdf

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