



New guidance on labels for plant protection products (pesticides)

The requirements for labels were amended in conjunction with the issuing of a new regulation regarding labelling requirements for plant protection products (Commission Regulation (EC) No 547/2011) pursuant to the Plant Protection Products Regulation (Regulation (EC) No 1107/2009 of the European Parliament and of the Council). Additionally, rules for CLP classification are applied in accordance with Regulation (EC) No 1272/2008 of 16 December 2008 on "Classification, Labeling and Packaging of Substances and Mixtures."

This guidance takes into account the rules for labelling according to the CLP rules. The guidance replaces the previous guidelines from 22 February 2012 and contains guidelines for mandatory text on the label for user-group (professional / non-professional) labeling, which, according to the Statutory Order on pesticides, must appear on the label. The criteria for non-professional products are stated in the Danish Environmental Protection Agency's framework for the assessment of plant protection products ¹.

With the CLP Regulation, new hazard pictograms, signal words, and hazard and safety phrases have been introduced that reflect the classification assigned to an active substance or agent. The appearance of hazard pictograms should follow the CLP Regulation (hazard pictograms can be downloaded on the UN page: <http://www.unece.org/trans/danger/publi/ghs/pictograms.html>). Homemade pictograms are not accepted.

ECHA has prepared guidance on labeling and packaging according to the CLP Regulation. Based on the CLP Regulation and ECHA's guidelines, the Danish Environmental Protection Agency has prepared an overview of CLP classification and labeling in Danish. The following is referred to the Danish Environmental Protection Agency's overview, where relevant.

The Danish EPA must approve the label and any leaflets before the product is authorised. For products that must be authorised directly pursuant to the Pesticide Regulation, the label is approved under Article 31 of the Regulation. This approval is granted on the basis of reproduction-ready material, so that any changes can be inserted before printing. The Danish EPA may also possibly authorise the user instructions to be printed in a special leaflet if there is not enough room on the label.

It is expressly stated in Section 8 of the Statutory Order on pesticides² that authorization holders who reclassify or update the classification of a registered product must submit information on the new classification. The Danish Environmental Protection Agency may decide that a submitted draft for a modified classification of a product is to match with a completely new application for authorization of the product.

All labels must be sent to pesticider@mst.dk. Please quote reference number MST-661-xxxxx, and state the product name and registration number in the subject field of the email.

¹ See latest version <http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/>

² Statutory Order on pesticides no. 1647 of 17 December 2017

GUIDANCE ON LABELS WITH CLP CLASSIFICATION FOR PLANT PROTECTION PRODUCTS

The rules on labelling plant protection products (pesticides) are in accordance with the CLP Regulation (Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008) and also in the regulations of the Ministry of the Environment's Order on Pesticides, EU Commission Regulation on Labeling Requirements for Plant Protection Products (Regulation EU No 547/2011 of 8 June 2011) and the plant protection product regulation (Regulation (EC) No 1107/2009 of the European Parliament and of the Council). The CLP Regulation modifies the 1107 Regulation, as this does not take into account the CLP regulation.

Any packaging must be equipped with a hazard label that contains some predefined information. The information which, according to the Danish EPA must be included in the label, will be set out in the label letter from The Danish EPA for the individual product in connection with its authorization.

The hazard label can be part of a larger label. It is important for this to be in a prominent position so that its purpose is met.

The user instructions and the other text on the label should not be misleading. This information must be consistent with the information provided on authorisation.

The information given on the label must comply with the specific pesticide requirements laid down in the PPP Regulation (1107/2009) and the Labeling Regulation (547/2011) as well as the general marketing requirements of the Marketing Act³. There must be technical evidence for the information on the label. The text must therefore not contain any claims such as "the best". Nor should it mislead with regard to potential risks to human or animal health or the environment with terms such as "non-toxic", "harmless" and "green".

Products may not market organic in addition to the sentence approved by the Danish Environmental Protection Agency: "[product name] is a non-organic product that can be used for organic farming according to the guidelines in Council Regulation (EC) no. 834/2007". It will be evident from the Danish Environmental Protection Agency's label letter if this sentence must appear on the label for a specific product.

The label text must be in Danish, easy to read and indelible. It must be possible to read the text horizontally when the packaging is positioned in the usual way. Adhesive labels must be properly affixed to the packaging.

A label for each pack size must be submitted, although if the layout is completely identical then one label covering several sizes can be submitted.

Label content.

The information on the label is to be placed in one of four fields as follows:

1. Hovedfelt
2. Advarselsfelt
3. Brugsanvisning
4. Deklaration

In this context, fields mean that the information must be in one place, but the fields do not necessarily have to be separated by typography, colours or grids.

³ Marketing Practices Act No. 426 of 3 May 2017

1. Hovedfelt (head field)

- a. Trade name (full authorisation name)
- b. The product's type of action (as set out in the label letter)
- c. The product's approved uses
- d. The product's user category

Products for professional users:

"Dette plantebeskyttelsesmiddel må kun købes af professionelle og anvendes erhvervmæssigt og kræver gyldig autorisation."

or

"Dette plantebeskyttelsesmiddel må kun købes af professionelle og anvendes erhvervmæssigt, men kræver ingen gyldig autorisation."

Products for non-professional users:

"Dette plantebeskyttelsesmiddel kan købes og anvendes af ikke-professionelle, fx private haveejere, og kræver ikke autorisation."

2. Advarselsfelt (warning field)

This section must be consistent with the label letter. The wording must thus be reproduced **exactly** as in the label letter. The warning section must be clearly separated from the next section, possibly with a line break.

- a. Heading (Signal word). "Select the word" FARE" in case of more serious hazards and the word "ADVARSEL" in less serious hazards. (see Article 20 of the CLP Regulation and the relevant table in Annex 1 to the Regulation) ". For a product without classification there is no requirement for a signal word according to the CLP regulation, but the Danish EPA recommends inserting the heading "FORSIGTIG". Then the following sentence must be stated: "The instructions for use must be followed in order not to endanger human health and the environment (EUH401)".
- b. Hazard information (Hazard statements). The phrases are formulated pursuant to Article 21 of the CLP Regulation in accordance with Annex 3 of the Regulation containing H-phrases as well as additional hazards concerning particular physical and health characteristics (EUH statements) according to Article 25 of the CLP Regulation.
- c. Safety sentences (P-sentences). In accordance with Article 22 of the CLP Regulation. In addition to the standard P-phrases for pesticides, no more than 6 P-sentences are chosen, unless more is necessary to reflect the nature and severity of the hazards, and cf. Articles 22 and 28, there is also the possibility of using combination sentences. The Danish EPA has prepared a guide in the use of P-phrases⁴.

For professional use applications, reference should be made to the Labor Inspectorate's rules using the following phrase: "*Vær opmærksom på, at Arbejdstilsynet har regler for arbejde med og udsættelse for plantebeskyttelsesmidler. Læs nærmere i det eventuelt lovpligtige sikkerhedsdatablad*".

- d. The product's uses and maximum number of treatments per season, if required by the risk assessment, as stated in the label letter.
- e. Rules for use, including the pre harvest interval (PHI) that must pass after using the product before harvest or use of crops, and the re-entry period that must pass after using the product until people or animals are allowed access. The treatment intervals must be given in days or months, but can if necessary be replaced with growth stages, as stated in the label letter.

⁴ See guidance <http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/classification-labelling-and-packaging/>

- f. Any additional storage requirements

Then the following phrase must be stated: "Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer".

- g. Hazard pictograms, if applicable (Article 19 of the CLP Regulation and the relevant tables). For funds classified for more than one hazard, the label will in some cases be applied to several pictograms⁵. Article 26 contains rules on precedence.
- h. Information on first aid, including rules laid down by the Danish EPA. The information can generally be more detailed in the supplier user instructions, cf. the Danish WEA's rules.

The rules listed in points d to g are binding for the user. This is indicated by the following text being placed above the rules: "*Overtrædelse af følgende fremhævede forskrifter kan medføre straf*". The rules must then be printed in **bold** and special fonts used to highlight the text.

3. **Brugsanvisning** (user instructions)

The user instructions must, among other things, contain information on

- a. Pests that can be controlled with the product, cf. the efficacy evaluation. In cases where the effect is insufficient on its own, it may be mentioned that the product has a moderate effect or side effect in line with indications in the efficacy evaluation. The pests are listed for each crop or category of crop.
- b. The time of use (often in BBCH), dose (in metric units) and number of uses per season or year (plus interval between use) for each area of use (crop). The text here **must** be consistent with the text under rules for use in the "**Advarselsfelt**" and the approved GAP table. Split doses must be stated. The dose can be stated as an interval, provided there is documentation for this. An indication of the period that must pass after using the product before sowing or planting of a subsequent culture/crop is required. Use in under sown crops must be stated.
- c. Special climatic conditions which have a bearing on the effects achieved.
- d. Application method, including spraying technology with proposals for all relevant use situations (e.g. fields, fruit growing, greenhouse culture). It must be stated that application must be made with equipment other than a sprayer, e.g. with trawler or handheld equipment. Annex 1 contains various examples of texts that can be used for field sprays.
- e. Ideally possible tank mixing partners (other pesticides) will be stated as active substance. No specific instructions for use of these may be mentioned, but refer to the applicable label and instructions for use. See suggestions for text in Annex 1.
- f. Information on undesirable effects on plants, including phytotoxicity and damage to neighbouring crops and succeeding crops.
- g. Information on mode of action and indication of group, cf. FRAC, IRAC or HRAC. It must be stated whether there is a risk of resistance forming. With moderate and high risk, an anti-resistance strategy **must** be specified and this must state in which species resistance has been identified. Similarly, it must be stated if there is any knowledge of cross-resistance. Annex 1 contains various examples of texts that can be used.
- h. Note on the product's compatibility with biological control, specifically for products used in greenhouses. Guidelines for selecting sentences appear from the Danish assessment framework⁶.
- i. Bee label if the Danish EPA has included a requirement for this in the label letter (link to bee label: <http://www.mst.dk/media/139909/bifare-pictogram.eps>)
- j. Where appropriate, a provision on responsibility for use of the product, if this is required (cf. examples of text which the Danish EPA finds acceptable in Annex 1).
- k. Instructions on suitable storage conditions and safe disposal of the pesticide and packaging. Safety statement P501 must be added: "Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

⁵ ECHA guidance prescribes that "all marking elements must be of such size and at such intervals that they are easy to read". The Danish EPA recommends that each symbol should record my. 1/10 of the warning area size (first aid information not included)

⁶ <http://mst.dk/kemi/pesticider/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/>

In addition, labelling must be done according to the following guidelines:

1a. If the product is classified H300, H310, H330, H340, H350, H360, H370 or H372:

"Tom emballage og rester skal afleveres til den kommunale affaldsordning for farligt affald".

1b. If the product is classified on health other than H300, H310, H330, H340, H350, H360, H370 or H372 or on the environment with H400, H410 or H411 and the packaging **is not rinsable**:

"Rester skal afleveres til den kommunale affaldsordning for farligt affald.
Tomme beholdere kan bortskaffes med dagrenovationen".

1c. If the product is classified on health other than H300, H310, H330, H340, H50, H360, H370 eller H372 or on the environment with H400, H410 or H411 and if it is to be mixed with water and sprayed out and the packaging is rinsable:

"Rester skal afleveres til den kommunale affaldsordning for farligt affald.
Tomme beholdere kan bortskaffes med dagrenovationen. Den tomme beholder bør skylles inden bortskaffelse. Skyllevandet hældes op i sprøjtevæsken".

1d. If the product is not classified on health or just classified with H412 eller H413:

"Tom emballage og rester kan bortskaffes med dagrenovationen".

2a. The packaging can be reused (only applies if specifically requested):

"Emballagen må kun genbruges af importør eller producent".

2b. The packaging must not be reused (all products):

"Emballagen må ikke genbruges".

3a. If the product is marketed in an aerosol can, under pressure:

"Beholder under tryk: Må ikke punkteres eller brændes, heller ikke efter brug". (P251)

l. If the product is to be used by professionals in organic production:

"Trade name is a non-organic product that can be used for organic farming in accordance with the guidelines in Council Regulation No. 834/2007".

m. If user instructions for minor use authorisations are given on the label, this must be stated separately. It must be stated clearly in the user instructions that minor use is the personal responsibility of the user with regard to efficacy and phytotoxicity.

4. Deklaration (declaration)

- a. Product's type of action, e.g. insektmiddel.
- b. Registration number.
- c. The phrase: "*Omfattet af Miljøministeriets bekendtgørelse om bekæmpelsesmidler og plantebeskyttelsesmiddelforordningen 1107/2009*".
- d. Name and content of active substances.

The name of chemical active substances must be stated consistently with the list in Annex IV to the CLP regulation or, if the substance is not listed there, its standard ISO name must be given. If the latter does not exist, the active substance should be named according to its chemical name under the IUPAC rules.

The content of each active substance should be specified separately as follows:

- in % w/w and g/kg for pesticides that are solid substances, aerosols, volatile liquids (boiling point max. 50 degrees C) or viscous liquids (lower limit 1 Pa · s at 20 degrees C);
- in % w/w and g/L (at 20 degrees C) for other liquids;
- in % v/v and % w/w for all types of air;
- in numbers of cfu (colony forming units) per g or L for microbiological pesticides or other indication of the biological activity, e.g. IU (International Units) per mg.

- e. Names of co-formulants that are very toxic, toxic, harmful or corrosive (e.g. "Midlet indeholder hvilket skal fremgå af deklARATIONEN" og "Indeholder Kan udløse allergisk reaktion" (EUH 208)). In general, four chemical names are sufficient to identify the substances in a product that constitute the greatest hazard to health and which have formed the basis for the classification and selection of accompanying risk phrases. In some cases more than four names may be necessary. For the selection of names, refer to Article 18 of the CLP Regulation.

If the product does not have an acute toxicity study for each of the three routes of exposure (dermal, oral and inhalation), the following sentence must be indicated (see Annex I, clause 3.1.3.6.2.2 of the CLP Regulation):

"x % af blandingen består af en eller flere bestanddele af ukendt akut oral/dermal/inhalations toksicitet".

- f. Net content.
- g. Type of product: Must be as accurate a description as possible, cf. the GIFAP codes.
- h. The expiry date must be stated. The expiry date should either be a specific date or a specific shelf life in relation to a production date. The expiry date on the label may, if necessary, be worded as a reference to a production date elsewhere on the packaging.
- i. Name and address of the authorisation holder.
- j. Batch number.

The Danish EPA may permit field 3 (user instructions), apart from the instructions on disposal, to be printed in a special leaflet. In such cases, the following phrase must be included on the label: "*Læs først vedlagte brugsanvisning*".

The Danish EPA must approve the label and any leaflet before the product is authorised.

User instructions for parallel products

User instructions for parallel products must cover the same uses as the original product. The text of the user instructions must be identical by content to the text for the original product.

FURTHER INFORMATION can be obtained from the Danish Environmental Protection Agency.

Annex 1: Examples of texts.

General:

The user instructions can be provided as a table in the format used in the efficacy evaluation.

Afgrøde(r)	Skadevolder(e)	Dosering	Tidspunkt/ kriterier	Bemærkninger, herunder tydeligt max. antal beh. og evt. beh.frist
Vårbyg	Bladlus	0,2 L/ha	Ved angreb over tærskel	Max. 2 beh. pr. vækstår. Beh.frist 35 dage. Vær opmærksom på egnet sprøjteteknik, se nedenfor
Vinterraps	Glimmerbøsser	0,2-0,3 L/ha	Ved angreb over tærskel, senest i vækststadiet BBCH 59	Max. 3 beh. pr. vækstår. Beh.frist 56 dage. Mange populationer er resistente osv. osv. osv.

Angivelser vedrørende resistens (indication of resistance)

For mange *herbicer/fungicer/insekticer* er der risiko for forekomst af biotyper, der er modstandsdygtige (resistente) overfor de anvendte aktivstoffer.

Fungicer

Produkt xxx tilhører gruppen af fx. strobiluriner (FRAC gruppe 11), som vurderes at have *en høj/ medium/ lav* risiko for udvikling af resistens. I Danmark er der fundet resistens overfor meldug, septoria og hvedebladplet.

Herbicer

Produkt xxx tilhører gruppen af fx. ALS-hæmmere (HRAC gruppe B), som vurderes at have en *høj/ medium/ lav* risiko for udvikling af resistens. I Danmark er der fundet resistens hos fuglegræs, kornvalmue og agerrævehale.

Repeated treatments with products with the same mechanism of action increase the risk of development of resistance. To reduce the risk, the product should be used at maximum X times per season.

In order to reduce the risk of development of resistance, it is recommended to mix with or switch between products with other mechanisms that have a good effect on the species in question.

The risk of resistance to fungicides may be reduced by early injection during the course of infection or by mixing with a multisite inhibitor.

General conditions and responsibility

The following proposals can be accepted by the Danish EPA:

"Producenten fralægger sig ethvert ansvar for produktets skader og følgeskader, som er opstået i forbindelse med ikke forskriftsmæssig brug eller opbevaring af produktet".

or

"Producenten påtager sig ikke noget ansvar for følgerne af forkert anvendelse af produktet i strid med de angivne instruktioner".

Standard tekst vedrørende sprøjteteknik (General text concerning spray application)

"XXX skal udbringes med en marksprøjte (eller anden sprøjte), som er kalibreret og lever op til de standarder og specifikationer, som er givet af sprøjteproducenten. Ved påfyldning af marksprøjte skal anvendes præparatfyldestyret eller udstyr til direkte injektion".

Vejledende angivelse af væskemængde, dysevalg, tryk og kørehastighed.

Afgrøde	Dyse nr	tryk	Km/h	Vand
Åben/lav	ISO F025/ISOLD025	2,5	7,3	150 l/ha
Tæt/høj	ISO F04	3	6,4	300 l/ha

"Bemærk at afstandskravet til vandmiljøet kan nedsættes ved brug af anerkendt afdriftsreducerende sprøjteudstyr (jf. Miljøstyrelsens Vejledning Nr. 17, Brug af afdriftsreducerende udstyr ved sprøjtning med plantebeskyttelsesmidler), som indeholder oplysninger om hvilke krav, der stilles til udstyret, og hvordan man beregner det reducerede afstandskrav. Husk at det skal dokumenteres, hvis der anvendes afdriftsreducerende udstyr til at nedsætte afstandskravet".

Blandinger med andre midler (Mixtures with other products)

"For at opnå bred effekt på almindeligt forekommende ukrudtsarter/sygdomme anbefales det, at der blandes med et egnet godkendt middel. Følg altid etikettens anvisninger for blandingspartnere".

eller

"For at opnå bred effekt på almindeligt forekommende ukrudtsarter/sygdomme anbefales det, at middel AAA blandes med en egnet partner, f.eks. aktivstof XXX, aktivstof YYY og/eller aktivstof ZZZ. Check altid godkendelsesstatus og følg etikettens anvisninger for blandingspartnere".

Tilberedning af sprøjtevæske (preparation of spraywash)

"Sørg altid for at sprøjten er korrekt rengjort samt eftersat for belægninger inden tilberedning af sprøjtevæsken begynder. Dette gælder især, hvis sprøjten har været anvendt til sprøjteopgaver i andre afgrøder".

Præparatfyldestyret (Use of fill equipment)

Flydende: Ved anvendelse af præparatfyldestyret og flydende præparater påfyldes den ønskede mængde præparat, som herefter suges op i sprøjtetanken.

Fast: Ved anvendelse af præparatfyldestyret og faste præparater fyldes stationen halvt med vand, hvorefter der påfyldes den ønskede mængde præparat, som herefter suges op i sprøjtetanken, samtidig med at rent vand tilsættes fyldestationen.

Altid:

Efterfølgende skylles præparatfyldestyret, samt evt. tomme dunke/ beholdere. Gentag proceduren med at åbne/lukke for bundventil til der ikke er synlige spor af xxxx i fyldestationen.

Additiv/penetreringsolier tilsættes til sidst, inden den endelige tankblanding er udført.

Direkte injektion (Direct Injection)

”Ved anvendelse af direkte injektionsudstyr, ledes det ufortyndede præparat automatisk ind i de slanger, som fører fra sprøjtens tank til dyserne. Ved skift og afslutning af sprøjteopgaver gennemføres en gennemskylning og rengøring af systemet. Vaskevandet udsprøjtes under kørsel på det behandlede areal”.

Rengøring af sprøjteudstyr (eksempel 1) (Cleaning of spray application equipment (example 1))

Indvendig rengøring for marksprøjter med præparatfyldeudstyr:

Restsprøjtevæsken og skyllevandet skal udsprøjtes eller anvendes på det behandlede areal uanset fyldeudstyr. Skyllevandstankens kapacitet skal være så stor, at restsprøjtevæsken kan fortyndes mindst 50 gange.

1. Ved hjælp af de indvendige spuledyser vaskes sprøjtetanken straks efter endt sprøjtning med vand fra skyllevandstanken. Skyllevandet fordeles så indvendig vask og udsprøjtning kan foregå ad 2-3 gange for at opnå den krævede fortyndingsgrad.
2. Skyllevandet udsprøjtes på marken under kørsel.

For rengøring ved anvendelse af direkte injektion henvises til afsnittet for Direkte injektion.

Udvendig:

Rengøring af marksprøjten og traktor skal ske på det behandlede areal eller på en vaskeplads med opsamling til gyllebeholder eller anden beholder. Rengøring på det behandlede areal forudsætter, at marksprøjten er monteret med udstyr hertil, samt at skyllevandskapaciteten er tilstrækkelig.

Rengøring af sprøjteudstyr (eksempel 2) (Cleaning of spray application equipment (example 2))

Efter endt sprøjtearbejde skal sprøjten og traktor rengøres enten i marken eller på vaskepladsen. En uvasket sprøjte skal placeres i den behandlede mark på vaskepladsen eller under tag. Sprøjten skal være monteret med spuledyser til indvendig rengøring af tanken, og sprøjten skal være monteret med separat vandtank med tilstrækkelig kapacitet således, at restsprøjtevæske kan fortyndes, og der kan foretages en grundig rengøring i marken. Restsprøjtevæske skal på passende vis fortyndes 50 gange med vand og udsprøjtes i den behandlede mark (uden at den maksimalt tilladte dosering for det pågældende middel herved overskrides). Rengøring i øvrigt foretages med egnede rengøringsmidler (se evt. etiketten for det sidst anvendte middel for specifikke anvisninger). Samtidig med at filtre, slanger og dyser kontrolleres for urenheder og eventuelle belægninger. Vaskevandet opsamles i egnede beholdere og udbringes iht. gældende regler.

I øvrigt henvises til Miljøstyrelsens vejledning angående påfyldning og vask af sprøjter til udbringning af plantebeskyttelsesmidler, jf. Miljø- og Fødevarerministeriets bekendtgørelse nr. 906 af 24. juni 2016.