



UPDATED REQUIREMENTS FOR SUBMISSION OF E-LABELS FOR FINAL LABEL APPROVAL

The introduction of electronic labels (e-labels) for final label approval has been eagerly adopted by the majority of applicants. Since the introduction of e-labels on 1 July 2006, approximately 60-70% of all submitted MPLs for final approval have been provided in an electronic PDF format. There is no doubt that the submission of e-labels provides applicants with both time and cost savings when compared to the submission of paper MPLs.

From 1 January 2007, the provision of MPLs in an electronic format (e-labels) becomes mandatory. From this date, paper copy MPLs will not be accepted unless there are justifiable circumstances.

The APVMA is also currently investigating how the use of e-labels can provide further efficiency gains through:

- submission of draft e-labels (as well as MPLs);
- electronically annotating required changes and other comments directly onto e-labels;
- electronically comparing varied labels against approved versions; and
- sending label comments and/or approved labels to applicants via email along with an electronic version of the notice of registration/approval.

The introduction of these improvements is planned to be implemented during 2007. These improvements will no doubt deliver a very significant productivity improvement to the registration process for both applicants and the APVMA.

To ensure that the benefits of e-labels are realised it is important for applicants to provide the e-labels in the required format. The APVMA has updated its requirements for e-labels for final label approval to include clarification in a number of areas.

REQUIRED FORMAT FOR E-LABELS

- Electronic labels (e-labels) must be submitted as Portable Document Format (pdf) files. PDF files must be generated using Adobe Acrobat (later versions preferable).
- PDF/A is the preferred specification for e-labels.
- The file must **not** be password protected.
- The labels must **not** be derived from scanning a printed label.
- E-labels can be provided to the APVMA either as an attachment in email or on a CD.

PROVIDING E-LABELS TO THE APVMA

Submitting e-labels by email

- If submitting by email send to: E-labels@apvma.gov.au.
- **DO NOT** email e-labels directly to Product Evaluators.
- **DO NOT** provide e-labels via email if you are also providing accompanying information through the normal post. In this case, submit the e-labels on a CD together with the accompanying data and/or information.

Email size limits

- PDF file sizes must be kept to a minimum where possible.
- Emails to the APVMA cannot exceed 3Mb. If the e-label exceeds this size, the e-label must be submitted on a CD - **DO NOT** send several emails each containing separate components and/or pack sizes of the overall label suite

Submitting e-labels by normal mail

- The mail address for CDs is:
Application Management & Enquiries
APVMA
PO Box 240
KINGSTON 2604
- Ensure CDs are clearly marked with the identity of the product (name and/or number).

FILE NAMING PROTOCOL

Each component of the e-label must adhere to the following protocol:

[Product No]_[ATS No]_[Packsize]_[Label component]_[Label status]_[Version].pdf

Product No:

- The unique five-digit number allocated to a *product* by the APVMA.

ATS No:

- The unique five-digit number allocated to an *application* by the APVMA.

Packsize:

- The packsize of the label, eg 10kg, 30L;
- Labels for leaflets, measure packs or other label components that are common across a range of pack sizes do not need to include a packsize;
- If the label is a representative label covering a range of pack sizes, then specify the range, eg 10-40kg, 20-30 sachets.

Label components:

- The component of the label is the 'primary' label, 'immediate' label, 'leaflet', and so on. Refer to *Table 1* for a list of commonly used terms to be used when describing a label component in the file name;
- It is preferable to maintain the terminology contained in the APVMA labelling codes. However, the APVMA will accept alternative terms provided that applicants ensure that the same term is consistently used to clearly identify all components of a label;

Label status:

- Refers to the proposed status of the e-label being submitted. For labels that are to be approved, the term '**MPL**' must be used.

Version:

- Is necessary if subsequent changes are required and newer versions of the e-label are submitted. The initial submitted e-label should commence with '**V01**', with the next version becoming '**V02**', '**V03**' and so on.

Table 1 - Terms to be used when describing a label component in the file name.

Term(s)	When to use term
“Label”	When the entire label is contained in a single pdf.
“Primary”	When the pdf only contains the label of the primary pack
“Immediate”	When the pdf only contains the label of the immediate pack
“Leaflet”	For leaflets, booklets or similar components.
“Front” and “Rear”	When the front and rear of a label , primary or immediate pack are submitted separately (<i>refer to Appendix I, Label Type A</i>)
“PartLabel” and “Breakout”	When overlarge labels are submitted (<i>refer to Appendix I, Label Type C</i>)

SEPARATE PDF FILES FOR EACH SEPARATE LABEL COMPONENT

- Where a label has several components, each component must be provided as a separate pdf.
- This has the advantage of allowing future labels to be varied by only submitting the varied component, rather than the entire label.
- Refer to *File Naming Protocol* and *Appendix 1*, for details on how label components of e-labels are to be named.

VARIOUS PACK SIZES

Where a product comprises a range of pack sizes, applicants must either provide :

- (i) a separate label for each pack size; or
- (ii) a representative label covering a range of pack sizes. For details when this option is available, refer to the document - *Labels For a Range of Pack Sizes* - available from the APVMA’s website.

OVERLARGE LABELS

- All submitted e-labels must be able to be printed onto either A4 or A3 paper. Some MPLs, however, are larger than A3 when at 100% size. Labels that fit into this category must be reduced.
- If any text for these e-labels becomes illegible when reduced to A3, breakout sections must be used. Refer to *Appendix I, Label type C* for further details on how this can be displayed.
- **IMPORTANT:** The relevant breakout area must be clearly marked on the partlabel component.

LABEL DIMENSIONS AND SCALING

It is important that all e-labels include the dimensions of the full-size printed label. Applicants must include the following information in a box as part of the pdf file next to each label :

File name	Refer to <i>File Naming Protocol</i>
Dimensions	The dimensions (in centimetres or millimetres) of each label component when printed as the full-size (100%) MPL (eg primary pack = 100mm x 80mm)
Scale	The approximate scale (%) at which the pdf file will print onto either an A4 or an A3 page.
Date	Used in combination with version control.

This box must be positioned beside the e-label. No part of this box should intrude on any part of the actual label.

APPROVAL OF TEXT LABELS (SHELF REGISTRATIONS)

- The file-naming protocol states that the applicant must include the label status 'MPL' to indicate to the APVMA that this is the e-label that is proposed to be approved.
- If the MPL is a word processing document with no colours or graphics, then that is the prerogative of the applicant.
- The inclusion of colours and graphics and other related formatting is not required for the APVMA to approve a label. However, the e-label approved by the APVMA must be identical to the MPL which is supplied with the product.

PROVIDED E-LABELS MUST BE CLEAN

Provided MPL e-labels **MUST NOT** contain any graphic, wording or comment field on the actual part of the label unless it is meant to be part of the label. This includes the information box containing the labels dimensions.

PROCESSING OF E-LABELS

- E-labels provided on a CD are processed as they are received by the APVMA.
- The APVMA processes the e-labels provided by email twice a day.

UNACCEPTABLE E-LABELS

- The Application Management & Enquiries Section (AME) is responsible for accessing, printing and saving e-labels provided to the APVMA.
- AME will only accept and forward labels to Product Evaluators (PEs) for technical assessment if the labels pass an initial quality check. AME checks:
 - that the e-label is in the correct electronic format (eg labels cannot be sent as word documents as conversion to word documents to PDF will ***not*** be undertaken by the APVMA).
 - whether the label is clear and readable (size, font, colours);
 - the label dimensions are clearly indicated (refer to *LABEL DIMENSIONS AND SCALING*)
 - the label does not contain any non-label matters (refer to *PROVIDED E-LABELS MUST BE CLEAN*)
 - whether it is clear what comprises the actual components of the complete label.
- If an e-label is received that does not pass the AME quality check, the APVMA will email the applicant requesting the label be rectified and resubmitted (as version “02”) prior to any assessment by an evaluator.
- The initially provided unacceptable version and subsequent APVMA email will be maintained as a record of correspondence.

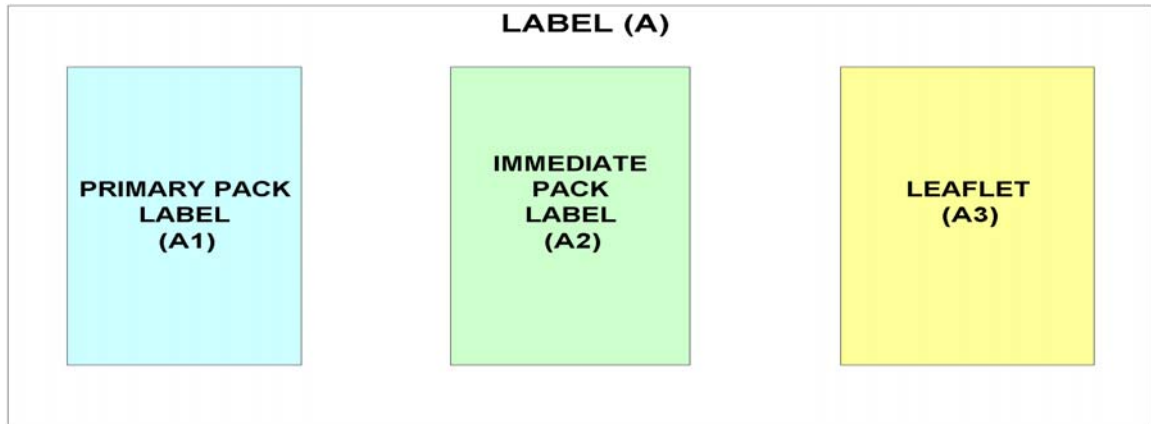
For enquiries please contact:

Peter Prammer
Manager, Application Management & Enquiries
Australian Pesticides and Veterinary Medicines Authority
PO Box E240, KINGSTON ACT 2604
Phone: (02) 6210 4703
Fax: (02) 6210 4721
email: peter.prammer@apvma.gov.au

Label type A: Label comprising more than one component

Label A = A1 + A2 + A3.

Cover information: Product Number: 12345 ; ATS Number: 67899;
A single label for pack sizes: 10 to 100L

**Separate pdfs**

Label A should be submitted as three separate pdf documents. The correct pdf file names are:

For the primary pack label (A1):

12345_67899_10-100L_primary_MPL_V01.pdf

For the immediate pack label (A2):

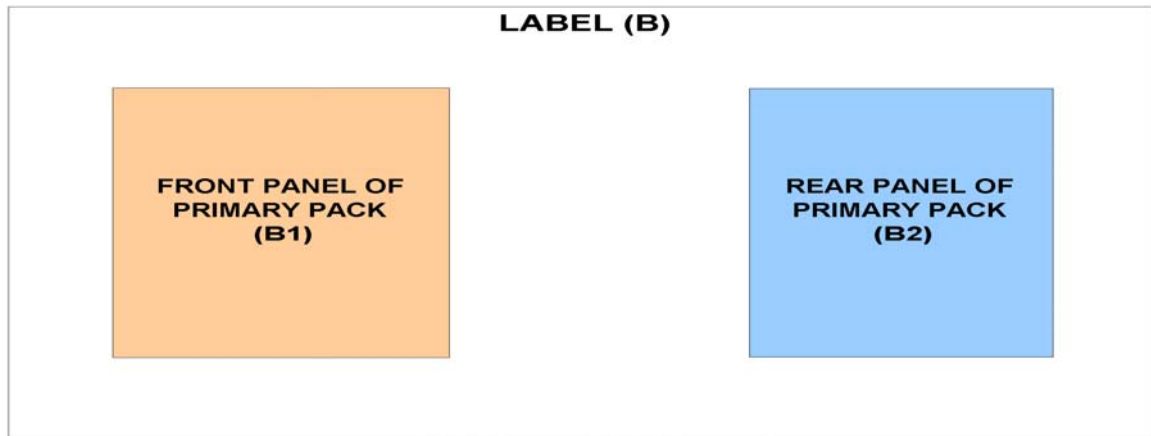
12345_67899_10-100L_immediate_MPL_V01.pdf

For the leaflet (A3):

12345_67899_leaflet_MPL_V01.pdf

Label type B: Label comprising one component, with a front panel and a rear panel

Cover information: Product Number: 12345; ATS Number: 67899
Pack Sizes: 10 & 20L



Single pdf

If the applicant submits Label B as a single pdf, the correct pdf file name is:

12345_67899_10-20L_label_MPL_V01.pdf

Multiple pdfs

If the applicant submits Label B as separate pdfs for the front and rear panels, the correct pdf file names are:

For the front panel (B1):

12345_67899_10-20L_front_MPL_V01.pdf

For the rear panel (B2):

12345_67899_10-20L_rear_MPL_V01.pdf

Label type C: Large single component labels where the pdf contains a number of break out areas.

Note: this is sometimes required for over-large labels which, when reduced in size to A3 or A4, contain text that may be too small to be legible.

Cover information: Product Number: 12345; ATS Number: 67899;
Pack Size: 200kg



The entire label C and the breakout details should be submitted as separate pdfs.

The correct pdf file names are:

For Label (C):

12345_67899_200_partlabel_MPL_V01.pdf

For the breakout sections:

12345_67899_200_breakout1_MPL_V01.pdf

12345_67899_200_breakout2_MPL_V01.pdf

12345_67899_200_breakout3_MPL_V01.pdf