



## **REQUIREMENTS FOR SUBMISSION OF E-LABELS FOR FINAL LABEL APPROVAL**

- electronic labels (e-labels) must be submitted as Portable Document Format (pdf) files. PDF files must be generated using Adobe Acrobat versions 5, 6 or 7 or other versions as stipulated by the APVMA.
- 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 sent to the APVMA by email or on CD by mail.

### **email**

- the email address is:  
[E-labels@apvma.gov.au](mailto:E-labels@apvma.gov.au).
- **DO NOT** email e-labels directly to Product Evaluators.
- do not submit 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.

### **email size limits**

- PDF file sizes must be kept to a below 250kb 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 and different components of the overall label.

### **mail**

- the mail address for CDs is:  
Application Management & Enquiries  
APVMA  
PO Box 240  
KINGSTON 2604

## FILE NAMING PROTOCOL

File names for e-labels must follow the protocol:

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

where:

- **Product No.** is a unique five-digit number allocated to a product by the APVMA.
- **ATS No.** is a unique five-digit number allocated to an application by the APVMA.
- **Packsize** is the representative packsize of a suite of labels.  
For example, if the approved packsizes range from 10L to 100L, and all labels within this range contain identical instructions and particulars, only one representative packsize needs be submitted.
- **Label component** refers to ‘primary pack’, ‘immediate pack’, ‘leaflet’ ,etc.  
Generally, it is preferable to maintain the terminology contained in the APVMA labelling codes. The APVMA will accept alternative terms, however the applicant must ensure that the same term is consistently used to clearly identify all components of a label. (Refer to Label A in Appendix 1).  
If a label consists of only one component, the term ‘**Label**’ should be used to indicate that only one pdf document is required and the label is complete (refer to Label B in Appendix 1).  
If breakout areas are used (refer to Label C in Appendix 1), appropriate terms must be used to clearly identify the relationships between the label and the breakout areas.
- **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. Applicants should commence with V1, with the next version becoming V2, V3 and so on.

## LABEL DIMENSIONS AND SCALING

It is important that all e-labels include the dimensions of the full-size printed label. The APVMA-preferred option is that applicants include the following information in a standardised box as part of the pdf file:

- the file name (refer to the file-naming protocol above)
- the dimension (in centimetres or millimetres) of each label component when printed as the full-size MPL (eg carton = 100mm x 60mm x 80mm); and
- the approximate scale (%) at which the pdf file will print at both A4 and A3.

## **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 Appendix 1, Label type A for the appropriate file naming protocol of label components.

## **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 identical to a text label ie a word processing document with no colours or graphics, 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.

## **OVERLARGE LABELS**

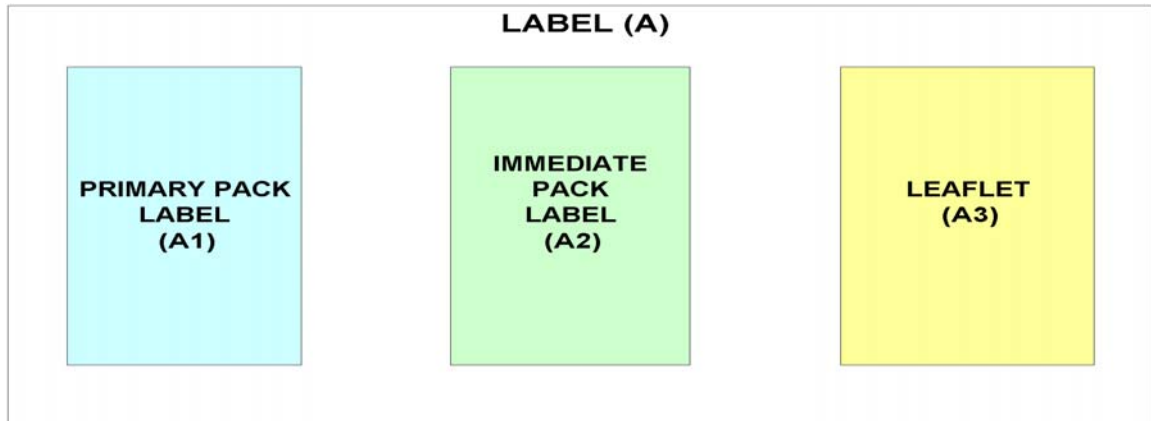
- MPLs for large cartons, bags, etc. may be larger than A3 and therefore must be reduced.
- if any text for these e-labels becomes illegible when reduced to A3, breakout sections can be used. Refer to Label C in Appendix I for further details on how this can be displayed.

For enquiries about these requirements, please contact:

Peter Prammer  
Team Manager, Application Management & Enquiries  
Australian Pesticides and Veterinary Medicines Authority  
PO Box E240  
KINGSTON ACT 2604

Phone: (02) 6272 3216  
Fax: (02) 6272 3218  
email: peter.prammer@apvma.gov.au

APVMA June 2006

**Label type A: Label comprising more than one component****Label A = A1 + A2 + A3.****Cover information:** Product Number: 12345; ATS Number: 67899;  
Pack Sizes: 1L 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\_1L\_primary\_MPL\_V1.pdf

**For the immediate pack label (A2):**

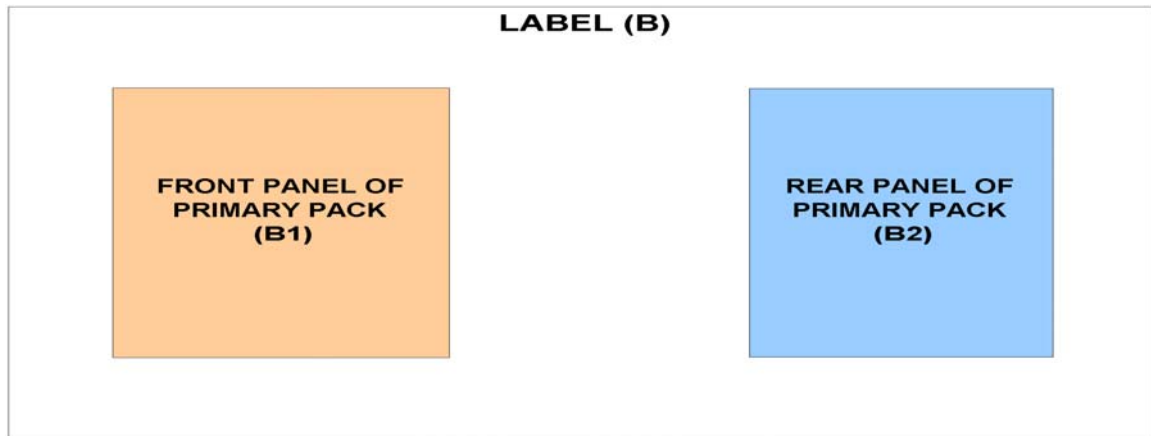
12345\_67899\_1L\_immediate\_MPL\_V1.pdf

**For the leaflet (A3):**

12345\_67899\_leaflet\_MPL\_V1.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\_10L\_label\_MPL\_V1.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\_10L\_front\_MPL\_V1.pdf

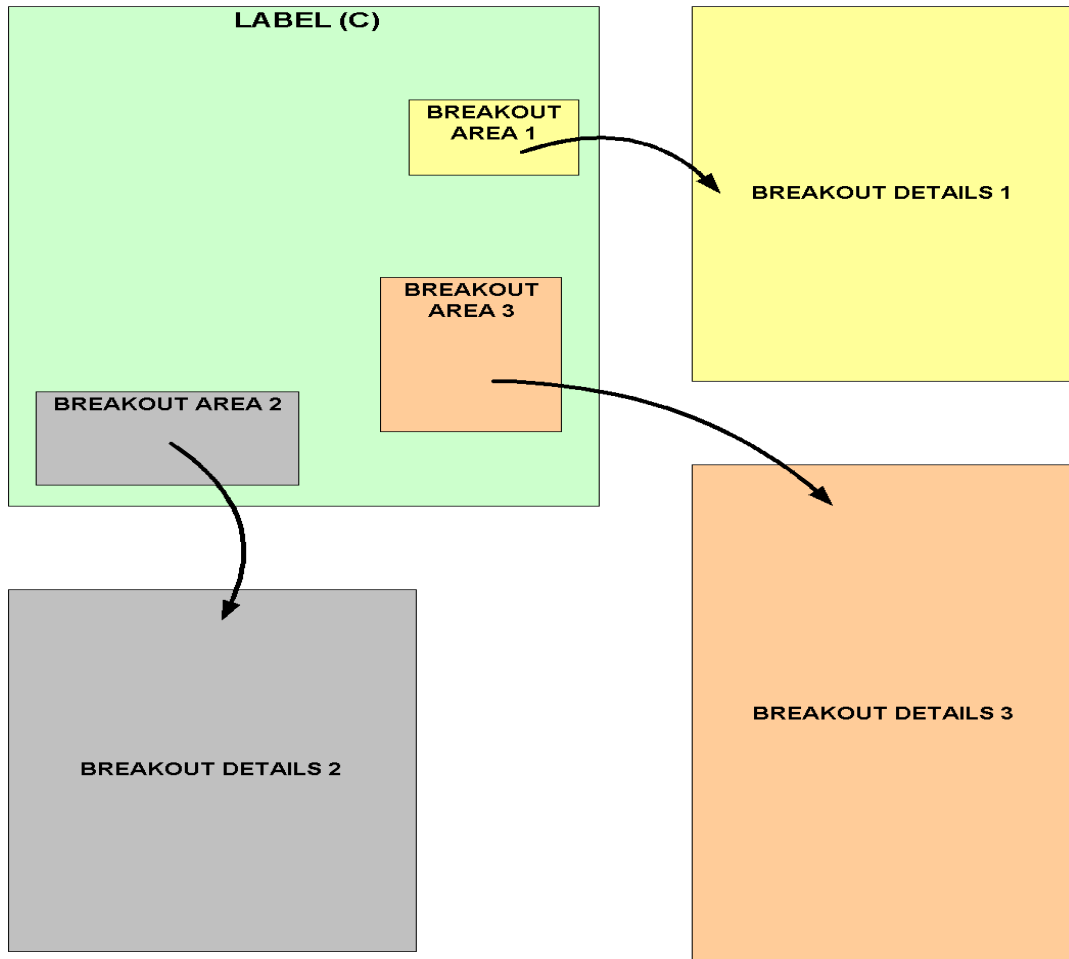
**For the rear panel (B2):**

12345\_67899\_10L\_rear\_MPL\_V1.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 Sizes: 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\_V1.pdf

**For the breakout sections:**

12345\_67899\_200\_breakout1\_MPL\_V1.pdf

12345\_67899\_200\_breakout2\_MPL\_V1.pdf

12345\_67899\_200\_breakout3\_MPL\_V1.pdf