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# **SAFETY FIRST**

## PHARMACEUTICAL LABELLING BY UPM RAFLATAC



**UPM** RAFLATAC



## Contents

STERILIZATION AND UPM RAFLATAC MATERIALS	3
Autoclave	
Ethylene Oxide	
Gamma radiation	
Electron beam	
SMALL DIAMETER APPLICATIONS	3
UPM RAFLATAC PRODUCTS FOR PHARMACEUTICAL LABELLING	4
PRODUCT LABELS	4
Paper product labels	
Filmic product labels	
INFORMATION LABELS	6
Laser	
Direct thermal	
Thermal transfer	
Digital	
Laser beam	
ADHESIVES	10
Permanents	
Non-migration properties: RP 31 C	
Luminescent labels	
Removables	
PRODUCTS FOR PHARMACEUTICAL APPLICATIONS	12
Blood bag labels	
Multitac labels	
Booklet labels	
Security labels	
STORAGE AND HANDLING RECOMMENDATIONS	14

# FOREWORD

There was a time when wet-glue labels were hand applied to amber-coloured glass bottles and vials. Those days are not over, but today's pharmaceutical labelling applications are much more varied in nature, especially now that plastics are in common use as packaging materials.

It is fair to say that no other industry is so widely oriented in terms of different types of packaging than the pharmaceutical industry, and it follows that there are numerous different labelling applications. As if this were not enough, exposures like sterilization and various labelling and storage conditions make it even more complicated to choose the right labelling materials.

UPM Raflatac has been producing pressure sensitive labelstock for pharmaceutical use for many years. Special constructions have been developed with flexible filmic or thin paper face materials, coated with special adhesives for labelling on small diameters. Other products have been designed for applications where any risk of migration should be avoided.

This brochure is intended primarily for the use of UPM Raflatac's customers – label printers and converters – to provide assistance in finding the right pressure sensitive materials for pharmaceutical end-use applications. Those working in pharmaceutical companies in the field of packaging development, such as packaging engineers and packaging technologists, will also find the following pages informative. Whichever the case, UPM Raflatac's experts welcome all enquiries.

## STERILIZATION AND UPM RAFLATAC MATERIALS

As part of the process to make product packaging and test tubes suitable for clean pharmaceutical purposes, labels may be exposed to extreme conditions through sterilization. Of the available techniques, four sterilization methods are in common use.

### AUTOCLAVE

Autoclave sterilization uses steam at high pressure, about 2 bar, at a temperature of 120 °C. The exposure time is usually 20 minutes.

### ETHYLENE OXIDE

The sterilization process uses toxic ethylene oxide, humidity, other chemicals and a range of temperature settings over a period of about 24 hours. Optional degassing can take a few days.

### GAMMA RADIATION

Products are irradiated as they pass a Cobalt 60 plate. UPM Raflatac has noted no change in the performance of label materials exposed to this process, though papers do have a tendency to yellow.

### ELECTRON BEAM

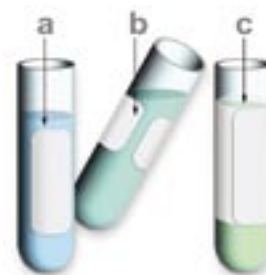
A high voltage of 5 to 10 megavolts sterilizes products as they pass an electron beamer. To date, UPM Raflatac has not seen that this process would influence its label materials in any way.

The charts in this brochure include information about the individual suitability of UPM Raflatac materials for each of the above sterilization methods.

## SMALL DIAMETER APPLICATIONS

Small packaging units with diameters as low as 7 mm are becoming more common as today's medicinal ingredients are increasingly stronger and more concentrated. UPM Raflatac's own research indicates that a diameter of 15 mm is the threshold at which the choice of labelling material becomes critical, though applications involving larger diameters should also be carefully tested. For papers it is the stiffness that is important, and for filmic materials the thickness. Finat has developed a method for testing label performance on small diameters, FTM 24 – Mandrel Hold.

Where paper-based labels are concerned, the direction in which the fibre's grain runs requires consideration. The grain should run perpendicular to the curvature of the substrate. Overlapped labelling provides the best performance.



### Three ways to apply a label:

a. axis-parallel, b. cross-parallel, c. overlapped





## Filmic product labels

- First choice
- Second choice
- Test first
- Not recommended

EAN	face	adhesive	backing	temp. min. lab. temp. °C	sterilization method					blood bags		small diameter		printing variable data
					storage at - 80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	labelling PP	labelling Topas®	
8036808	PE GLOSS WHITE TC	RP 31 C	HD70	10										
8017562	PE GLOSS CLEAR TC	RP 31 C	HD70	10										
79803	PE GLOSS WHITE TC 85	RP 37	HD70	10										
79841	PE GLOSS CLEAR TC 85	RP 37	HD70	10										
8046388	PP WHITE TC 60	RP 31 C	HD75	10										
8070987	PHARMACLEAR PP 50	RP 31 C	HD70	10										
96824	PP WHITE 40	RP 37	HD70	10										
86177	PP CLEAR 30	RP 37	HD75	10										
8001332	RAFLEX CLEAR TC	RP 37	HD70	10										
57849	PET WHITE TC 50	RP 37	HD70	10										
26364	PET CLEAR TC 50	RP 37	HD70	10										
106172	PET CLEAR TC 36	RP 37	HD70	10										
99634	TYVEK BRILLION 54	RP 33	WG85	5										
97005	TYVEK 75	RP 33	WG85	5										
99627	PE WHITE STRONG 75	RP 33	WG85	5										



## INFORMATION LABELS

Labels that carry variable data belong to the information labelling segment. Several pieces of data, such as a batch number, expiry date, EAN code or other bar code, are often combined on one label before it is applied to a pharmaceutical product. A range of printing techniques may be employed, and each technique necessitates the use of specific materials. UPM Raflatac's information label materials are presented below according to printing technique.



## Laser

Labels for hospital and laboratory end-uses are commonly printed by laser. A4 sheets containing a number of small die-cut labels are printed with special bar codes or variable data. The labels can be manually applied to different substrates and stored under a variety of conditions. UPM Raflatac's Jetlite face material has been specifically developed for hospital-laboratory end-uses. It is smooth, thin and flexible, providing excellent toner anchorage for reliable bar code reading and good properties for test tube labelling.

Hospital and laboratory end-uses normally require the KS70 backing, though KS80 is a good choice if highly perforated short-grain converted sheets are used or if the face is die cut with many small labels.

- First choice
- Second choice
- Test first
- Not recommended

EAN	face	adhesive	backing	temp.		sterilization method				blood bags		small diameter
				min. lab. temp. °C	storage at - 80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	labelling PP
8006467	JETLITE	RP A4	KS70	5								
8006436	JETLASER	RP A4	KS55	5								
8030806	POLYLASER MATT WHITE	RP 37	KSMC100	10								
8030820	PE LASER WHITE	RP 37	KSMC100	10								

## Direct thermal

Labels printed in pharmacies contain information about medicines or instructions for the user; those in clinical trials carry variable information. In logistical use, labels secure the proper internal or external transportation of pharmaceutical raw materials or pharmaceutical products.

- First choice
- Second choice
- Test first
- Not recommended

EAN	face	adhesive	backing	temp.		sterilization method				blood bags		small diameter
				min. lab. temp. °C	storage at - 80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	labelling PP
77434	THERMALITE TOP P 300	RP 51	HG50	0								
138227	THERMAL TOP P 200	RP 31 C	HG65	10								
63659	THERMAL TOP P 200	RP 31	HG65	5								
87303	THERMAL TOP P 300	RP 31	HG65	5								
99078	SYNTHERMAL P 200	RP 37	HG65	10								

## Thermal transfer

Thermal transfer is a widely used technique in pharmaceutical labelling. Batch numbers and expiry dates in particular may be printed with this technique, as can the variable data required for pharmaceutical product information and clinical trial labels.

- First choice
- Second choice
- Test first
- Not recommended

EAN	face	adhesive	backing	temp.		sterilization method				blood bags		small diameter
				min. lab. temp. °C	storage at - 80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	labelling PP
55951	VELLUM TTR	RP 31 C	HG65	10								
10271	VELLUM TTR	RP 31	HG65	5								
84135	TRANSFER MATT	RP 31 C	WG85	10								
8031971	TRANSFER XTRA	RP 51	HG65	0								
85712	SYNTRANSFER	RP 37	HD75	10								
70367	POLYPRINT 100	RP 31 C	HG65	10								



### Laserbeam

Variable information printed by laser is one of the latest applications of new printing technology. Suitable inks are used to print a solid area and a laser beam 'engraves' the variable data by selectively removing the ink layer to expose the material beneath.

### Digital

Digital printing machines require dedicated materials to print what are typically smaller-sized labels in low volumes.

EAN	face	adhesive	backing	temp. min. lab. temp. °C	sterilization method				blood bags		small diameter	
					storage at -80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	labelling PP
162239	PHARMAGLOSS IL	RP 31	HG65	5								
162260	PE GLOSS WHITE IL	RP 37	HD75	10								
162277	PE GLOSS CLEAR IL	RP 37	HD75	10								
162284	PE MATT WHITE IL	RP 37	HD75	10								
162291	PP SOLID WHITE IL 60	RP 37	HD75	10								
162314	PP CLEAR IL 60	RP 37	HD75	10								

- First choice
- Second choice
- Test first
- Not recommended

# ADHESIVES

## Permanents

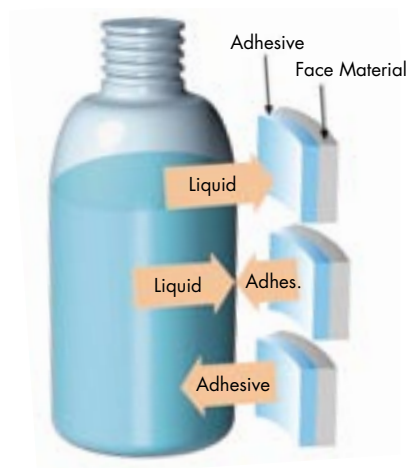
Most pharmaceutical labels use a permanent adhesive to secure the information they carry. UPM Raflatac's RP 51 adhesive provides the required performance to cover a wide range of standard applications.

A4 applications are in many cases best served with UPM Raflatac's RP A4 adhesive. RP 31 has been specially designed to provide the high cohesion required for labelling on curved substrates and small-diameter containers packaging. Where the application requires a filmic face material, UPM Raflatac recommends RP 37.



## Non-migration properties: RP 31 C

Whenever labels are applied to liquid-filled LDPE containers, there is a risk of migration. Pharmaceutical companies are obliged to make tests to prove the safety of their products. UPM Raflatac strongly advises that an accelerated-aging test is implemented and has a history of providing pharmaceutical companies with the necessary support.



EAN	paper	adhesive	backing
18758	PHARMAGLOSS	RP 31 C	HG65
11698	PHARMAGLOSS	RP 31 C	WG65
105892	PHARMAMATT	RP 31 C	HG65
105892	PHARMAMATT	RP 31 C	HG65
55197	RAFLACOAT	RP 31 C	HG65
75430	RAFLAGLOSS	RP 31 C	HG65
55951	VELLUM TTR	RP 31 C	HG65
84135	TRANSFER MATT	RP 31 C	WG85
138227	THERMAL TOP P 200	RP 31 C	HG65
8001103	JETLITE	RP 31 C	KS85

EAN	filmic	adhesive	backing
8017562	PE GLOSS CLEAR TC	RP 31 C	HD70
8046388	PP WHITE TC 60	RP 31 C	HD75
70367	POLYPRINT 100	RP 31 C	HG65



## Luminescent labels

Every pharmaceutical product needs to be clearly identifiable to assist tracking and tracing. Code labels are very often used for this purpose, and as part of the procedure to attain a zero-defect labelling rate, each product should be inspected to ensure the presence of a label. White labels are relatively easy to detect. Transparent filmic labels, however, require a transparent adhesive that can be detected by a luminescent scanner. Please ask your nearest UPM Raflatac contact for further support with luminescent label constructions incorporating the RP 35 L adhesive.

## Removables

The main part of pharmaceutical labelling centres on permanent adhesion to ensure traceability. There are, however, certain applications that require a removable label and an adhesive to match – labels are removed from test tubes and containers before washing, for example. UPM Raflatac's removable adhesives are RR 21 for paper-based materials and RR 28 for filmics.

# PRODUCTS FOR PHARMACEUTICAL APPLICATIONS

## Booklet labels

The use of a booklet label in place of a leaflet is a growing trend. Several techniques are used to fold these labels, and many converters specialized in booklet labels have patents on their products. The main part of a booklet label is made from double-sided coated paper, without adhesive. A pressure sensitive laminate forms the base layer used to attach the booklet label to the package or container. Raflacoat is well suited to booklet applications, and if there are constraints set on the thickness, Raflalite provides an appropriate alternative. The booklet can be protected by varnishing the outer layer or overlaminating it with PP or PET.



EAN	face	adhesive	backing
11728	PHARMAGLOSS	RP 31	HG65
11704	PHARMAGLOSS	RP 31	WG65
74242	RAFLALITE	RP 31	WG65
11025	RAFLACOAT	RP 31	HG65

EAN	face	adhesive	backing
65035	PP CLEAR TC 50	RP 37	HD70
86177	PP CLEAR 30	RP 37	HD75
106172	PET CLEAR TC 36	RP 37	HD70
96664	PET OVERLAM. FILM 12 µ	RP 35	HG65

## Multitac labels

For laboratory and hospital purposes, UPM Raflatac supplies double label construction materials that allow the user to peel off part of the label and affix it to documents or other substrates.



- First choice
- Second choice
- Test first
- Not recommended

EAN	face	adhesive	backing	temp. min. lab. temp. °C	sterilization method					blood bags small diameter						
					storage at -80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	inkjet	laser	copier	thermal transfer	
58310	PHARMAGLOSS MULTITAC	RP 31	HG65	5												
58914	PHARMAMATT MULTITAC	RP 31	HG65	5												
8006542	JETLITE MULTITAC	RP A4	KS55	5												
8010136	JETLASER MULTITAC	RP A4	KS55	5												
57931	VELLUM MULTITAC	RP 31	HG65	5												



## Bloodbag labels

Blood is crucial for people and a crucial product in health care. Both the blood bag and its labels need to be safe to ensure the quality of the blood. There are two stages to blood bag labelling. Primary blood bag labels are applied during the manufacture of the blood bags, one primary label on each bag. A secondary blood bag label is applied over the existing primary label after the bags have been filled with blood – the blood is tested and the result printed on the label. UPM Raflatac recommends that the first tests for secondary blood bag labelling begin with the following products:

EAN	face	adhesive	backing
18758	PHARMAGLOSS	RP 31 C	HG65
11728	PHARMAGLOSS	RP 31	HG65
105892	PHARMAMATT	RP 31 C	HG65
11773	PHARMAMATT	RP 31	HG65
70367	POLYPRINT	RP 31 C	HG65

## Security labels

The pharmaceutical industry is seeking solutions for tamper-evident labelling and the prevention of counterfeiting. Special material constructions, holograms and special techniques at the point of conversion are among the approaches used to support safe labelling. Tamper-evident labels ensure that products remain safe and intact by revealing any attempt to interfere with or remove the label. UPM Raflatac has several security materials in its range. Easy-tear materials like Tamperproof disintegrate when any attempt is made

to remove the label. And materials that have low internal strength, like Tamperproof, Security White PE and Voids, split if any attempt at removal is made. Voids are available in white, silver and clear. The residue left from the voids can appear as a chequerboard pattern or the word 'void'. Good tamper-evident property requires that the labels are applied to the substrate a minimum of one day before full functionality is required. Information about UPM Raflatac's wider security range is available from your nearest UPM Raflatac contact.

- First choice
- Second choice
- Test first
- Not recommended

EAN	face	adhesive	backing	temp.		sterilization method			blood bags		small diameter	
				min. lab. temp. °C	storage at - 80°C	autoclave	ethylene oxide	gamma	electron beam	secondary labels	labelling glass	labelling PP
8019924	SECURITY WHITE PE	RP 77	HD70	0								
93502	TAMPERPROOF	RP 51	HG65	0								



## STORAGE AND HANDLING RECOMMENDATIONS

UPM Raflatac recommends that labelstock is stored in room temperature (+20 °C) at a maximum relative humidity of 50%. Labelstock should be kept in its original packaging and protected from light. Damp or hot conditions should be avoided. The shelf life is calculated from the date of the labelstock's manufacture and is based on the adhesive's ability to maintain optimal labelling properties during storage.



## WARRANTY

Our recommendations are based on our most current knowledge and experience. As our products are used in conditions beyond our control, we cannot assume any liability for damage caused through their use. This publication replaces all previous versions. All information is subject to change without notice.



