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METAL CONTAINERS

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Introduction

Although the use of metal in packaging appears to be on a slow decline, the trend towards continuing reduction in weight has meant that more containers are being made from the same overall weight of metal. It therefore remains generally competitive with other materials, particularly as it can be manufactured and filled at high speeds. However, metal is being increasingly challenged by plastics, glass and composite materials which involve a wide range of coating processes such as metallisation, silica oxide and carbon.

With pharmaceuticals, metal, particularly tinplate, was at one time widely used for pastille tins, ointment tins and various built-up containers for powders, tablets, capsules, etc. As the early use of tinplate declined, aluminium containers had a period of success, but other than aerosols, are now reducing in usage mainly because of their high cost compared with plastics and glass. However as raw materials vary significantly across the world and processing equipment, once installed, has to justify its initial expenditure, metal usage can vary from country to country.

The main metals currently in use are the following.

1 Tinplate, with various types of base steel and coating weights. Since tin is now a high-cost material, lower coating weights are frequently supplemented by lacquers, enamels, print coverage to add to protection from potential corrosion.
2 Tin-free steel where additional protective coatings are essential, i.e. enamels and lacquers.
3 Aluminium and various alloys of aluminium.
4 Aluminium as a foil, often laminated to other materials.
5 Metallisation involving the deposition of aluminium or oxides of aluminium onto other materials such as paper or plastic.
6 Stainless steel.

The main uses of the above in the pharmaceutical industry today include the following.

1 Tinplate

- Built-up containers made from a number of components with a range of possible closure features, e.g. ring pull, diaphragm seal, aerosol.
- Lidded shallow drawn containers with a rolled edge.

2 Aluminium and various alloys

- Impact extruded rigid containers—especially aerosols. Also used for rigid tubes.
- Impact extruded collapsible tubes.
- Shallow drawn containers.

3 Aluminium foil, usually as laminations for blister, strip, and sachet packaging.
4 Metallisation, often used as a more economical substitute to foil but has lower protective properties.
5 Stainless steel, i.e. a chromium (12–14%) and nickel (up to 0.7%) steel widely used for mixing vessels and manufacturing equipment.
6 Other metals—tin is occasionally used for collapsible tubes.

Metal closures are still in wide use, being manufactured from tinplate, aluminium and alloys of aluminium, and these cover screw closures, various forms of lidding, aerosol valves, overseals (e.g. for vials), etc.

Metal containers

Metals were first used as containers as early as 4000 BC, and probably before that. The first metals used were those found in their native state requiring only gathering and hammering into shape. These included gold, silver, copper, and white gold (electrum). Some very early examples of pottery vessels were obvious copies of metal prototypes, as they show simulation of seam lines and rivets.

Since the modern era of packaging dates from about the time of the industrial revolution of the eighteenth and nineteenth centuries AD, the metals we need concern ourselves with today are almost exclusively steel, tinplate and aluminium. Tinplated sheet iron was developed in Bohemia in 1200 AD and kept a jealously guarded secret for several hundred years.

Aluminium was not isolated until 1825 and remained a rare curiosity until the late 1880s, when a practical method of extraction from bauxite was developed. From that time on its price steadily dropped. Its widespread adoption in packaging came in the mid-1940s, when techniques for rolling and decorating thin aluminium foils were perfected.

Metal containers are strong, relatively unbreakable, opaque, and impervious to moisture vapour, gases, odours and bacteria, providing they are pinhole-free. They are also resistant to both high and low temperatures. However, metals require the application of coatings and lacquers to prevent chemical reaction and corrosion from the inside or outside. Special coatings and coating techniques have therefore been developed for this purpose, e.g. tinplate is in fact a coated material.

Metal containers are available in a variety of shapes, sizes and styles ranging from small elongated collapsible tubes and shallow drawn containers to large built-up containers including steel drums of up to 110 gallon capacity. Many of these containers are in direct competition with equivalent containers produced in glass or plastic, e.g. collapsible metal tubes compete with laminated and plastic tubes and rigid metal tubes compete with glass or plastic vials.

Although metal containers exist in many different styles, most are parallel sided and of relatively simple cross-section, e.g. square, rectangular, oval or circular, the majority being circular. This is due to limitations in manufacturing techniques which do not apply to glass or plastic. However, the technique of building-up metal containers from sheet by means of seaming confers one advantage over glass and plastic in that right angles can be easily achieved. Blown glass or plastic containers require radii, particularly at the base of the container, in order to avoid excessive thinning (Figure 10.1).

The use of sheet material also allows decorating before container fabrication instead of after, with fewer limitations than for processes applicable to finished containers. Furthermore this enables the decoration to be carried right up to junctions and around curvatures which would otherwise be difficult, if not impossible, to decorate.

It is in the field of aerosols that metal containers have predominantly established themselves. Although glass, plastic and plastic-coated glass aerosols are finding their own specialised applications, metal aerosols are likely to retain the bulk of the market as long as cost advantages are offered.

In common with glass and plastic containers, the performance of a metal container is partly governed by the nature of the closure involved. Some of these closures are similar to those used on glass and plastic containers, e.g. plastic and metal screw closures and frictional closures such as plug or slip lids. Others, which are mainly used on metal (or metal composite) containers, are lever lids and permanent mechanically seamed-on closures.

Modern packaging metals

Tinplate and associated materials

Tinplate is mild or low-carbon steel sheet or strip which is coated on both sides with commercially pure tin. Other steel-based materials which are occasionally used in packaging are steel itself, blackplate, galvanised and stainless steel. Blackplate is uncoated steel which is highly susceptible to corrosion and is of limited application. Galvanised steel is produced by coating the steel with zinc by hot-dipping or electroplating. The materials in this group are mainly restricted to making larger containers, e.g. drums for bulk chemicals. Stainless steel finds wide usage in the pharmaceutical industry, mainly as types 316 and 304.

Within the past three decades tin-free steel (TFS) has been developed. This material consists of a mild steel base—exactly as used for tinplate—but with a coating of chromium-chromium oxide only about 1/30 as thick as an average tinplate coating. The function of this coating is merely to protect the steel base from corrosion prior to fabrication. TFS containers need to be coated on the inside and outside with one of many organic coatings in order to make them at least as corrosion-resistant as uncoated tinplate containers. To date the main usage of TFS has been for can ends.

Manufacture of tinplate

The steel base, which contains small amounts of carbon (also known as a low carbon steel with a carbon content of less than 0. 25%), sulphur, phosphorus, copper, manganese and silicon is rolled from ingots into slabs and then into continuous strip or

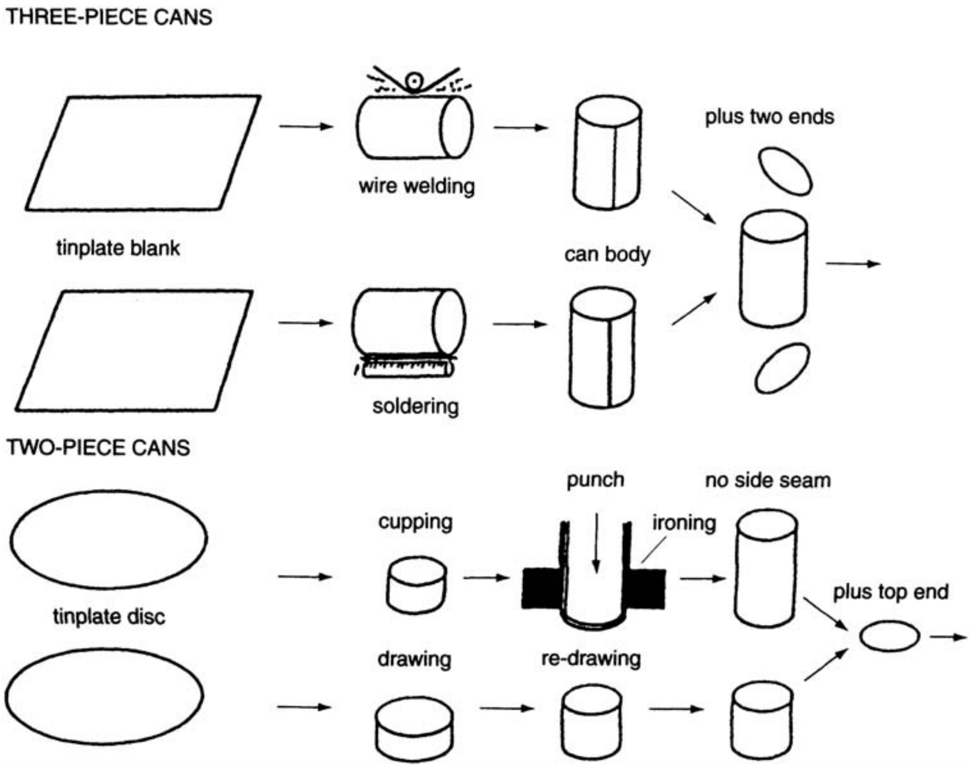


Figure 10.1 Some methods of can manufacture

sheets of from 0.20 to 0.25 mm thickness. The process is known as 'continuous cold reduction' and involves pickling in hot dilute sulphuric acid, oiling, rolling, electrolytically degreasing, annealing and tempering to the required hardness.

The tin coating is then applied either by electroplating or by the older process of hotdipping in molten tin, to a coating thickness less than 0.002 mm for electro-tinplate but higher for hot-dipped tinplate. Electro-tinplate is produced in a continuous strip form and may include a flow-brightening operation whereby the newly applied coating is momentarily melted and then allowed to cool, giving a bright surface and better corrosion resistance by improving the continuity of the tin coating. Hot-dipped tinplate is normally produced in sheet form although occasionally strip is used, and does not require flow-brightening. Unlike hot-dipped tinplate, electro-tinplate may be produced with a different coating weight on each side, known as differential tinplate. Electrotinplate has almost entirely superseded hot-dipped tinplate for can manufacture.

Thinner sheets down to about 0.15 mm may be achieved by an additional coldreduction (known as double reduced tinplate) before tinning. Thicknesses down to 0.12 mm may be achieved by cold-reduction after tinning (i.e. re-rolled tinplate), but the brightness and protectiveness are reduced.

Specification of steel and tinplate

Steel contains a small percentage of other elements, the quantity and proportion of which can be varied to produce four chemical sets of steel: MC, MR, L and D. The degree and type of cold-reduction and annealing or tempering affect the formability of the steel sheet. In the USA, as many as nine different hardness of temper classifications are available. There are five recognised commercial finishes of tinplate, namely bright, matt, silver, stove, and shot blast, all of which are achieved by the use of textured work rolls during the final stages of temper rolling. With the exception of matt finish, each requires flow brightening after electro tinning.

Several different systems are used to express the thickness of steel and these vary according to whether it is being used with or without a tin coating. The thicker sheets of steel which are used for drum manufacture are specified in terms of gauge rather than thickness, the gauge being defined in terms of the area covered per unit weight. A comparison of the US and UK systems is given in Table 10.1.

Thinner gauges of tinplate are specified in terms of their nominal thickness, which ranges from 0.31 mm down to 0.12 mm in 0.01 mm steps. In practice the thickness is calculated from the weight per unit area divided by the density rather than by direct measurement. Although tinplate is a combination of steel and tin, the actual difference in density is relatively small (0.5

g/cm^2) and the proportion of tin present is very low (~1%). Therefore for practical purposes the density of tinplate can be taken as identical to that of steel (7.85 g/cm^3).

The tin coating on tinplate is more conveniently expressed as the coating weight per unit area (as g/m^2) for each surface separately. These figures are prefixed by the letter E for electrolytic (equally coated) tinplate, D for differential tinplate and H for hotdipped tinplate. There are standard coating weights for electrolytic tinplate in the UK (1.1 to 14.0 g/m^2) and on hot-dipped tinplate (11 to 22 g/m^2).

Prior to metrication the coating weight was expressed in terms of the total weight applied in lb per base box (as in the USA). The base box being defined as the total coated surface area of 112 sheets of size 14×20 inches, i.e. 31,360 in^2 (20.2325 m^2) of tinplate or 62,720 in^2 (40.465 m^2) of tinned surface.

Thin nickel coatings are being developed as a cheaper alternative to tin and may be plated electrolytically down to one-tenth the thickness of a conventional E 2.8/2.8 tin coating.

The type of solder used with tinplate is normally tin/lead but antimony has replaced lead where there is a possible extractive hazard, e.g. for aerosols containing aqueous formulations. Efforts are being made to reduce the lead content of solder for health reasons. The tin coating is essential for soldering, since tin-free steel cannot be soldered. Leadfree solders are now available but these are largely being replaced by welding.

Table 10.1 Comparison of commonly used steel gauges: USA and UK

Gauge no.	*UK Birmingham gauge*		*US manufacturer's standard gauge*	
Imperial (in)	*Metric (mm)*	*Imperial (in)*	*Metric (mm)*	
14	0.079	1.99	0.075	1.90
16	0.063	1.59	0.060	1.52
18	0.050	1.26	0.048	1.21
20	0.039	1.00	0.036	0.91
22	0.031	0.79	0.030	0.76
24	0.025	0.63	0.024	0.61
26	0.020	0.50	0.018	0.46
28	0.016	0.40	0.015	0.38
30	0.012	0.31	0.012	0.31

The protective value of the tin coating increases with coating weight. The more corrosive chemicals and certain pharmaceuticals require use of coatings at the top end of the range.

Differential tinplate may be used, e.g. where higher corrosion resistance is required inside the ultimate container, or conversely used with the heavier coating on the outside, e.g. for shipment of inert materials to tropical regions. The drawing and wall ironing process also requires the heavier tin coating on the outside for lubrication.

The heaviest tin coating is extremely thin and rarely completely continuous, so the risk of external corrosion can be reduced by application of an enamel, and possible chemical reaction with the product can be eliminated by internal lacquering.

Can enamels and lacquers

A wide range of internal lacquers developed for the heat processed food industry also find uses in the pharmaceutical and cosmetic field. The lacquers, which include acrylic, phenolics, polyesters, epoxy and vinyl resins, are normally applied via an organic solvent which is subsequently evaporated during curing. The use of aqueous carriers and powder coatings has also been developed. Ferrolite is a plastic coated metal using polypropylene, polyester, etc.

The choice of resin is based mainly on satisfying product compatibility requirements such as resistance to acid or alkali, and freedom from flavour or taint. The resin must adhere well and have sufficient flexibility to withstand the container fabrication process. It must also be resistant to damage if the container is soldered. On shallow drawn or formed foil containers, protective coatings are applied to the foil or sheet prior to container fabrication. On deep drawn or extruded containers, coatings are applied after fabrication. With soldered or welded cans the opposite internal area can be protected by a 'side-stripe', after fabrication.

Aluminium

Aluminium sheet is used for drawn or formed one-piece container bodies and also in the fabrication of multi-piece built-up containers.

The first stage in the extraction of aluminium from bauxite is to extract the aluminium oxide (alumina) which comprises 40% to 60% of bauxite, by a chemical process. The alumina is then dissolved in molten cryolite (a double fluoride of sodium and aluminium) at 1100°C and separated into oxygen and metallic aluminium by the passage of a direct current. The reduction operation requires almost 8 kW h to produce 1 lb of aluminium, having started with about four pounds of bauxite.

The molten aluminium which accumulates at the bottom of the reduction cell is regularly syphoned off and cast into rectangular moulds to cool and solidify. The resultant ingots are then scalped to remove 4–5 mm of the rough exterior which may contain aluminium oxide inclusions. In order to relieve internal stresses resulting from casting and to distribute any alloying constituents more thoroughly, the scalped ingots are homogenised by reheating to about 600°C for 24 h.

Aluminium can be produced up to 99.99% purity, but this is not only expensive but mechanically weaker than aluminium of a lower purity. Therefore a small percentage of other elements is included, e.g. 0.4% iron, 0.2% silicon, plus traces of copper and manganese. Where maximum rigidity is required, e.g. for formed containers, an alloy containing 1.25% manganese is used such as NS 3 in the UK or 3003 in the US. The latter also contains up to 0.2% copper.

Sheet rolling

The first stage is hot rolling whereby ingots are heated to 550°C and passed back and forth through vertical roll mills, resulting in a considerable increase in length as well as reduction in thickness. When the thickness has been reduced to about 20 mm the material is passed in line through a series of mills known as ‘tandem’ mills to differentiate them from the original reversing mills. Each succeeding mill stand rotates at a higher speed to accommodate the elongating metal. Water-soluble lubricants are continually sprayed onto the surface of the aluminium to avoid excessive temperature rises and build-up of aluminium powder or oxide.

The material emerging after continuous hot rolling is coiled up and then cold rolled to complete the reduction. The thickness of material is approximately halved with each pass. Heat generated during cold rolling is removed by spraying on a mineral oil blended with organic load-bearing additives such as oleic acid, palm oil or higher alcohols. This also serves to prevent sticking of the metal to the rolls. If intended for foil the coils are annealed to relieve built-in stresses and submitted to additional cold rolling. Unless hard temper foil is required, the material is annealed again to make it flexible and at the same time to remove the remaining film of rolling oil.

Sheet to be used in container manufacture is rolled to the desired initial gauge. In the case of formed semi-rigid foil containers the final gauge of the finished container is in the region of 0.1 to 0.2 mm, depending on size. In such containers there is very little change in gauge in the forming operation. In rigid formed containers, such as drawn cans, body stock sheet gauges are about 0.25 mm and stocks about 0.32 mm. In the drawing process gauge is substantially changed.

Properties of aluminium

Aluminium is very malleable and ductile and easily formed into containers. During the process it is subject to work hardening which can be used to advantage in producing rigid containers. Alternatively the formed containers can be annealed to restore the softness and flexibility, e.g. in producing collapsible aluminium tubes.

Aluminium is light in weight with a density of 2.7 compared with steel (and tinplate) at 7.8. Although the density of aluminium is slightly greater than that of glass, the ability to utilise very thin wall sections enables lightweight containers to be fabricated which are easy to handle and reduce shipping costs. The metal surface is highly reflective and bright in appearance, enabling striking decorative effects to be achieved.

Chemically aluminium is odourless, tasteless, non-toxic and sterilisable. It is relatively resistant to corrosion but forms a layer of the denser oxide which, being relatively impervious, inhibits further attack. The formation of this oxide is exploited in anodis ing to form a more permanent barrier, often with the inclusion of colours to give copper or brassy effects.

Since aluminium is subject to attack by strong acids and alkalis it is frequently coated or lacquered. The aluminium surface is receptive to lacquers, inks and enamels, enabling components to be protected internally and decorated externally.

Decorating metal containers

Although it is possible to modify the planar surface of a metal container by indentation inwards (debossing) or outwards (embossing), the term ‘decoration’ usually refers to one or other of the printing processes. This may be preceded or followed by a coating process: roller coating, spraying, anodising, etc. However, it is the print process itself which is mainly responsible for identifying the container and enhancing its presentation.

The vast majority of metal containers built-up from sheet materials are decorated in the flat prior to fabrication. The process most used (offset lithography) was used for printing on metal long before it was adapted for printing paperboard. A process which is basically dry offset lithography is also being increasingly used.

Metal containers produced by impact extrusion must be decorated as the last stage rather than the first stage. The process normally used is rotary dry offset letterpress. Drawn containers may be decorated either before fabrication (by offset lithography) or after fabrication (by dry offset letterpress). The choice depends on the depth of draw and the amount of distortion which can be tolerated. Deep drawn components are invariably decorated after forming.

Any of the metal containers discussed can be labelled instead of printed. Labelling is often used for small quantity and short runs, and is also advantageous when a packer requires several print variations on otherwise identical containers. In this instance the packer is usually able to operate on a smaller stock holding of empty containers and has greater flexibility to meet changing market requirements. 'Labels', include paper- or plastic-based materials, and stretch-shrink sleeving.

Screen printing

The screen printing process—or silk screening as it is still sometimes called—is a stencilling technique which employs a screen mesh instead of a solid stencil. The screens nowadays are more normally made of nylon, polyester or steel. The resultant thick ink film has a good body and high gloss. The main pharmaceutical application of screen printing is for steel drums where small quantities of a given design are often required. Where the design is very simple, stencilling itself can be used. Both screen printing and stencilling can be carried out either in the flat or on the finished drum.

Offset lithography

Offset lithography is a planographic process and depends on the chemical modification of the surface of the printing plate so that only the image areas accept ink and the nonimage areas accept water.

For litho printing metal it is usual to apply an opaque coloured (often white) base coat in order to provide a suitable background for printing. This base coat or enamel is normally applied by roller coating but can also be printed, e.g. to leave uncoated areas for a metallic effect, or for printing with transparent inks. The surface of tinplate is superior to tin-free steel or aluminium for this purpose. If the tinplate is ultimately to be soldered a strip is left free of enamel and print to avoid unsightly scorching. (This can still be achieved with roller coating.) Metal sheet for drum manufacture is more often roller coated overall and then 'touched up' by spray painting after the soldering operation.

Nowadays the most commonly used enamels are synthetic resins, e.g. vinyls, acrylics, epoxy resins, which are usually stoved after application. Sometimes a priming coat is applied before the base coat to facilitate subsequent forming operations.

After the base coat application, the metal plate is printed either half-tone or solid depending on the design. Either one or two colours can be applied in a single pass using either transparent or opaque inks, followed by baking for about 10 min at about 240°C. The heat drying mechanism is a combination of polymerisation and oxidation plus some evaporation. The printed sheets are then over-varnished by a roller coater and baked once again. The over-varnish is usually a synthetic resin similar to the base coat but without the pigment. Some machines can apply the varnish in line over the wet inks, the process being known as trailing varnish. UV curing of inks and external coatings is now being widely used, with a considerable saving in energy and a reduction in emissions of volatile solvents into the atmosphere.

The varnish film must be tough enough to protect the print during fabrication as well as during container handling and usage. The base enamel, inks and varnish must be flexible enough to withstand the forming operation without cracking, and physically stable and colour-stable to withstand repeated baking, e.g. the base enamel of a six colour job could be stoved up to a total of eight times.

The process described above is sometimes referred to as wet offset lithgraphy and uses bimetallic plates, e.g. copper on steel, prepared by photochemically etching away the non-image areas so that the steel base is exposed, leaving the copper image areas slightly raised. On application of water by the damping rollers the hydrophilic steel attracts a film of water and at the following inking station the hydrophobic copper attracts the oily ink. The alternative dry offset process utilises a plate of a single metal, e.g. steel covered with a photosensitive compound. This is again etched away so that the non-image steel areas are slightly recessed, but damping rollers are not used although the equipment is similar.

Offset lithography is used to decorate metal sheet for shallow drawn containers and lids since the resultant distortion is inherently small. When deeper one-piece containers, e.g. drawn and wall ironed aerosol cans, are printed most of the decoration is normally on the sidewall. One technique used is known as distortion printing. The original design is printed in the flat in a condensed or distorted fashion which is calculated geometrically so that when the three-dimensional can is formed the print becomes elongated and assumes the correct dimensions. More usually the containers are printed after fabrication in the same way as extruded tubes.

Rotary dry offset letterpress

This is a relief printing process in which the image areas are raised above the level of the non-image areas and transferred from the inked printing plate to the metal surface by means of an intermediate resilient rubber surface.

This process is used to print cylindrical containers. Since the tubes must be supported on a mandrel during the printing process, it is essential that one end of the tube be of unrestricted aperture. This is one of the reasons that 'monobloc', DWI and DRD cans are necked-in after decoration and the bodies for two-piece cans are printed before seaming on the end. The other reason is to allow the decoration to go beyond the shoulder and right into the seam itself. A base coat of white enamel is first applied to the container by roller coating and set by partial baking, which aids keying of the inks at the printing stage. The base coat can also extend marginally around a corner radius, e.g. at the base of a rigid tube or over a bead or shoulder where present. However, the next operation of printing itself is restricted to the cylindrical surface as the actual (relief) printing plate is wrapped around a cylinder in a similar manner to a lithographic plate.

Each tube is supported separately on a mandrel which can rotate freely on its axis. The inking stations apply their separate images to the same rubber-faced blanket cylinder and the composite image is transferred to the tube in a single revolution of the latter. The printed tubes are then dried again. The tubes are held on pins for both the initial base coat baking cycle and the print baking cycle. A period of 4 min at 170–230°C is normally adequate, depending on the nature of the enamel and the inks. Where there is a possibility of the product reacting with the decoration, an over-varnish is applied by roller coating, and set by baking.

The decorative effects which can be achieved by offset letterpress printing are much more limited than those available by offset lithography on sheet materials. The design is limited to a maximum of six colours and a second pass is not possible.

It is not advisable to print wet on wet. If it is desired to achieve an effect of one colour superimposed on another, it is preferable to reverse the required image out of the first (background) colour and to 'fit' the second colour into this area. With very fine type matter where 'fitting' is impractical, a darker colour may be superimposed directly onto a lighter background, but if this dark colour appears elsewhere on the design there will always be a difference in shade.

Full colour half-tones cannot easily be produced by offset letterpress since they would inherently involve wet on wet printing. However, screened work in a single colour is possible, e.g. to achieve a black and white photographic effect. More recently half-tone work has successfully been completed, but there is a problem in achieving a gradual fade-out of any colour. Hence, designs tend to feature a relatively sharp edge around the half-tone section. Another point to be borne in mind is that a design which involves lining up a strip of colour running around the entire circumference of the container should be avoided, because lining up is difficult as the tube may not be truly cylindrical and in any case it is rotating freely on its mandrel; also, where the overlap occurs there is a double ink film which can mar the desired effect, particularly with light colours. It is therefore preferable to leave a gap rather than insist on an overlap. This is a typical example of the importance of producing a design capable of reproduction by the printing process which will ultimately be used.

Types of metal containers

Metal containers can be classified into several general categories based on methods of manufacture, as follows.

1. One piece seamless containers
    - formed foil or sheet
    - shallow drawn
    - drawn and redrawn/drawn and wall ironed
    - impact extruded.
2. Multiple piece built-up or fabricated containers
    - open top
    - closed top
    - aerosols.

Formed aluminium foil containers

By definition, a formed aluminium foil container is made by forcing the material to assume a shape with little or no metal 'draw'. Corner folds help provide some rigidity and prevent leakage. Folded back edges provide strength, avoid finger cutting, and better accept a matching lid. Folded containers cannot be made round or oval. Few if any of this type of container are used for pharmaceutical packaging.

A later type of formed container was made by using matched male and female dies with sufficient clearance between them to permit the metal to slip and form wrinkles rather than be stretched. A much greater versatility in shape is available in this container. Smooth drawn flanged containers which accept a peelable lidding have been used for unit dose packs of liquids and semi-liquids. These packs may be lacquered or unlacquered.

Shallow drawn containers

The term 'drawing' in container manufacture refers to the process whereby an article is formed by drawing or pressing it from a sheet of the material, using matching male and female dies. Both tinplate and aluminium are used. Decoration can be carried out in the flat prior to forming and thus has more in common with built-up containers than impact extruded seamless containers.

Obviously drawing puts a severe strain on the metal sheet, and the amount of distortion which can be tolerated depends on the thickness of the metal and the ability of the surface finish, e.g. tinplate coating or decoration, to adhere firmly to the base metal. The containers produced by drawing are relatively shallow with a maximum depth up to half the diameter if circular. Metal screw caps and aluminium roll-on cap shells are also produced by the same process.

Tolerances are so close that flanges and bottoms are smooth and walls are nearly wrinkle free. Vacuum or compressed air may be used to assist the forming operation. In one extreme example, aluminium containers are air formed using either a female die only or a female die and a plug assist. The open end is tailored to receive its closure by curling it inwards or outwards and beads may be added around the container to strengthen it and to assist in locating or removing the ultimate closure. The base of the container is often inset slightly for added strength and to protect any decoration.

Shallow drawn containers are produced in two basic shapes—round and rectangular. Round containers are used for packing viscous pharmaceutical ointments and creams which may be difficult to fill or dispense from collapsible tubes. Since the containers have full apertures and vertical side walls, filling may be accomplished with wide bore filling tubes.

Rectangular containers are more normally used for packing discrete items such as tablets, pastilles, surgical plasters and dressings. However, it should be noted that even so-called rectangular containers must have rounded corners. The depth of draw is in practice limited to twice the corner radius.

Both tinplate and aluminium sheet may be used to produce shallow drawn containers, the choice depending on cost versus product resistance. Dry products and nonaqueous creams are usually satisfactory in tinplate, whereas aqueous creams are better packed in aluminium. Alternatively, lacquered tinplate can be used for aqueous creams but there is always a chance of corrosion at any raw edges. Tinplate is stronger than aluminium for a given thickness.

Deep drawn containers

Deeper containers or more complex shapes can be produced either by drawing and redrawing or by a combined drawing and wall ironing process.

In the draw and redraw (DRD) process, sheet material—prelacquered if required—is fed to a cupping press where it is stamped out into a disc then formed into a shallow cup. The cup then passes to the second drawing stage where the depth is increased and the diameter reduced. The process is repeated as many times as may be necessary prior to trimming and flanging.

Since the DRD process is carried out on prelacquered sheet, TFS can be used. There is little or no reduction in gauge, the sidewall and base remaining essentially the same as the starting gauge. This feature makes the process ideal for food cans where the finished container must withstand both internal and external pressure created during retorting and cooling.

The alternative drawing and wall ironing (DWI) process also begins with a simple drawing stage, but is followed by ironing of the sidewall to increase the depth of the container while maintaining the diameter. This results in a substantial reduction in gauge, e.g. material starting at 0.25 mm or more may be reduced to 0.1 mm on the sidewall, and is ideal for certain aerosols where the internal pressures make the can stronger after it has been filled and sealed. The process is applicable to either tinplate or aluminium. When used on tinplate the tin coating serves as lubricant. Internal coating by spraying is carried out after forming.

Both DRD and DWI cans are seamless and hence more aesthetically pleasing than built-up cans. Technically they are more secure, as there is no side seam or base seam at risk. Beads or corrugations may be added to the sidewall of both types of can for strengthening purposes. This is essential for the DWI can to enable it to be used for foodstuffs. Frequently the base of the can is domed upwards to maximise the resistance to internal pressure, e.g. for aerosols.

Closures

The closures used for shallow drawn rigid containers are slip lids for round containers and either slip lids or hinge lids for rectangular containers. They are produced from the same materials and by the same technique of drawing as the containers on which they are used.

When used on round containers, slip lids normally rely on forming a closure between the side wall of the container and that of the lid. Hence the effectiveness of the closure is governed by the difference in diameter of the two components, their relative rigidity and the depth of engagement. The lid itself—which is often domed—may stand considerably proud of the upper rim and allows brimful filling.

An outward curled rim is frequently used on containers for ointments and creams, keeping the raw edge away from the product and away from the customer's finger. The lid itself may also feature a similar outward curled rim. The use of curled rims is more common with tinplate than with aluminium, since cut edges are sharper and there is a higher risk of corrosion.

When slip lid containers are used for aqueous creams or ointments with volatile constituents, a glassine or foil laminate membrane is often placed across the rim of the container resting on the product. This serves to reduce losses on storage and in use and the membrane can also carry additional instructions to the customer or patient. Sometimes this membrane is sized to overlap the rim so as to become entrapped on closuring. In this case allowances must be made when specifying tolerances of fit for the container and lid. The slip lid should support the weight of the filled pack when it is lifted by the lid.

Although slip lids are also used on rectangular drawn containers, the geometry of the two components does not allow as tight a fit as is possible with round lids. Hence moisture sensitive tablets or pastilles are better packed in round containers. Alternatively a slip lid of the type commonly used on both round and rectangular tobacco containers can be used. This is usually referred to as a vacuum sealed lid but is more accurately described as a differential pressure lid. The lid itself incorporates a flowed-in PVC or EVA gasket to form a closure with the upper rim of the base.

In production the filled container—with the lid loosely applied—is fed into a vacuum chamber where a vacuum is first applied followed by a top loading to force the lid into intimate contact with the container rim. When the external pressure is restored to atmospheric, the 'vacuum' within the container maintains the seal. The effectiveness of the closure can be checked visually or automatically by observing a depression in the lid due to the pressure differential. The container is opened by releasing the vacuum with the aid of a coin slot built into the base. Both container and lid are constructed of tinplate rather than aluminium and in a fairly thick gauge in order to withstand the pressures applied.

Hinge lids are restricted to rectangular containers. Hinge lids are unsuitable for products which are at all moisture sensitive, but they can be used for dressings or adhesive plasters. The hinges may be formed from matching tabs and slots formed in the container and lid, or involve a separate wire hinge entrapped within a curled under extension to the lid and whose ends slot into two notches in the container sidewall.

Both slip lid and hinge lid rectangular containers often have retaining pips or ridges to give a more mechanically secure closure. A strip of pressure sensitive tape can be used as an extra safeguard, i.e. for tamper-evidence and accidental opening. For additional protection and lid security, a complete band of tape can be applied around the junction of the container and lid.

Impact extruded containers

The impact extrusion process is used to produce open-ended collapsible tubes from softer metals such as tin and lead. When aluminium is used, it work-hardens during the forming process and the resultant tubes must be annealed to regain flexibility. Alternatively aluminium tubes may be left in their work-hardened state as rigid containers. Impact extrusion is a particularly useful process to produce containers with a high length to diameter ratio, e.g. up to 7:1. A slug of the metal to be formed is held in a female die and is struck by a punch which has the same form as that of the inside of the ultimate container. Upon impact the metal flows up the outside of the punch. A stripper plate then removes the extruded container on its return stroke.

Although any parallel sided shape can be produced, the most common shape is cylindrical. The slug to produce a cylindrical tube is a metal disc approximately equal in diameter to the finished tube. The thickness of the disc governs the volume of metal available to form the tube base and wall. The clearance between punch and base of die governs base thickness. Hence a container could, if required, be produced with a thick base and thin wall section.

Rigid impact extruded aluminium containers

Full aperture rigid extruded aluminium containers are suitable for packing a wide range of dry pharmaceutical products, e.g. powders, tablets and capsules. Although not as inert as glass, they are lighter, more compact and unbreakable and the addition of an internal lacquer is normally adequate to prevent product-container reaction.

An advantage over glass is that relatively small quantities of containers can be printed economically, which obviates the need for labelling. However, in order to effect a true cost comparison, differences in production line speeds must be considered as well as basic container prices.

Containers with restricted apertures suitable for packing liquids can also be produced by first extruding a cylinder and then necking or spinning it in at the open end. Seamless containers in a range of sizes are used for the bulk shipment of expensive items such as perfumes, essential oils, antibiotics, vitamins and hormones. These containers can be designed with no sharp corners so that they can be easily cleaned and sterilised by autoclaving if required.

The use of 'Monobloc' cans produced by this method is usually restricted to smaller sizes for cost reasons, but in countries where aluminium is cheaper relatively large aerosols are produced. Impact extrusion is also used to produce open-ended cylinders onto which bases are seamed, e.g. general purpose liquid containers and two-piece aerosol cans. In this case a ring slug is used rather than a disc, and the lower end is formed in the shape of the shoulder during the extrusion process, e.g. as for collapsible tubes.

Aluminium for impact extruded rigid containers is usually of 99.5% or 99.7%+ purity. A slab of aluminium is rolled down to the required thickness and the slugs stamped out. These slugs are lubricated then fed from hoppers into horizontal or vertical automatic impact extrusion presses where the container is made. The wall thickness for rigid containers is usually in the range 0.2–0.4 mm. After forming, the container is trimmed to length and the appropriate finish applied. This can be a simple inward or outward curl, a screw thread or an outward flange for double seaming. 'Monobloc' aerosol cans are sometimes given an inward domed base for added strength and stability.

Organic fatty chemicals used as lubricants in the extrusion process are washed off in caustic soda and the containers rinsed and dried in ovens. The containers can then be spray lacquered internally with a vinyl or epoxy type lacquer and decorated externally.

Closures

The simplest form of closure for a full aperture container is a friction fitted wadless polyethylene closure, of the snap-on type or the plug fitting type. The rim of the container is usually curled outwards to avoid sharp edges and facilitate closuring, and is ideal since it does not impinge on the fullness of the aperture for filling or dispensing. Friction fitted caps can also be fitted with an integral bellows or spiral device to eliminate the need for separate foam pads or cotton wool packing. To improve protection against moisture ingress a variation of the bellows type of closure can be used in which a small quantity of silica gel is incorporated in a compartment in the cap.

An alternative method, which provides a greater degree of protection than a simple snap-on cap is to apply a screw finish to the container so that it will accept a prethreaded plastic or metal cap. The actual neck finishes applied to metal containers, and hence the caps used, are not identical to those applied to glass. Aluminium caps are usually preferred for compatibility and appearance reasons in that they can be made to match the container itself. Like the container they can be plain or lacquered internally and externally and decorated or embossed/debossed with a logotype. Due to their relatively shallow depth, caps are produced by drawing rather than impact extrusion.

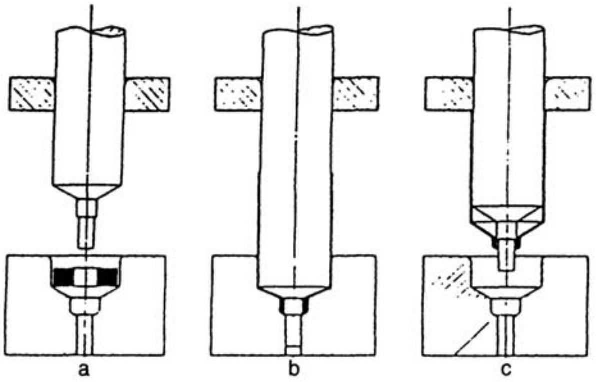
Although such aluminium caps may be fitted with any of the commercially available cap liner materials, it is becoming increasingly common to use a flowed-in PVC or EVA liner. Smaller sizes may incorporate a complete disc whereas larger sizes only require a circular gasket to mate with the rim of the container.

To achieve an even distribution of the compound and ensure the optimum seal, it is preferable that the cap has a circular channel into which the gasket is flowed. Closure efficiency is further improved if the rim of the container is curled inwards to give a smooth edge and gives an effect similar to a body bead in strengthening the container where it most needs it, and facilitates the capping operation. Size for size the efficiency of the closure obtained by this method is similar to that for a glass bottle with a foil-faced cap liner. Such closures are preferable to desiccant closures for products such as gelatin capsules.

Where the ultimate in protection is required, aluminium containers can be flanged and fitted with seamed-on aluminium easy-open ends. These containers are tamperevident, but once opened the product must be used within a short space of time, unless polyethylene overcaps can be used during the use of the product.

An alternative tamper-evident feature consists of a foil laminate diaphragm which is heat sealed across the aperture of the can before capping. Child-resistant closures are being developed for aluminium tablet containers similar to those used on glass and plastic bottles and vials. Carnaud Metal Box is marketing a version of the Pop-Lok closure developed by Safety Packaging Corporation, NJ, USA. This closure is of the friction fitted plug type and operates on the press and lift principle. If the container were required to be tamper-evident as well as child-resistant this could be achieved by combining with a foil diaphragm as described above.

Reduced aperture containers for liquids are usually fitted with screw caps similar to those described above for full aperture containers for dry products. The larger containers used for bulk chemicals are often fitted with additional safety devices such



(a) Pierced slug in die of impact extrusion press
(b) Impact of punch
(c) Retraction of punch: tube removed by stripper plate

Figure 10.2 Collapsible metal tubes produced by impact extrusion

as tinplate or polyethylene wells or shives and crimped-on tamper-evident overcaps for extra security. At the other and of the scale is the miniature aluminium bottle of capacity 4 ml which is used in the UK for a breath deodoriser and has a polyethylene neck insert swaged into the open end of the container, enabling a conventional screw closure to be used.

Impact extruded collapsible metal tubes

Collapsible metal tubes are used extensively for packaging a wide range of pharmaceutical and cosmetic creams, pastes, ointments, jellies and semi-liquids.

Metal tubes are impermeable to moisture, gas, odour and light provided they are adequately closed. They are convenient for a customer or patient to use and as the contents are expelled by squeezing the tube, there is no tendency for the walls to recover their original shape when the pressure is released. Consequently the risk of air entering the pack and reacting with the product or causing it to dry out is minimised. Internal coating may be necessary to prevent chemical reaction. The joint properties of impermeability and collapsibility are advantages over most plastic tubes, which are not only permeable but also tend to snap back into their original shape after each application.

The properties of metal and plastic have been combined in the form of a laminated tube, which consists of a polyethylene/aluminium foil/polyethylene or similar laminated body fitted with a polyethylene nozzle and is less permeable than a conventional polyethylene tube with less tendency to draw air back. To date the main usage of laminated tubes has been for toothpastes, but wider pharmaceutical applications are now found.

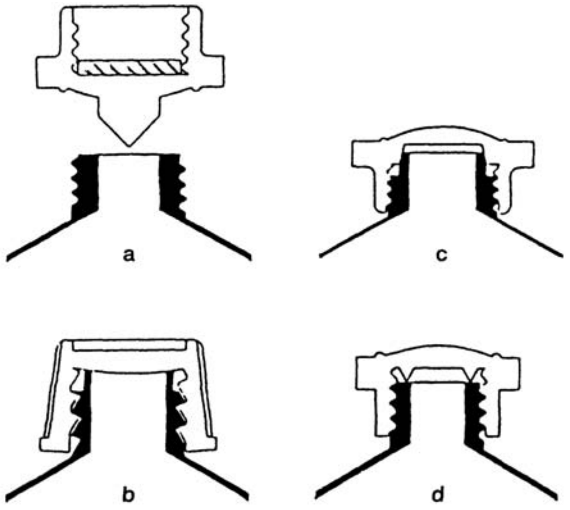
The basic extrusion process used for metal collapsible tubes is identical with that used to produce rigid aluminium containers except that the slugs used are rings rather than discs and the female die which holds the slug is shaped so that the metal is forced downwards into the die to form the shoulder and nozzle as well as upwards around the plunger (Figure 10.2).

The formed tubes then pass to a trimming machine where they are cut to length, a thread cut or rolled on the nozzle, and the face of the nozzle orifice cleaned. The shoulder, which is relatively rigid, may be decorated, e.g. with concentric rings, if required. The tubes are then ready for the finishing operations of internal coating, enamelling, printing and capping.

Whereas rigid containers can only be produced from aluminium, collapsible tubes can be produced from any of the softer metals such as aluminium, tin, lead and tin/lead alloys. Aluminium tubes must be annealed after forming and finishing, otherwise they are too springy. This process also serves to remove all traces of lubricant.

Tin is the least reactive of the metals available, is very bright and is also non-toxic. However, it is inherently expensive and its usage is therefore restricted to pharmaceuticals such as antibiotic and some ophthalmic ointments where maximum protection is required. Lead-based tubes are now not recommended for pharmaceutical products, for toxicity reasons.

The majority of collapsible tubes are made from aluminium, which is relatively cheap but subject to attack by some acidic or alkaline products. The widespread use has been made possible by the development of internal coating systems which are sprayed into the tube immediately after forming it. A wide range of coatings are used including vinyl, epoxy and phenolic resins. The use of epoxy and phenolic resins is restricted to aluminium tubes due to the high curing temperatures required. Most internal lacquering systems involve two coatings, the first being partially dried before applying a second coat and drying completely. Needless to say, where lacquers are used it is essential that they be pinhole-free for the whole length of the inside of the tube, including the interior of the nozzle. After the internal coating has been applied the tubes are enamelled externally,



(a) Membrane sealed with 'v' thread and spiked piercing cap of urea, wadded
(b) Buttress thread and polythene wadless cap
(c) Urea wadless cap on 'v' thread
(d) Urea wadless cap on 'v' thread and with special sealing device

Figure 10.3 Caps for collapsible tubes

baked, printed and the print dried by heating again. It is essential that the enamel and print—as well as the internal coating—be flexible or the tube may become unsightly when the product is dispensed.

The finished tubes are then capped automatically and packed into shipping outers for dispatch to the packers. Tubes are normally packed open end upwards, for ease of removal, in fully divisional slip lid fibreboard outers, sufficiently rigid to protect the tubes from denting in transit and impeding the filling and closing operation. It is also important to avoid contamination of the open tubes during transit and in storage.

An interesting development which is claimed to save over 75% in storage space was the conical tube developed by the Metal Closures Group in the UK. The tube is extruded as a parallel sided tube and then expanded mechanically at the open end to form a slightly tapered shape. Empty tubes can be nested for shipment to the packer where a special dispensing unit is necessary to feed them into the filling and closing machine. The tubes are also flared slightly at the open end to minimise mechanical damage of the decoration between tubes.

Closures and closuring

A collapsible tube has two closures, one formed at the open end by the packer after the product has been filled, the other at the nozzle through which the customer expels the contents of the tube. The majority of reclosable tubes are fitted with screw closures or flip-top variants on screw closures.

Thermoset caps are fitted with any of the commercially available cap liners used in caps for glass bottles and rigid metal tubes. The choice of liner facing depends on satisfying product compatibility requirements. Injection moulded polyethylene and polypropylene closures have gained ground, since a separate liner is unnecessary due to the inherent softness of these materials. Sometimes a pattern of concentric rings is embossed in the sealing surface to deter leakage. Alternatively an internal plug may be incorporated in the cap so as to form a seal with the nozzle bore (Figure 10.3).

Various shapes of cap are used, the most common being the straight taper or flowerpot style. Full skirted caps are occasionally used so that the tube may be displayed standing vertically on its cap without a carton. Most metal tubes are in fact individually cartoned after filling to facilitate handling, storage and inclusion of a leaflet, etc.

Although the tube filling and closing machine may incorporate a device for tightening any loose caps, the main concern of the packer is to ensure a leakproof permanent seal at the open end after the product has been filled. This is achieved by shaping the tube, folding it over on itself and crimping it. In general the effectiveness of the closure increases with the number of folds. However, it should be borne in mind that the more complex folds require a greater length of tube. A saddle fold requires 10 mm more than a double fold (Figure 10.4).

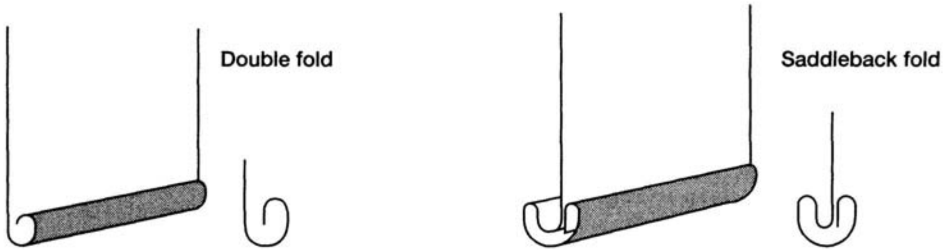


Figure 10.4 Metal tube-end closures: typical folds

With printed tubes it is essential to leave an adequate unprinted section at the end of the tube so that the design is not obscured when the fold is made. The base enamel can be continued virtually to the end of the tube where a registration mark is usually incorporated, and picked up by a photoelectric cell on the filling machine to ensure that the tubes are closed and crimped in the appropriate position relative to the printed design. Provided the design is not too complicated, it is possible to arrange for it to be repeated three or more times around the circumference of the tube so that registration of the crimp is not necessary.

The crimp pattern which is applied on the final fold often incorporates a space for batch and expiry marking. Care is needed to ensure that the enamel or metal—particularly the harder metals such aluminium—is not pierced by the debossing action. As an additional insurance against leakage at the end fold, a band of anti-seeping compound is often applied by the tube manufacturer just inside the open end of the tube. Various compounds are used including wax, rubber, latex, pressure sensitive materials and vinyl lacquers. These must be checked for product compatibility in the same way that the tube material and internal coating is tested. Sometimes heated closing jaws are used to obtain the maximum benefit from vinyl-type lacquers.

Nozzles

Collapsible tubes are produced in a range of standard diameters, the length being selected to suit the required fill volume and method of closing. The nozzle and orifice size are governed by the viscosity of the product and the amount to be dispensed per application.

Many pharmaceutical products require special applicator nozzles which are permanently attached to the tube. Alternatively, separate applicators may be supplied for fitting onto the end of the tube (by screwing or pushing) immediately prior to use. With many products, contact with a metal applicator is undesirable. Elongated plastic nozzles have therefore been developed which are either swaged into the tube shoulder in place of the normal metal end or subsequently fitted as a separate component.

When used for ophthalmic tubes the plastic nozzle has the added advantage of eliminating the risk of metal spicules which occasionally result from machining screw threads onto metal nozzles. There is a mandatory FDA standard on particulate conta mination of eye ointment tubes including both metal particles and other foreign matter. Special precautions are therefore taken in the production, cleaning and packing of tubes for pharmaceutical applications. Ultrasonic cleaning is sometimes used. Having produced clean tubes, it is then essential to prevent recontamination by careful outer packaging, e.g. by using die-cut non-fibrous divisions and special masking tape to cover the open ends of the tube. Depending on construction, eye ointment tubes are usually sterilised by irradiation or exposure to ethylene oxide prior to filling.

If the ultimate in protection is required, a membrane of metal less than 0.1 mm thick is left across the nozzle face and provides visible tamper-evidence. Sometimes a special double-ended cap is used, incorporating an integral piercing device. The tube is pierced by removing the cap, reversing it and screwing it back onto the tube until the inverted cone pierces the membrane. If the product is of the unit dose type a membrane tube is used without a cap or threaded portion, e.g. taper or torpedo ended tubes. In this case piercing of the nozzle must be carried out with a pin or similar device. Alternatively a break-off style tip can be used.

Built-up containers

Built-up containers consist of at least two components, namely a base and a side wall, which are mechanically secured together by a seamed joint. With the exception of aluminium extruded bodies, the side wall itself also involves a seam. Frequently a third component is affixed permanently to the side wall and it is this extra component which accommodates the closure itself.

Before discussing built-up containers and their closures it is necessary to define the most common forms of seam.

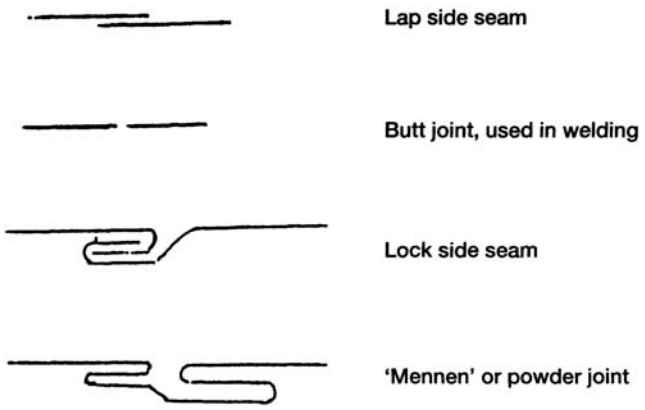


Figure 10.5 Typical metal joints used in tinplate containers

Seams

The seam which joins the two edges of the rectangular blank together to form the container body may consist of a lap seam, a butt seam, a locked seam or a 'Mennen powder' seam. Both lap and butt seams require the addition of a joining compound to make them mechanically secure. The locked seam is strong in tension but weak in compression and is therefore used for containers which need to withstand internal pressures, e.g. aerosols, whereas the 'Mennen' seam is used when the container needs to withstand compression, e.g. talcum powder containers (Figure 10.5).

The seam of the base to the body may be a simple crimped seam, a single seam or a double seam. The double seam is the most secure mechanically. The seam of the end to the body or side wall is often referred to as a chime.

If the product is not difficult to contain, and there is no problem of moisture ingress, e.g. a dry product or viscous liquid, and does not require complete protection from environmental hazards, a dry jointed container seam may be adequate. At the other extreme a fully soldered or welded can will offer the ultimate in protection, i.e. equivalent to a seamless container. The process of soldering or welding also aids mechanical strength.

The most common other method of seam treatment is by lining the ends with a flowed-in compound such as rubber latex or synthetic rubber during manufacture. On subsequent double seaming these compound lined ends are capable of giving hermetic seals. The alternative is to treat the joint after forming with a solvent-based lacquer (known as doping or solutioning). If the joining compound is applied during the seam forming operation it is known as cementing. Solutioning and cementing are usually encountered with side seams.

Can dimensions are expressed in terms of nominal diameter (or base dimensions if rectangular)×height. By tradition the first digit is in inches and the second pair in six-teenths, for example, 202×408 represents a cylindrical can of diameter and height inches.

Container fabrication—the open-top can

The actual process of forming the container is probably best described by taking the open top food or beverage can as an example. Sheets of metal (0.12–0.30 mm thick), pre-printed and lacquered if required, are slit first in one direction and then at right angles to produce blanks of the correct size. A stack of these blanks is fed into the bodymaker where each blank is notched at one side and slits are cut in the other side after which the seam hooks are formed.

The body blank is formed into a cylinder over a mandrel and the hooks are engaged and rolled closed to form the side seam, which is then soldered or welded. A recent development consists of making a cylinder long enough for three bodies, which is parted across previously made score lines into three separate can bodies. Speeds of up to 900 bodies per minute can be achieved, compared with around 500 for the conventional method.

The exact shape of the blank is dictated by the necessity of forming a locked seam for the whole length of the cylinder except for the two extremes which are left as a lap seam. The open ends of the cylinder are then flanged outwards. There are thus two overlaid thicknesses where the seam is flanged rather than the four which would have resulted if the locked seam had been extended for the full length of the cylinder. This is extremely important for the next stage, which is double seaming the base into position. The base or end is previously punched out and a lining compound flowed into the rim. The base is supported by an internal chuck while the body flange is held in position and the double seam is made by a series of rollers. During this operation the body flange is doubled back on itself to form a hook which engages with a similar hook in the base to form the double seam. Although the seamer is able to cope with the change from two or four thicknesses of side wall, it would not be able to accommodate the increase from four to eight thicknesses if the flange consisted of a locked rather than a lapped seam (Figure 10.6).

If the metal is TFS rather than tinplate then a variation of the process is used, since TFS cannot be soldered. Instead the side seam can be made by welding, which gives much higher output speeds. The welding system employs a rectangular blank with no notching or hooking and a simple lap seam (1 mm overlap is adequate). The width of the visible side seam is only 4 mm compared with 20 mm for a soldered tinplate can, resulting in a smaller blank and a saving in tinplate. The finished seam is usually given a side-stripe of lacquer internally and externally for protection. Welding using butt edges is now preferred.

The cementing system also involves a simple lap seam, although the actual overlap is greater (6 mm). The joint is made mechanically secure by applying a strip of plastic (usually Nylon) at one edge of the body blank before forming it into a cylinder. The two overlapped edges are heated to about 300°C to melt the plastic, which then acts as a cement when it cools. Once the side seam has been made the body is flanged and double seamed exactly as for the soldered can (Figure 10.7).

Cans are tested by air pressure on rotating wheels, and faulty ones are automatically rejected. The tested cans are then packed in cases, cages, pallets or directly onto freight cars according to the customer's preference, with end closures shipped separately. Noncylindrical containers, e.g. rectangular or oval cross-section, are more difficult and slower to make.

Open-top cans themselves are not widely used in the pharmaceutical industry, since by their nature these packs are not reclosable although polyethylene overcaps are sometimes provided for this purpose. An easy opening feature may be incorporated by means of a ring pull device in the lid.

Similar full aperture cylindrical cans are occasionally used for dry pharmaceutical products in conjunction with simple friction closures such as slip lids or plug lids. The open end of the container is usually rolled over to avoid a raw edge. Although these two-piece containers are easily opened and reclosed, the efficiency of the closure is reduced by the presence of the side seam. Consequently they are only used for relatively non-moisture sensitive products, the seams being left untreated. The same considerations apply to rectangular cross-section cans, but there is the additional possibility of applying a hinged lid closure. In general, if the best performance is required from any of these frictional closures it is preferable to use a container with a continuous rather than interrupted side wall. Alternatively, a third (seamless) component can be seamed onto the body, making a three-piece container. The simplest example of this technique is the lever lid or ring and cap container.

Ring and cap containers

In the pharmaceutical industry, ring and cap containers, lever lids or multiple friction containers are mostly used for powders —health salts, dietary supplement powders, etc. —which are only moderately susceptible to moisture pick-up but require an easy and effective reclosure.

The containers are usually constructed in tinplate with double seam base and 'Mennen powder' side seams since the container needs to be capable of withstanding considerable compression when the lid is applied. The seams themselves may be dry or treated, depending on end use. Since both the ring and the cap are seamless, a very effective frictional closure can be achieved. The amount of interference can be varied and depends on the lidding equipment, the quality of closure desired, and the relative ease with which the customer is required to open and reclose the pack. If necessary, lids can be secured with special clips or spot soldered, the latter adding a degree of tamper-resistance. Sometimes a double ring is used to ensure a more effective closure.

A more elegant method of achieving tamper-evidence is the addition of a diaphragm affixed to the lower side of the ring. In this case the can is supplied to the packer with the diaphragm and lid in place and the other end open for filling. The packer then double seams on the end which will become the base of the closed container. The diaphragm may be simply paper or, if an additional barrier is desired, foil can be used.

Note that the lever lids discussed are applied only to cylindrical containers.

Talcum powder containers

The principle of attaching an extra component so that the packer can add the final closure is also illustrated by the talcum powder container. Talcum powder containers have a simple cross-section, e.g. round, rectangular (with radiused corners) or oval. They are usually constructed of tinplate for cheapness with a single seam base and 'Mennen side seam', both seams being untreated since the container is only required to be relatively siftproof. A shoulder is then either seamed on or pushed on to give a friction fit, and incorporates a central orifice through which the packer fills the powder then plugs with a two piece rotary plastic or metal sprinkler closure. If the shoulder is of the pushedon variety the packer has a choice of filling and closing as described or receiving shoulders and closures already assembled and completing the pack by pushing on the shoulder. The second alternative has the advantage of giving a larger filling orifice and is preferred where metal closures are to be used since these are not as easy to apply as the plastic type and are probably best left for the container manufacturer to

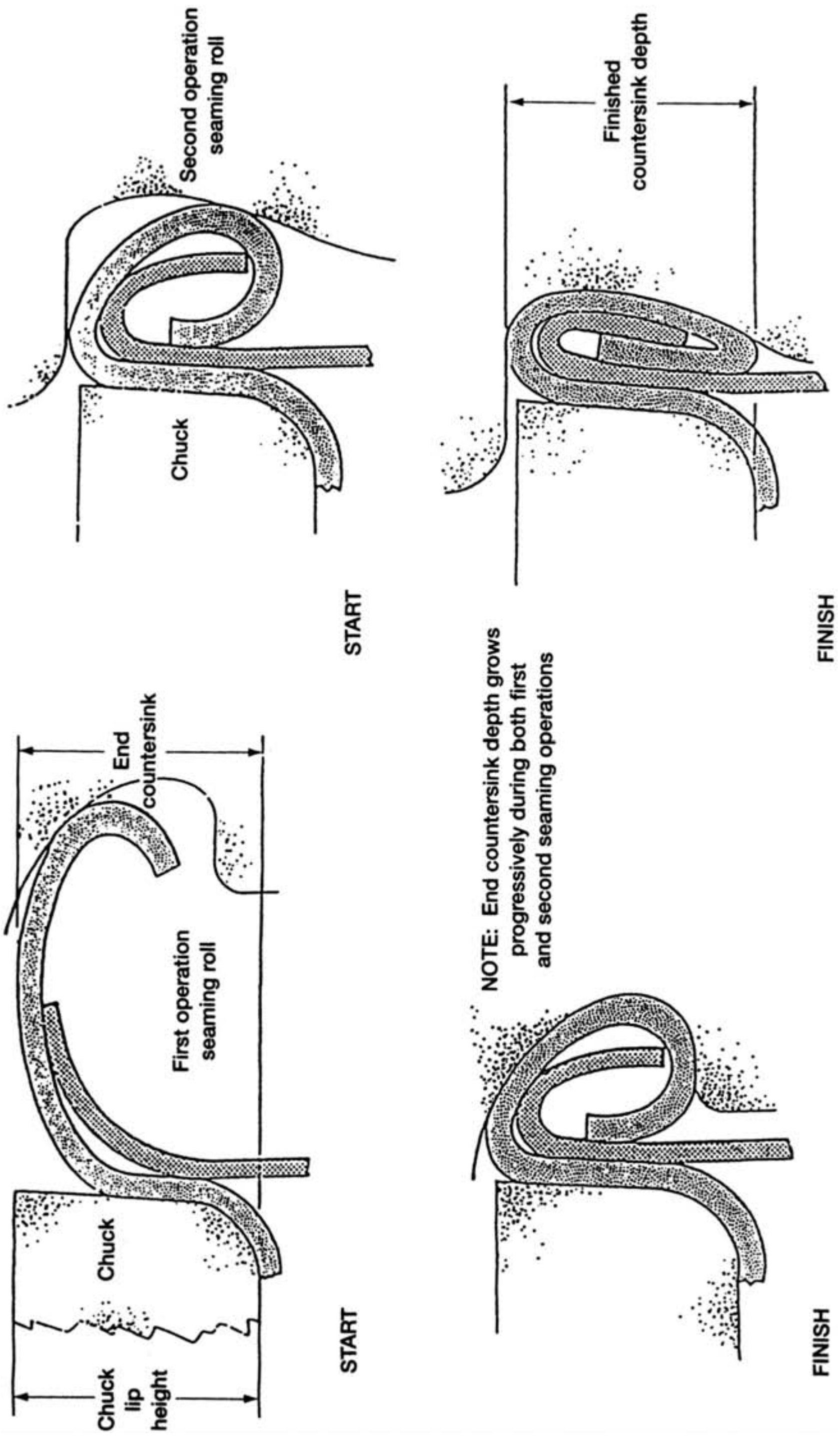


Figure 10.6 Two stages of double seaming

assemble. On the other hand, open two-piece containers with no shoulder lack rigidity and can be very prone to transit damage.

Liquid containers

Reclosable containers for liquid products are usually three-piece containers, the closure itself being formed with the third component. A common example is the cylindrical cone top container fitted with a screw neck to which a conventional cap is applied. Similar necks may be fitted to rectangular section containers with flat rather than conical tops. Press caps can also be used on this type of container. The principle of a press cap is essentially the same as a screw cap except that the tension which

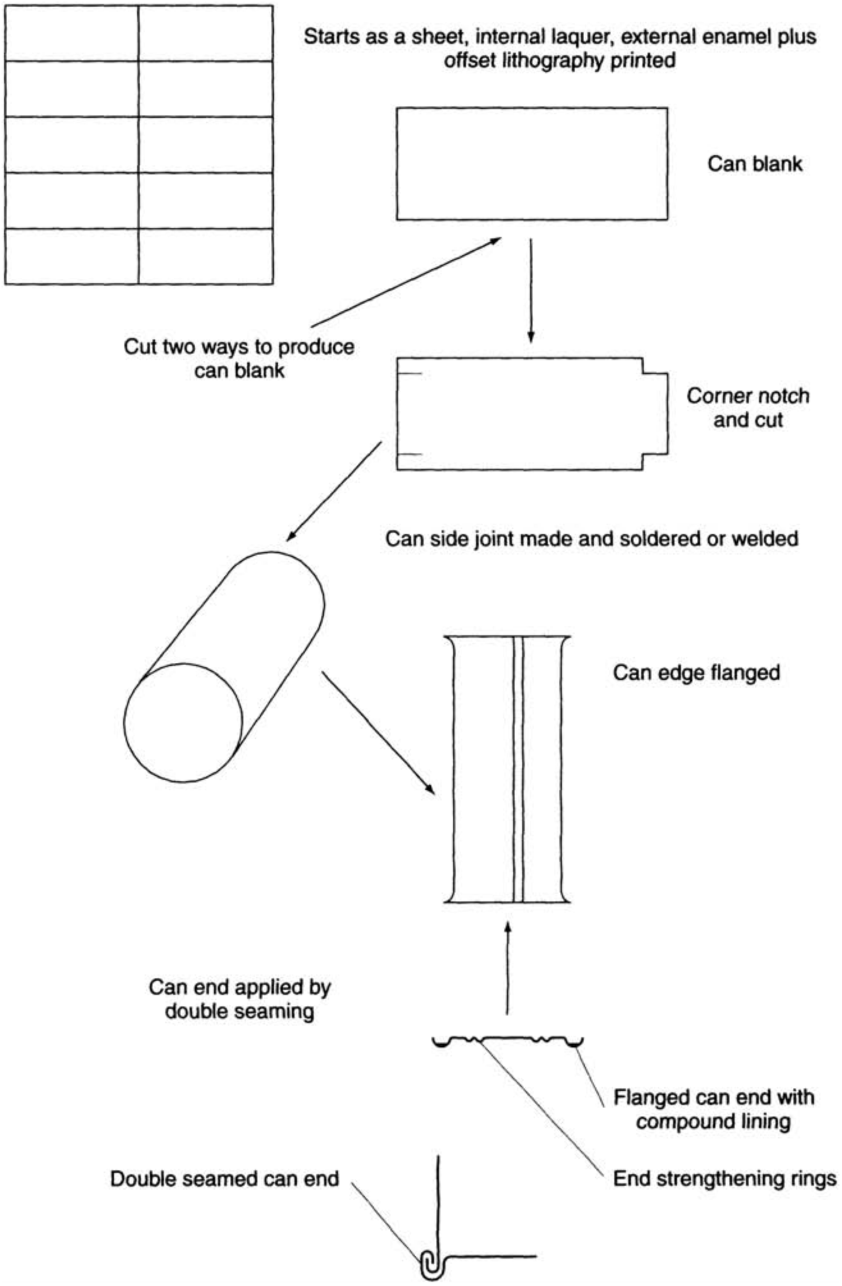


Figure 10.7 Three-piece built-up can (tinplate)

is applied to the resilient cap liner is built into the press cap. Since the press cap is opened, as the name implies, by simply pressing on the top of the cap, it is necessary to provide overseal protection against accidental opening and spillage. This type of closure is more frequently encountered with bulk containers.

Nowadays the smaller sizes of round and rectangular section containers for liquids are often fitted with plastic dispensing closures. It is also possible to produce two-piece screw top containers in aluminium in a similar manner to that in which two-piece aluminium aerosol cans are produced. In this case the base, which may be either flat or domed, is invariably constructed in aluminium so that the resultant container may be used for corrosive chemicals without further internal treatment.

Three-piece aerosol cans are constructed by seaming a cone onto the body of a twopiece built-up tinplate can. The can itself is constructed in a similar way to an open top can but with a strengthened locked and lapped side seam so that it will withstand internal pressure. The base of the container is domed upwards for the same reason and is invariably compound-lined and double seamed onto the side wall.

Shipping containers

Built-up metal containers are used for the storage and transport of a wide range of bulk chemicals, e.g. dry powders and liquid. Although the heavier gauges of tinplate can be used for containers of up to about 5 gallons capacity, from this size upwards steel is invariably used.

In the USA steel drums are defined as single-walled shipping containers of capacity 13–110 US gallons, whereas containers of less than 13 gallons are called pails. (In the UK pails may be referred to as kegs.) Pails are constructed from steel of 29 gauge to around 24 gauge. Lightweight drums up to 55 gallons are constructed in steel ranging from 26 to 20 gauge. Heavy drums vary from 18 to 14 gauge. If the ends of drums are constructed of a different gauge from the sidewall, the gauge of the sidewall is quoted first and then the ends, e.g. a 20/18 drum has 20 gauge sidewall and 18 gauge ends. Specifications for pails and drums for packaging dangerous or hazardous products such as acids, flammables, explosives and poisons are governed by the US Department of Transportation regulations.

Steel containers are fabricated from sheet steel in much the same way as open-top cans are made from tinplate. Apart from the obvious difference in size and hence production rate, the main difference in their construction is the nature of the seams. The side seams may be merely folded over if the container is intended for dry products or welded to provide strength and liquid-proofness.

The welded cylinder is then flanged, ready to accept the base and top if applicable. At the same time circumferential corrugations or beads are added to increase the strength of the container. With large drums a pair of extra prominent beads are often applied to serve as rolling hoops. The base may be double- or treble-seamed into position using a seaming compound or solution as for open-top tinplate cans. However, in order to ensure liquid-proofness, a peripheral weld is often applied just inside the double seam itself. In addition the end seam is sometimes protected from mechanical damage by reinforcing it with a band of metal around the chime. With large drums the ends may be welded to the side wall and a reinforcing band either shrunk on or welded into position.

There are two basic types of container, namely open-headed (or full aperture) and tight-headed. The former are used for dry products, semi-solids and viscous liquids whereas the latter are used mainly for liquids. The term ‘tight-headed’ implies that the top of the container is permanently secured by the drum manufacturer, apertures for filling and emptying being provided in the lid itself. Pails and small drums for liquids usually have only one aperture in the lid but larger drums invariably have two apertures, the second (often smaller) aperture serving as a vent when dispensing the contents. A variety of closures is used including press-caps with overseals, lever type closures, and internal or external screw-threaded closures in metal or plastic. The most commonly used closure is probably the ‘Tri-Sure’. This consists of an externally threaded bung fitted with a plastic or rubber gasket plus an overcap.

Closures for open-headed pails and drums are full-diameter lids. The seal is usually effected by a rubber or plastic gasket contained in a channel in the lid. The closure is then completed and made mechanically secure by means of a separate metal closing ring fitted with a bolt or lever type fastening. The lids of pails sometimes incorporate lugs which are mechanically clinched to the upper flange of the pail.

Since pails are small enough to be handled manually, steel handles are often attached for this purpose. It is also common to reduce the diameter of the bottom or top chime to facilitate stacking. These containers are widely used in the pharmaceutical industry for the in-house handling of tablets. Tight-headed pails with one closure only are often fitted with specially shaped tops which have a raised portion instead of a recess above the double seam. This is known as an interrupted chime, and its purpose is to allow the pails to be stored in the open without the risk of water accumulating in the head and penetrating the closure by capillary action.

Although all the containers discussed so far in this section are cylindrical or near cylindrical, small containers are sometimes made with rectangular cross-sections in order to save space in storage. A number of proprietary designs are available, but the best known is probably the ‘Jerrican’.

The inner surfaces of drums and pails are usually treated, epoxy and polyurethane resins being the most common. Instead of applying the lacquer to the base sheet it can be sprayed inside the drum after fabrication to ensure that all seams are adequately protected. This is particularly important for welded drums where the welding process destroys the original coating on the sheet. The container is then stoved to cure the resin. The efficacy of the coating depends to a large extent on correct surface preparation, e.g. mechanical roughening or phosphating. A phosphate coating is frequently used externally prior to decoration. Galvanising is used for heavy duty multi-trip drums. In this instance the complete drum is immersed in a bath of molten zinc.

If the product demands complete protection from metal contact, a polyethylene liner can be used. The liner can be applied *in situ* by a sintering process or formed as a separate blow-moulded bottle. The resultant container is more accurately described as a composite container rather than a steel drum, as it combines the virtues of plastic and metal in one container.

Aerosols

Aerosol containers may be produced by any of the main methods for manufacturing metal containers, i.e. by impact extrusion in aluminium, by building-up from tinplate, or by drawing and wall ironing. Since the technology of all metal aerosols, as well as those constructed in other materials, is similar irrespective of the method of construction, it is convenient to group them together under one heading.

The number of aerosol fillings in the UK is approximately 1.25 billion pa, with slightly less in France and Germany giving a total of well over 3 billion for Western Europe and approaching the US figure of 4.0 billion. Total worldwide consumption is over 10.0 billion units. Of these about half are attributable to hairsprays, personal deodorants, antiperspirants, perfumes and other pharmaceutical or cosmetic products. In this market the choice of container is often based on shape, appearance and possible decorative effects provided that the basic compatibility requirements can be satisfied. Internally applied epoxy-phenolic lacquers are commonly used to prevent interaction between the container and product. Built-up tinplate containers may have an epoxy phenolic side-stripe in addition to protect the seams. Tinplate aerosols account for nearly 90% of the aerosol market in the UK and the USA, the balance being mainly aluminium. The proportion of aluminium aerosols is much higher (~50%) in the rest of Western Europe.

The built-up tinplate container is the cheapest form of aerosol but was initially considered unacceptable for most pharmaceutical products due to the unsightly appearance of the soldered side seam. However, the development of reduced width side seams by jet soldering, cementing or welding e.g. soudronic weld, makes the built-up container a more attractive proposition. Most of the built-up aerosol containers produced in the UK nowadays have welded side seams. Alternatively the side seam can be concealed by applying a printed wrap-around label to the finished aerosol.

Aluminium aerosols are inherently more expensive than tinplate but can be made in one piece with neither side seam nor bottom chime. However, for practical or economic reasons these 'Monobloc' containers are usually restricted to the smaller sizes of aerosol. Larger sizes are produced in two pieces, i.e. with a continuous side wall and a seamed-on base. In the past few years the process of drawing and wall ironing has enabled continuous side wall containers to be produced from both aluminium and tinplate sheet. Unlike two-piece extruded body containers, these containers have no base chime but instead have a seamed-on cone. When two different metals are involved, e.g. aluminium body and tinplate base, additional product compatibility checks must be carried out due to the risk of electrolytic corrosion. Again special coatings are available to inhibit this effect.

Components and types of aerosols

The principle of all aerosols is that a liquefied gas in a pressurised container will provide a constant pressure while the container is being emptied. The essential components of an aerosol beside the container itself are the product, propellant, and valve assembly. The valve is designed to dispense the product in the required manner while maintaining both the product and propellant hermetically sealed until the product is expended. The fact that the product is sealed in the container and protected from air and other outside contaminants has obvious advantages in the field of pharmaceuticals. The intimate mixture of propellant and product in a true aerosol results in a rapid expansion of the propellant as it leaves the valve orifice. This breaks up the product into small particles giving a fine mist, coarse spray, foam, or dust according to the nature and relative quantity of the product and the propellant and the type of valve.

The cup is usually formed in tinplate and incorporates a grommet or flowed-in compound lining (usually nitrile rubber) to ensure a leak-proof seal with the cone. Except for the smallest 'Monobloc' containers, the cone is invariably fitted with a standard 1 inch aperture. The method of closing the valve cup into the cone—known as crimping, clinching or, more correctly, swaging—consists of mechanically expanding the valve cup just below the curl of the cone so that the joint is mechanically secure and when filled the pack is able to withstand pressures of up to 150 lb/in^2. The swaging process is naturally critical, and the swage depth and diameter must be closely controlled to avoid leakage (Figure 10.8).

In the centre of the valve cup is mounted the valve housing into which fits the valve stem itself. This is maintained in the 'off' position by a stainless steel spring. The valve is opened by depressing or tilting the actuator or button when the product is dispensed via a dip tube. A seal between the valve housing and cup is usually affected by a neoprene or nitrile rubber gasket. The spray is influenced by valve design, product/propellant system and also the dip tube bore.

A wide variety of propellants originally included the fluorinated chlorinated hydrocarbons, paraffin hydrocarbons such as propane and butane and inert gases. Originally the use of fluorochlorohydrocarbons was predominant but there has been a trend to the straight paraffin hydrocarbon or alternative HFAs. The main disadvantage with hydrocarbon propellants is their flammability and the need for special filling plant. Most of these gases in the liquefied state fulfil the function of a true two-phase aerosol, i.e. for a given temperature they provide a fixed pressure as the product/propellant mixture is expelled, providing there is always some liquid propellant left. The pressure is usually within the range 10–70 lb/in^2 at 21°C and mixtures of propellants are used to achieve the desired pressure. Compatibility with the product formulation is obviously the

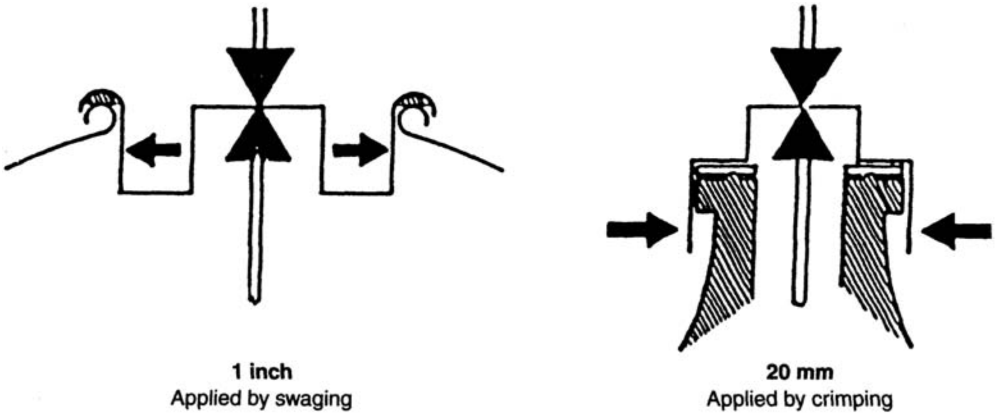


Figure 10.8 Aerosol cups

other main requirement. The liquid propellant may be either in solution with the product (the vast majority of aerosols) when it produces a true aerosol spray or in an emulsion with the product whereby a foam is produced. With powder aerosols the product is dispersed in the propellant itself with the assistance of a dispersing agent.

There is another class of aerosols, known as single phase aerosols, in which the propellant is a compressed inert gas, for example carbon dioxide, nitrogen and nitrous oxide. With this type of pack a high pressure is used initially (90–150 lb/in^2) since the internal pressure diminishes as the container is emptied. A single phase aerosol is more acceptable as a foam dispenser for toothpaste and hand cream than a spray pack, but if used inverted all the gas will be released quickly (unless it is specifically designed to be used inverted) and the product will remain with no means of dispensing it.

There is a third class of aerosols which use a three phase system consisting of separate layers of liquid propellant, product (usually aqueous) and propellant vapour. These often operate at low pressures.

Valves

The type of valve used is selected according to the formulation, the propellant system and the way in which the product is to be delivered. There are five main types of valve, namely spray, foam, stream, metering, and drop dispensing valves. Spray valves themselves can be classified according to the proportion of propellant in the formulation and the nature of the active ingredient. The metering valve type is used in pharmaceuticals in conjunction with a specially designed applicator cap for throat, lung inhalations and nasal sprays. A unique pharmaceutical application is the pain relieving spray which relies entirely on the cooling effect of 100% propellant vapour. Suspensions of antiseptic powders or talcum demand yet another type of valve, as do spray-on bandages. Compartmental aerosols have been developed for products which are basically incompatible with conventional propellant systems. The product is contained either in a plastic bag or on the upper side of a piston. Product filling is accomplished in the normal manner from the top but the propellant is filled through a small valve in the base of the can. One example of the former is the Press Pak produced by Cebal.

Currently metered dose inhalations are showing significant growth, particularly for the treatment of asthma (Figure 10.9).

Filling and packaging

The process of filling aerosol containers involves four main operations, namely product filling, purging, swaging, and propellant filling, the order of which may be varied. There are two filling methods, ‘cold filling’ and ‘pressure filling’.

In cold filling both the product and propellant are refrigerated and filled volumetrically as liquids through the 1 inch aperture before the valve is swaged into position. (This process is self-purging.) The product formulation must be able to withstand cooling. Pressure filling also begins with product filling but the propellant is handled as a gas. After the product has been filled—allowing for headspace—it is purged with propellant vapour and the valve swaged or clinched in position. The bulk of propellant is then filled either through or around the valve system. Special valves are available to allow filling—through the button. A variation of pressure filling—known as under cup filling—is first to fill the product and then, with the valve loosely in position, to draw a vacuum on the container, inject the propellant under the cup and finally swage the valve cup onto the container. Pressure filling equipment is more expensive than cold filling equipment, but the running costs are lower.

With all these processes, removal of the headspace air by vacuum or purging with propellant vapour is essential, as otherwise the internal pressure would be lowered.

After filling and closuring, the containers are tested in a water bath at 55°C or above to check for leakage. The containers are then dried, and the buttons applied. All containers are spray tested in a special spray booth. Unprinted containers are then

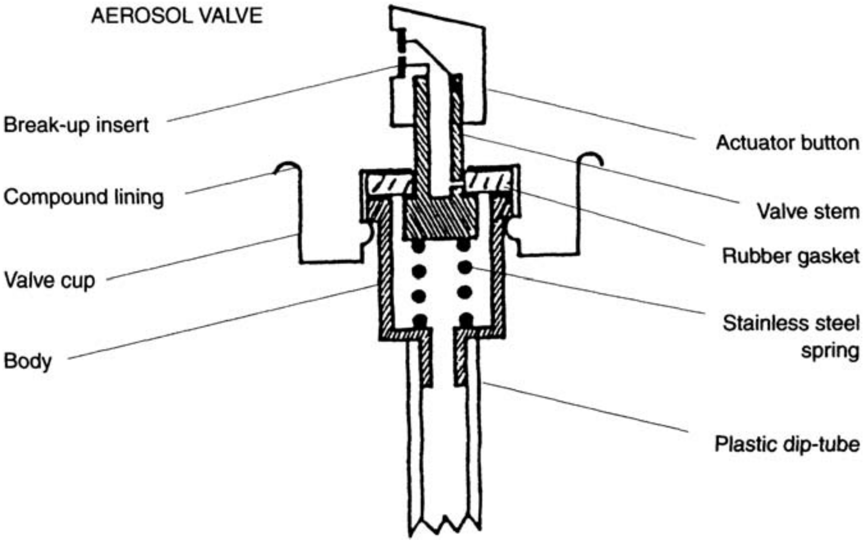


Figure 10.9 Aerosol valves

labelled and covers applied. At this stage some products are trayed off, then check weighed for losses following a storage period (allowing for swelling of gaskets).

Sometimes a two-part cover is used where the inner section serves as an actuator and the outer section is rigid and performs the usual function of a cover in preventing accidental spraying by top pressure. The capped and labelled aerosols are then either packed into outers with or without divisions, or shrink wrapped.

Cautionary wording such as 'Pressurised container, Protect from sunlight, Do not expose to temperatures exceeding 50°C, Do not puncture or burn, even after use, Do not spray on a naked flame or any incandescent material' is mandatory in many countries. If the spray emitted when the valve is operated is adjudged to be flammable according to the appropriate standard test method, then this must also be stated. Such warning statements are often required on the outer packaging as well as the unit container.

Another requirement which is likely to become of increasing importance with aerosols is the demand for child-resistant and tamper-evident closures. Although current FDA legislation only requires such closures to be applied to oven cleaners, it may well be extended to other aerosol products including some pharmaceuticals, and a number of approved child-resistant closures are already available. Most of these closures rely on the user either replacing the overcap or rotating the cap to a safe position for their effectiveness.

Conclusion

Metal containers still play a very important role in packaging, accounting for one-quarter of the total sales of all packaging materials. In the total UK production of metal containers, 10% is aluminium, the remainder being mainly tinplate. To put this figure into perspective it is worth noting that only 4% of total steel production is accounted for by packaging end uses. Although the proportion of aluminium used for packaging is considerably higher at 16%, it does not reach the dominant levels achieved for glass, paper or even plastics.

Notwithstanding the relatively small contribution of metals used for packaging compared with other uses, efforts are constantly being made to reduce the amount of material used for each application. For example, the use of thinner steel base materials and lighter weight tin coatings helps to conserve the world's resources as well as reducing costs. The development of replacements for tin coatings and the extended usage of tinfree steel will help in prolonging supplies of this scarce resource. Alternative manufacturing techniques such as DRD, DWI and the use of welding rather than soldering all give material savings.

Most packaging is non-returnable and is destined to end its life—or at least its primary life—in the refuse bin. Although nearly all packaging ends up as rubbish, by no means does all rubbish consist of packaging. A study in the UK by Incpen (Industry Committee for Packaging and the Environment) has shown that packaging materials account for only 28% by weight of domestic rubbish. The contribution of metals to this is about the same as that for glass at approximately 8%. It should be borne in mind that these estimates are based on weight and do not take into account density considerations, the presence of hollow-ware or compaction.

The fact that most packaging is one-trip is particularly true with pharmaceuticals, where the hazards of contamination and admixtures far outweigh other considerations. Hence the emphasis on recovery and recycling of the basic materials rather than reusing containers is to be welcomed.

Although tin comprises less than 0.5% by weight of tinplate, its recovery is now an economic proposition, but mostly from the waste which occurs at various stages of production. The recovery of metals from domestic mixed waste is naturally more difficult owing to the difficulties of sorting and general contamination.

Another factor governing the viability of recycling is the energy content of the material concerned. As energy becomes more expensive it will become increasingly more attractive to recover those materials such as aluminium which are not in themselves scarce but where the energy content is relatively high.

Supplementary notes on foil (aluminium) and its use in packaging applications

In the early 1930s foil could be found as tin foil, lead foil (widely found as a lining in tea chests), and aluminium foil. The fact that the general public picked up the word ‘tin foil’ and carried it forward from generation to generation has caused a certain amount of embarrassment, in that virtually all uses of the earlier ‘tin foil’ have now been replaced by aluminium foil. The USA, however, still uses tin foil as a cap lining material, with small similar usage in Europe.

Most aluminium is derived mainly from an ore called bauxite, which produces approximately 1 tonne of aluminium from 4 tonnes of ore and is a highly energy intensive process. As a result of this, aluminium is widely produced and used in those countries which have the cheapest energy supplies, e.g. hydroelectric power. Aluminium is one of the lighter metals with a density of 2.7 (note that glass lies between 2.25 and 2.5, covering neutral and soda glasses).

The production of aluminium foil

Aluminium foil is produced from a billet or ingot of aluminium hot rolled to a strip with a thickness from around 5–6 mm down to 0.4–0.5 mm (foil strip). Since aluminium undergoes a phenomenon called work hardening, the coiled foil strip is subsequently annealed to reduce the hardness. This is then cold rolled to around 0.038 to 0.025 mm when, to produce even thinner gauges of foil, two plies are brought together for the final rolling processes. When these two layers are ultimately separated, gauges of 0.006 (6 μm) to 0.025 (25 μm) are achieved with one side (outside) bright and one side (inside) matt.

Foil rolling involves high speeds (1000 to 2000 ft per minute), high pressures (0.25 to 0.75 t/in^2), and long areas as the material halves in thickness and doubles in length during each pass. Lubricants both ease the rolling action and help to remove the heat generated by the rolling processes.

If soft foil is required (note that further work hardening has occurred in these processes), the material is again annealed. Since the foil is constantly lubricated to aid the rolling process, the final annealing burns off the lubricant which would otherwise make coating, lamination, printing, etc. difficult. In the case of hard foil the lubricant is removed either by a lower heating treatment or by solvent (more expensive). The annealing temperature for aluminium lies between 400 and 500°C. The lubricant used in the rolling process includes various oils such as cocoa butter.

The thinner gauge foils are considered commercially free from pinholes at 17 μm and above. Pinholes occur from small particles of dust and grit which contaminate the foil during the rolling process. A typical figure today for 0.009 mm (9 μm) soft foil would be 200 per m^2. Typical foil yields at these thinner gauges (see Table 10.2) are:

- 9 μm—29,000 in^2/lb
- 12 μm—22,000 in^2/lb
- 25 μm—10,400 in^2/lb.

The properties of aluminium foil

These properties generally apply to both hard and soft foil.

1 Foil normally carries an extremely low bioburden and, provided it is dry, does not support microbial growth.

Table 10.2 Aluminium foil caliper/gauge/area

Europe		*USA*		
Thickness (μm)	*Yield (g/m^2)*	*Thickness (Mil)*	*Yield*	
			(lb/in^2)	(lb/m^2)
6	16.3	0.24	0.105	0.036

Europe		*USA*		
Thickness (μm)	*Yield (g/m^2)*	*Thickness (Mil)*	*Yield*	
9	24.4	0.35	0.155	0.054
25	68	1	0.96	0.15

All data are approximate. Foil yield might vary if either side carries a wash coating. 1 Mil=0.001 in.

2. Foil provides a good printing surface (usually by flexography or gravure printing). However, ink adhesion may deteriorate with storage time, hence the surface is often coated with a primer or wash coating of 1–2 g/m^2, e.g. nitrocellulose and vinyls.
3. Light in weight.
4. Exhibits dead-fold characteristics—stays relatively flat when folded.
5. Impermeable to moisture, gases, etc. if pinhole-free.
6. Excludes light (i.e. totally opaque).
7. Reflective to both light and heat.
8. Relatively resistant to corrosion, oils and greases.
9. High yield in thin gauges.
10. Taint and odour resistance.
11. Readily attached to other materials (laminations, heat sealants, etc.).
12. Alternative surface finishes, e.g. embossed, mechanically grained, extra bright, matt both sides, anodised, etched.
13. Non-toxic—broad inertness.
14. Non-magnetic, good electrical conductor.
15. Good heat conductor (cold and heat).
16. Does not burn/heat-resistant (cf. plastic).

There are also a few negative features.

- May be extensible in thin gauge—hence may stretch and perforate.
- Not heat sealable unless coated or laminated.
- Creases fairly easily—may increase level of pinholes and perforations.
- Scuff and rub resistance—foil will abrade fairly easily (foil to foil, foil to product, etc.), producing dark particles.
- Foil can be attacked by stronger acids and alkalis.
- Foil may corrode in contact with other metals as an electrolytic cell is set up when the product (or condensed moisture) acts as an electrolyte. To minimise corrosion risks, storage in a warm dry place is recommended.

Uses of aluminium foil

Aluminium foil has found a wide range of packaging applications. These include foods, drinks, pharmaceutical, toiletry, cosmetic, etc. Foil, although primarily used for its barrier properties, is widely used for its quality image and decorative appeal coupled to effective machinery handling. Gauges normally range from around 40 μm down to 6 μm, with soft foil being predominant. A few applications for hard foil are found, with a major use being as a lidding for pharmaceutical push-through blister packs. The tensile strength of hard to soft foil is usually of the ratio 8:3.

Unsupported foil

Early use of aluminium foil (well before the introduction of plastic and plastic coatings) involved unsupported foil, but this has limited use in the pharmaceutical industry.

Supported foil

The extensibility of foil has already been quoted as one possible disadvantage whereby the material would show stretch and possible perforation. This results in most foils being supported by the use of cellulosics including paper and board, plastic films or coatings, etc.

The fact that foil has no heat seal properties initially limited expansion of foil usage (until plastic heat sealants became more readily available). Early heat sealants included waxes and microcrystalline waxes, either on their own or as coated or impregnated paper. Subsequent to the use of wax, other heat seal (HS) coatings and then the seal plies (polyethylene and pliofilm) were developed. Heat seal coatings (as distinct from materials which also act as a barrier ply) are usually less than 25 g/m^2 whereas film plies used as a heat sealant usually start around 20 g/m^2. Weights for a coating start around 4 g/m^2 and are offered in 2–3 g/m^2 ranges up to 25 g/m^2 as previously quoted. For further details on how foil may be bonded to other materials (wet and dry bonding, extrusion coating, etc.), see Chapter 9.

Where foil is laminated to paper, attention must be paid to both the composition of the paper and moisture content if subsequent corrosion is to be avoided. Ideally the moisture should be 7% and less, and chloride and sulphate controlled so that the pH (acidity) is not below 5. If the foil is laminated by an adhesive, similar factors apply.

Example of foil usages are:

1 general overwrapping (as an additional moisture barrier)
2 sachets for a wide range of products, e.g. various powders, liquids, shampoos
3 diaphragm seals for various containers by adhesion, heat seal or induction sealing
4 linings for closure facings (waxed or unwaxed)
5 seals and labels
6 lined carton systems for solids and liquids (Hermatet, Cekatainer, Tetrapak, Combibloc, etc.)
7 linings (inner or outer) for composite container packs (spiral or convolute windings)
8 strip packs/blister packs
9 push-through lidding—hard or soft foil
10 cold formed foil blisters
11 tear tapes (as used on various film wraps)
12 hot foils stamping—special printing ‘foils’
13 collapsible tubes—laminated materials.

In these applications foil is contributing to such aspects as tamper-evidence/resistance, child-resistance (sachets, strips, blisters, pouches, etc.) and high barrier packs, and many have special features related to the use of aluminium foil. Some of these special features are identified below.

Selecting a gauge or foil

Foil gauges down to 6 μm are now available. However, the amount of ‘support’ required tends to increase as the gauge reduces, e.g. 0.025 mm foil laminated to 30 or 25 g/m^2 LDPE is a widely used strip pack laminate. In theory an 0.018 mm foil lami nated to 30 g/m^2 LDPE would be a more economical proposition. However, this combination would likely exhibit stretch, hence would possibly tear and perforate the foil. As a result it is necessary to increase the tensile strength of the support ply, e.g. by the addition of paper. Thus if cost savings are to be made the final laminate will probably be:

- 37 g/m^2 GIP (paper)/0.009 or 0.007 mm foil/25 g/m^2 LDPE or Surlyn
- 44 g/m^2 GIP (paper)/0.008 or 0.007 mm foil/25 g/m^2 LDPE or Surlyn.

Opinions vary on the gauge of foil to use as the outer paper (printed) may have an antiscuff overlacquer which also adds to the overall strength of the material. Paper/foil/heat seal is generally preferred.

Since the above has moved from a double-ply construction to a multi-ply lamination (the paper to foil may be an adhesive or extrusion coating), the latter is more costly to produce. As a result of this, any change to the new combination is only likely to be economical (how increase in cost of manufacture is counterbalanced by the reduction in material costs—i.e. savings on foil) if the thinnest gauge of foil ‘acceptable’ is employed. What is ‘acceptable’ depends on the product properties (is it extremely moisture or oxygen sensitive?) and the handling characteristics of the processing equipment.

Pinholes and pinhole theory

The significance of pinholes in foil has a relatively small influence on the overall barrier properties, provided the pinholes are ‘filled in’ on either or both sides by a plastic film or coating. Pinholes normally occur randomly and are usually less than 25 μ m (0.001 inches) in diameter. Due to the random nature, a proportion fall in the seal area and non-seal area of most packs. Where the pinhole falls into the latter, the permeability relates to the area of the pinholes and the permeability of the film(s) involved.

If the water vapour transmission rate for LDPE is 3 g/m^2 per 24 h at 38°C 90% RH for 25 μm, then permeability for a single 50 μm pinhole is likely to be as follows.

$$\begin{aligned}\text{Area of pinhole (a circle)} &= \pi r^2 \\ \text{One pinhole} &= 3.1416 \times (0.025)^2 \text{ mm} \\ &= 0.00197 \text{ mm}^2\end{aligned}$$

Moisture permeation over 1 year (as mg)

$$\frac{0.00197\ (\text{mm}^2)}{1000 \times 1000\ (\text{m}^2)} \times 3000 \text{ mg} \times 365 \text{ days} = 0.00215 \text{ mg}$$

i.e. permeation through a defined single pinhole is 0.00215 mg per year or a negligible amount, and for a sachet containing five pinholes per side (ten in total), permeation over 5 years is in theory only 0.11 mg. For example, with a layer of LDPE on both sides of the foil permeation should be even lower. Further details on pinholes can be obtained from the PIRA/BAFRA report published in 1974 and entitled *Barrier Properties of Aluminium Foil*.

In general, a foil-bearing laminate containing a few pinholes is an excellent barrier material and significantly superior to most economical plastic materials. This picture only changes if the foil lamination become perforated by handling operations which may include creases and creasing. If creases into a heat seal area lead to capillary-type leakage this may also reduce the overall barrier properties. Capillary channel leakage is more likely to be highlighted by temperature changes in cycling conditions (the pack expands and contracts, hence undergoes a breathing action) which are less likely to occur if stored under a controlled condition environment, e.g. 25°C 60% RH or 40°C 75% RH, i.e. ICH conditions.

Permeability to gases may be more critical than moisture. Gas permeabilities of plastics generally follow the ratio of 1:4:20 for nitrogen to oxygen to carbon dioxide and are usually significantly greater than moisture permeability.

Laminates for collapsible tubes

The use of laminates for collapsible tubes is an example of the success of a new approach. The fact that the word 'collapsible' has been maintained indicates that the pack may be subjected to rather severe handling. It is for this reason that the usually central foil ply is 40 μm thick. Most laminated tubes are five to seven plies with the decoration being a sandwich print.

Two conversion processes are available to produce laminate collapsible tubes which involve a cylinder of the laminate to which an injection or compression moulded shoulder and nozzle are attached. A rondelle (a specially shaped disc) is frequently added to the latter to reduce any permeation risks via the plastic shoulder and nozzle. Foil of 40 μm, widely used in these constructions, is currently being challenged and replaced by a layer of EVOH, SiO_x or diamond carbon type coatings.

Foil lined carton systems

The use of foil lined carton systems for both dry and liquid products is another success story. Since in most instances the cartons are sealed by heat (the inner ply is a heat seal), the 7–9 μm foil may be attached to either the outside or the inside of the carton board. Foil lined carton systems may be employed for certain oral powder or granule based pharmaceuticals.

Diaphragm or membrane seals on plastic, glass and metal containers

The advent of the Extra Strength Tylenol poisonings in 1982 in the USA put new demands on tamper-evident/resistant packs. As a result of this, diaphragm or membrane seals increased in popularity for two reasons.

1. Diaphragms can be applied by adhesive, heat seal or induction sealing after product filling.
2. As well as being an excellent tamper-evident feature this can also make a very good primary seal on glass, metal and plastic containers. This is a particularly useful closure adjunct for plastic closures on plastic packs. If a foil diaphragm is the effective primary seal then closure torque (long-term) becomes less critical.

Of the three methods mentioned for making a diaphragm seal, induction sealing is proving particularly successful. Although the ultimate seal between the diaphragm and the closure relies on plastic, it is the foil ply which acts as a receptor to the induction waves, causing the creation of heat which softens the plastic sealant. Foil is therefore an essential component of induction diaphragm sealing, normally carried out via the closure which has the diaphragm or membrane lightly adhered within the cap. Induction sealing only applies to plastic caps, which should be retorqued after the operation.

Cold forming

Another more recent technology is the cold forming of a foil sandwiched between two plastic plies. The process involves the forming of a relatively shallow, well radiused draw by a mechanical (cold) stretching action between male/female dies, or air pressure forming into a female mould. The outer plastic plies are usually oriented polypropylene or nylon and the inner ply is PVC, polyethylene or a heat seal lacquer. The middle foil ply needs aluminium of a special crystalline structure to permit the flow of the foil without perforation. For this, a foil within the gauges of 40–60 μm is employed. Cold formed packs of this gauge, if correctly formed, give 100% protection in terms of moisture, gases, odour/flavour pick-up (or loss), etc. The latest advanced forming technology (AFT) uses a double forming process which reduces the blister size.

The preforming of foil based materials also occurs in certain strip packaging operations and for the tropicalised blister packs (i.e. a conventional blister is covered on the plaster (blister) side with shaped foil tray), thus enclosing the whole pack in foil.

Blister packs

Pharmaceutical blister packs are mainly used with a foil lid which may be ‘pushthrough’ (as used in Europe) or peelable (as used in the USA). Push-through foil lidding is made from either hard foil (15–20 μm) or soft foil (25 μm). Laminations using these may also be used to increase child-resistance.

Overwrapping laminations—incorporating aluminium foil

Various combination materials are available to improve moisture and gas protection, which are either used as an internal liner or bag or as an external overwrap. Most incorporate heat seal plies and use support materials such as nylon, polypropylene or more likely polyester which are recognised for their tensile strength and resistance to tear. Overwraps may involve large sachets, large bags, pouches, flowraps, grocery wraps, etc., all of which act as moisture or gas barriers. In certain instances this may allow the use of more economical or standardised primary packs.

Metallisations and coated plastics

Although the continued use of aluminium foil appears assured, it is facing increased competition from special coating processes which are being used on a range of plastics. These processes include metallisation which involves the vacuum deposition of aluminium particles, coatings of silicon dioxide, etc., using such methods as sputtering, electron beam deposition and plasma coating, and the incorporation of certain ‘solids’ into the plastic (e.g. mica particles).

Although each of the above improves the general barrier properties of the plastic, handling and creasing may lead to significant barrier reduction in certain situations. However, these improvements are being consistently developed, hence may create a longer term threat to the relatively high cost of many foil-based materials. For example when two metallised layers are laminated together, e.g. PET/metallisation/metallisation/PET/LDPE, a barrier approaching that of foil can be achieved—but at a cost which is similar to that of a foil bearing laminate.

Conclusions

The usage of foil, in spite of down-gauging (use of thinner gauges), has steadily increased, mainly due to the constant discovery of new packaging concepts. Since foil is relatively expensive due to the initial high cost of aluminium ($1450, £ 900/t) it is under increasing challenge from other materials. However, foil (for its thickness) remains an excellent barrier material, which, supported by its other assets, keeps it as an effective packaging material. Foil (and aluminium-based materials) can be recycled with a recovery value of around £600 per tonne. At the present moment the future of foil as a packaging material appears assured.