

**The Legal Challenge**  
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**Introduction**

The year for 2007 was one that seemed to be obsessed with litigation and one in which more companies were targeted for compensation than ever before. We offer some ideas for the fight ahead and suggest that patience and a sense of humour is the key to retaining sanity.

**Litigation and related issues**

The growth of opportunistic treasure seekers has led to large increase in accident claim solicitors fighting on behalf of clients to seek compensation for irritation received as a result of using a cosmetic or skin care product. It is hard to remember when so much time was spent fighting off these parasites whose claims are at best ill-founded and opportunistic.

Companies should have a strategy and action plan for this event, because it is likely that they will have to pull a team together at a moment's notice with a leader given responsibility for ensuring the matter is dealt with competently and quickly. This paper hopes to provide you with a checklist of ideas and procedures to ensure success in the case of a challenge. An industry expert from outside of your team or company can often discourage a case from going to court.

The scenario often starts with a consumer demanding compensation and claiming that they have skin damage resembling a third degree burn and have been to the doctor who says that medical science is unable to help despite having prescribed vast amounts of corticosteroids. Pictures are often available, but only through their solicitors. On no account admit any liability at this stage, by all means express concern that this event should have occurred in their lives and without prejudice refund the cost of the product and the postage. A useful paragraph in these circumstances is to confirm that your products completely satisfies The Cosmetic Products (Safety) Regulations 2004, as amended and that there has been no complaint for this product in its history of sale. Always reply to a consumer and always fully investigate every complaint. [Naturally, if there has been a history of complaints then as a responsible company you should have fully investigated and dealt with every single one and even recalled a suspect product].

In the event that a customer writes again, then consider the option of offering a patch test with a dermatologist to find out what raw material they may be allergic to or may find irritating. Explain that on very rare occasions this can occur despite every duty of care and that is why every ingredient is listed on the pack to enable consumers to identify those things which may not agree with their skin type.

If this helpful attention fails, then the consumer may go to a specialist solicitor or to the Trading Standards Office. The legal representative is often aggressive, hateful and not at all understanding of the law and the regulations we follow. The tenant to remember is that “we are all innocent until proved guilty”. The second major point to remember is that you have all the time in the world and are only required to acknowledge the receipt of their letter within a week or so. The Trading Standards Officer is normally most understanding and well used to this type of complaint which rarely makes it to court (if you are properly prepared).

These are the action points that any company faced with a claim against then should follow.

Look back in the files to see whether this customer wrote to your company initially and retrieve your reply/replies, which should have been dealt with as described above. Make copies of this correspondence and the solicitor’s letter and start a new file.

Contact your insurers and copy them with copies of the correspondence in the new file.

### **Trading Standards and the Product Information Pack**

In the case of the Trading Standards Office you must have a full PIP (Product Information Pack) available in 2-3 working days. The faster you can supply the information, the more respect they will have for you and the less worried they will be about the competency of your business. The data should be as follows:

- Product description and codes or formulation code
- Product formula including percentages, INCI names, trade names and suppliers.
- Raw material ingredient specifications and technical data sheets
- Manufacturing procedure summary or single page flow chart
- Summary GMP statement (a statement on company headed paper declaring ISO standards and/or GMP compliance)
- Product safety assessment statement
- Undesirable health effects summary
- Claim substantiation summary with references – this is proof that pack claims are able to be substantiated.
- Stability summary, with reference to methods – this is usually a spreadsheet showing the stability at ambient, 30°C, 40°C, freeze-thaw etc.
- Specification – viscosity, pH and other test data listed.
- Microbiological challenge test records for products that contain water.
- Proposed pack copy or artwork for each carton and label
- It is useful to include a picture of the final product in the PIP.
- Perfumes and flavours should have IFRA and/or RIFM compliance statements from the perfume house.
- Perfumes should have the 26 potential allergens content list from the perfume house.
- Additional data may include user trials, instrumental data, analytical data and other

facts to support the claims and/or safety of the product.

Trading Standards will prosecute if this PIP (and all of its components) is not available, because it is mandatory in law. If your company can demonstrate that they are in control of their legal requirements, have shown all fair and reasonable duty of care to their consumers, not been negligent in their surveillance and monitored their product through its entire history (including all complaints) then they are not likely to prosecute.

### **Claims Solicitor**

This is never going to be pleasant if they do not win because then, like their client, they do not usually get paid. They try and prove all manner of ridiculous assertions like your company is using forbidden drug materials. There are some materials that are not allowed internally in pharmaceuticals but are perfectly legal in topical products. We include some extracts from a letter to one of these legal accusers which contained a long list of materials that in any case were excluded from use under Annex I. The purpose was to show them that the defendant's knowledge of the law was greater than their own.

*Kava Kava (Piper methysticum)* although banned in dietary supplements is not banned for use in topical products and appears in Commission Directive 2006/257/EC amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products dated 9<sup>th</sup> February 2006. We draw your attention to the exact ruling MLX 286 by the (then) Medicines Control Agency in 2002.

Thiomersal is legally permitted in eye makeup and eye make-up remover up to a maximum of 0.007 per cent calculated as mercury. When mixed with other authorized mercury compounds the total mercury concentration must not exceed 0.007 per cent. Such products are required to be labeled "Contains thiomersal".

Likewise there are lightening products apart from hydroquinone (such as kojic acid and arbutin) that are perfectly legal in topical skin care products.

Mixture of 5-chloro-2-methylisothiazol-3(2*H*)-one and 2-methylisothiazol-3(2*H*)-one with magnesium chloride and magnesium nitrate [Methylchloroisothiazolinone and Methylisothiazolinone] is a well known preservative (trade name Kathon CG) used at 0.0015 per cent of a mixture in the ratio 3:1 of 5-chloro-2-methylisothiazol-3(2*H*)-one to 2-methylisothiazol-3(2*H*)-one. This blend is a permitted preservative in Annex VI Part 1 of the regulations and in no way related to Thiazolidinediones (a diabetic drug).

A phrase guaranteed to gain a modicum of revenge is "we are very particular when it comes to the law governing cosmetics and the need for accuracy should not be obscured or threatened by an ignorance of that law".

Contest every statement made against your company and have evidence to support every statement you make. Challenge every nonsensical statement with authority, because

many of these solicitors know a lot less than you do and are trying to intimidate with legalistic jargon.

Eventually there will come a time when the correspondence cycle is complete, often dozens of letters will have been exchanged between your insurers, the claimants legal team and whoever else has been lucky enough to be sucked into the loop. Hundreds of hours will have been wasted and it is a wonderful time for those who are being paid for their time.

After more than a year the barristers will be called in, which means that the legal costs escalate from around £50 per hour for each player to around £500-1000 per hour for the new teamsters. If your company does not have insurance, then this is the time to go into receivership. Remember that diligence and the willingness to fight every argument leads to many cases failing because they appear too hard to win. If your company seems to have covered all the bases and is eager to fight, then most cases will evaporate.

In all the time that this round of legal banter has been in progress, you have been assembling a file of information that puts your product beyond all reasonable doubt. You have commissioned a repeat insult patch test, conducted user trials, sought dermatological proof that your product is as harmless as you knew it was. An eager defendant will have done a full battery of animal alternative tests in preparation for a court appearance.

During this time there will be two files, one is a beautiful electronic version on CD ROM which is all perfectly indexed and all the documents linked through to a hyperlinked spreadsheet (for the defense team with the really useful documents highlighted). The other version is the paper alternative in at least half a dozen lever arch files which is for the plaintiff's team. Most legal teams are exceptionally grateful for this seemingly endless supply of paperwork and are always thrilled to receive a crate full of information.

### **The Legal Portfolio of Evidence**

Every document you can lay your hands on has been placed in these file and all the documents are labeled in a way that is fully understood by you and your defense team. The files contain:

- The full Product Information Pack now extensively supplemented as described above (and a lot more)
- The MSDS for every single raw material used in the product.
- The Technical Data sheet for each and every raw material.
- The Folklore and Ethnobotany of a natural product is a really fascinating topic which sadly can run into vast numbers of pages that are essential evidence in proving the safety of an individual raw material.
- Toxicity files (where available) should also be included for each ingredient, and regrettably these can also tend to be quite verbose and lengthy
- Copies of the inspection reports for every single raw material at the time of production are essential but dull reading. Lots taken before and after the production date is always helpful for comparison to show a normal compliance and that there was nothing out of the ordinary. Regrettably this puts an additional burden on the

volume of paper supplied.

- Certificates of Conformance for every raw material used are absolutely vital
- The batch sheet for the product under dispute and all related documents like the demineralised water conformance report for that month (just in case it is asked for).
- The qualifications and personnel reports for the staff involved in the production of the batch including details of all relevant training received.
- The Quality Control sheet for the proof of compliance to the product's specification and the full protocol for the use of the equipment to make those measurements accurately (the standard operating procedure)
- The provision of helpful information like published papers should be included for the active ingredients
- A survey of information from the Internet should be a part of the package showing a history of safe and common usage for the raw materials
- A copy of the Cosmetic Regulations and all its Appendices
- The PAO (Product After Opening) explanation document
- The Challenge Test protocol
- The MHRA Guidance Note 8 is an excellent read and will provide a good read to the attacking solicitor and his team
- HACCP (Hazard and Critical Control Points) analysis will also have been conducted for this product and should be included in the data.

This information should be sectioned into reasonable categories where you and your defense team can easily locate any document, but which the plaintiff's team will find a paper maze of unfathomable complexity. Your barrister has the headlines of your defense well laid out in two to three concise pages.

### **The Winning Stroke**

In one last lever arch file is kept the

- Instrumental data
- Clinical data
- Statements of opinion and other last minute defense strategies.

This last file is supplied on the morning or on the day before the trial as late evidence and best supplied direct to the plaintiff's solicitor by courier. The first morning of most trials is spent seeing what evidence has been lost or misplaced. The chances of losing are quite slim if you have all the data and if the case has been prepared well. The last consolation is to remember that this vast data can be assembled very easily and will tie up a legal brain for many hundreds of hours, which is why cases can last four years or more.

It is only by making this industry an unattractive target that we will discourage the "ambulance chasers" from making a profitable living.