



## Creating Aromatherapy Blends and Preparing Case Histories

**W**hile you are completing your Aromatherapy training you should get into the habit of thorough assessment and writing up your aromatherapy blends and formulations, whether you are blending for yourself or clients. Treat yourself as a client to get into the habit of preparing thorough case histories and documenting your blends and protocols.



As a Registered Aromatherapist you will naturally develop your own assessment technique and recording procedures. Aromatherapist Carolyn Sajdecki suggests the following guidelines to help you plan your essential oil consultation for a specific individual.

- ◆ Collect intake data - information about specific needs, aims, and expectations for essential oil use. Use questions, observation, and touch if you are appropriately licensed. Social, medical, family, and lifestyle issues are all relevant.
- ◆ Based on this information, decide on objectives for your overall proposed protocol (over a period of time) and objectives for this specific application (now).
- ◆ Select suitable essential oils, carrier, and route of application to achieve the objectives. Always involve your client in this selection.

Ask your client to review a small selection and to let you know which of the selection appeal. Remember that individual perception of a fragrance can override the normal physiological response.

- ◆ Give your rationale for selection based on the original aim. For example, "Lavender *Lavandula angustifolia* essential oil chosen for its anti-inflammatory and sedative properties. For this application we've chosen to blend it with cold pressed peanut oil for its anti-arthritis benefits."
  - ◆ Keep records of everything. Note dosage and breakdown of essential oil concentrations and ratios. Also note specific carrier oils used, the appropriate route of application, and frequency of application.
  - ◆ Discuss the potential experience and outcome for your client. Explain any procedures in detail and get your client's input and agreement to objectives and protocol. Holistic health involves empowering your client to take responsibility for his or her own health. As such, their input is essential in the consultation process.
  - ◆ If appropriate, carry out the specific administration of the agreed protocol (for example, today's massage or compress as a part of a set of seven, one per day for the next week).
  - ◆ Record your findings as the administration was carried out. Did your client comment or respond? What are your personal notes and impressions? Was the administration well received, badly received, or did they fall asleep?
  - ◆ Give clear directions for continued self or home-care relevant to routes of administration and the essential oils suggested.
  - ◆ Explain cautions and precautions for home use including likely responses and what to do about them.
  - ◆ Get feedback after application and administration from your client at regular intervals to evaluate the protocol.
  - ◆ Maintain or adjust the protocol and administration of essential oils accordingly until the desired objectives are achieved.
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Australasian College of Health Sciences (ACHS) has an opening for an online instructor for its Aromatherapy courses. A full description of the Aromatherapy courses can be found here <http://www.achs.edu/course.aspx?id=1>

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## EFFA's Citral, Farnesol and Phenylacetaldehyde submission is thrown out by the SCCP.

Being an excerpt from forthcoming Cropwatch Newsletter Aug 2008

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Curiously ignored by the cosmetics trade press, whose hacks probably failed to understand its significance, the SCCP Opinion SCCP/1153/08 on *Dermal Sensitisation: Quantitative Risk Assessment (QRA) for Citral, Farnesol and Phenylacetaldehyde* (adopted 24<sup>th</sup> June 2008) **threw out** the 'industry-proposed' QRA approach for setting safe levels of exposure to citral, farnesol and phenylacetaldehyde in cosmetic products. The Opinion is extensively argued and fairly damning - the SCCP noted that the QRA approach is based on data from experimental sensitisation tests on humans, e.g., the Human Repeated Insult Patch Tests (HRIPT) and that model suffers a lack of detailed method description, application experience, is not (yet) validated, and has no strategy to make it so. Epidemiological and experimental data are not integrated into the QRA model and whereas the model allows for various product categories of exposure, the risks from aggregated exposure (including occupational exposures) are not considered. The SCCP further remark that there is no scientific consensus on the safety factors used. Perhaps most tellingly, the committee considers that safe levels of exposure to existing substances known to cause allergic contact dermatitis in the consumer should be based on clinical data and/or elicitation low-effect levels (*Cropwatch comments*: as has proven successful for nickel and chromium allergic contact dermatitis). In this light, the required data for citral, farnesol and phenylacetaldehyde was not forthcoming, in spite of a specific request made by Brussels for EFFA to provide it (all that was provided were a series of model-generated numbers, the relevance of which, in terms of consumer safety, being unknown).

Cropwatch had previously put forward an objection to SCCP 'expert' committee over the EFFA submission (of IFRA QRA-based data) on citral, farnesol and phenylacetaldehyde, a copy of which can be seen at <http://www.cropwatch.org/objectcitral.pdf>. Cropwatch had maintained that this particular submission passed on by EFFA was uniquely important because it represented first use of the QRA methodology in submissions to the SCCP 'expert' committee, to further restrict newly alleged allergens (a process we described as 'sneaking allergens in by the back-door'). Since the existing classification of allergens under 2003/15/EC has proven so scientifically controversial, it seemed both inappropriate and extremely unwise to legislate to include further allergens in the Cosmetics Directive until the underlying science is better sorted out.

### Background

A considerable head of pressure is building up over the apparent misclassification of a number of fragrance chemicals as allergens under Council Directive 2003/15/EC (the '26 allergens' debacle) which is



becoming impossible to ignore. Amongst the highlights of relevance here, you will remember that Storrs (2007) pointed out that the basis for inclusion of fragrance ingredients as allergens has never been defined by the SCCP committee, that Schnuch *et al.* (2004) have presented evidence showing that a number of fragrance chemicals listed in the '26 allergens' debacle (including citral and farnesol), are rarely found as allergens, and

that Sanchez-Politta *et al.* (2007) had indicated that there was little independent peer-reviewed evidence to support the case showing phenylacetaldehyde as a sensitiser. It is not immediately apparent therefore why EFFA chose to make this QRA-based submission in such an incomplete form, as they must have expected rejection.

Perhaps at this point we should pause briefly to explain some procedural theory. The QRA is basically an exposure-based methodology for dermal sensitisation risk assessment, a key component of which is consideration of the dose (of sensitiser) per unit area to determine sensitiser potency. IFRA has expressed its intention to employ this particular methodology "as the core strategy for primary prevention of dermal sensitisation to these materials in consumer products." Allergic contact dermatitis itself is a skin disease which is classically considered to arise from a series of immunological events, the first being an induction process from a low-molecular weight chemical (for example, a component of an essential oil). Continued exposure to this chemical at a sufficient concentration gives rise to an elicitation process which results in the physical manifestation of the disease. Risk assessment models to predict the potential skin sensitisation potential of fragrance ingredients incorporate three factors: predicted no-effect levels of sensitisation under experimental conditions, an appropriately deemed safety factor, and an exposure assessment. No-effect levels can be derived from predictive tests to determine the sensitisation potency of fragrance ingredients using animal based methodology (as in the Murine Local Lymph Node Assay or LLNA), or by using humans volunteers via the Human Repeated Insult Patch Test (HRIPT). In the HRIPT, fragrance ingredients are tested at ten times the use level on healthy human volunteers - if sensitization occurs, the maximum permitted level is taken as a tenth of the no effect level - but the HRIPT test is now considered an unethical procedure. Results obtained in the LLNA test can be mathematically treated to give an EC3 value (the concentration causing a threefold increase in the lymph node stimulation index) which is obtained by linear interpolation of the LLNA response data; these values being used to give an estimate of sensitiser potency, or to rank contact allergens.

Overall, Cropwatch has major concerns over the interpretation of data obtained from these procedures - amongst them are worries that these predictive tests do not sufficiently distinguish between (weak) sensitisers and irritants; that outcomes for single ingredients are highly dependent on test substance purity (which is causing on-going controversy e.g. in the cases of linalool and coumarin), and that, anyway, different animal-based tests (such as rat popliteal lymph node assay or PLNA) yield conflicting results to the LLNA. For example, the LLNA results categorise citral as a low to medium potency sensitiser, whereas Friedrich *et al.* (2007) found that citral was an irritant and not an immuno-sensitising substance at all, in primary positive PLNA responses.

Regarding the occurrence of the individual fragrance ingredients in question, we explained in our submitted objection detailed above, **citral** is a mixture of two acyclic monoterpenoids, neral and geranial, which can be regarded as branched chain aliphatic unsaturated aldehydes (*cis*- and *trans*-3,7-dimethyl-2,6-octadien-1-al). Citral occurs widely in varying component isomer ratios in many natural products including citrus oils, and concentrated and terpeneless citrus oils such as lemon oil and orange oils, in lemongrass oils, Litsea cubeba oil, black pepper oil, verbena oil, melissa oil, ginger oil, etc. etc. In layman's terms, most people are regularly exposed to citral in their daily lives, e.g., hand exposure occurs when peeling and cutting citrus fruits, and citral is regularly imbibed in the diet as a natural or synthetic flavouring component of some spices and in fruit-based or fruit-flavoured soft

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drinks.

**Farnesol** is a common sesquiterpene alcohol component of many essential oils, the isomers of which may be typically be found to 4.5% in neroli oil, and to 1% in rose oil. *E,E*-farnesol also occurs in *Santalum spicatum* (Australian sandalwood) oils and extracts to 5% (subject to confirmation, IFRA quote to 8%), which distinguishes it from the lower concentrations found in the oil of *Santalum album* (E.I. Sandalwood). Farnesol is also an impurity in many commercial grades of bisabolol; Cropwatch has recently described [<http://www.cropwatch.org/newslet8.pdf>] the demise of the Candeia Plant (*Eremanthus erythropappus*) which was harvested to the point of extinction in the Atlantic Brazilian rainforest to furnish demand from the German pharmaceutical trade for its natural (-)-*a*-bisabolol content.

**Phenylacetaldehyde** has a piercing green odor, which on dilution is reminiscent of hyacinths, and is a minor component of many essential oils and fruits – for example it occurs at up to 5% in the headspace of the sweet-pea blossom, *Lathyrus odoratus*.

### Concluding Remarks

To sum up, it remains to be seen whether the SCCP committee will be able to stick to the principles enshrined in their Opinion SCCP/1153/08, in the face of inevitable pressure from industry, and are able to insist that clinical evidence be provided

which shows that allergic contact dermatitis is unequivocally linked to exposure effects from specific fragrance chemicals. If they are able to maintain this, and the required forensic examinations of the available clinical and experimental evidence are independently carried out, the list of allergens fulfilling the required allergenic listing criteria could be very short, and

the committee will need to reverse their own previous Opinion on allergens and make changes to Directive 2003/15/EC. Meanwhile IFRA plunges even deeper into its predictive QRA-based sensitiser policy, with the announcement of the 43<sup>rd</sup> IFRA Amendment (a summary of which will be put out by Cropwatch shortly). Remember, in spite of the pretence of a state of voluntary regulation, iFRA & EFA members are required to fulfill the requirements of the IFRA CoP to the letter, right or wrong. Overall therefore, the casual observer could be forgiven for thinking that the gulf between toxicological theory/conjecture about sensitisation issues, and the link to robust clinical evidence, is becoming an ever-wider chasm, and we are merely observers in a power-struggle between toxicologists and regulators. Cropwatch pessimistically believes the outcome is inevitable - the regulators' salaries depend on the continual passing of new legislation (whether it is appropriate or not) and the data-providing toxicology machine is now the most powerful force in the aroma/cosmetics world. One way or another therefore, aroma ingredients will continue to be restricted and prohibited unnecessarily. The status quo is maintained by the attitude of the fragrance customers, who seem to worry little about whether legislation is either scientifically sound or fair, they just want to know that the fragrance providers are following the current rule-book.

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Continued

(2005) Öko-Test, No. 7 (July) 2004, 55.

Schnuch A., Uter W., Geier J., Lessmann H., Frosch PJ. (2007). "Sensitization to 26 fragrances to be labelled according to current European regulation. Results of the IVDK and review of the literature." *Contact Dermatitis*. **57**(1), 1-10.

Storrs F.J. (2007). "Allergen of the year: fragrance." *Dermatitis*. **18**(1), 3-7.

## Upcoming Test Dates

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