Complying with

GOOD MANUFACTURING PRACTICE

In the Cosmetics Industry
GMP Compliance

I understand that it is a requirement under Regulation EC 1223/2009 to produce cosmetic products according to Good Manufacturing Practice, the law doesn’t require GMP certification, only to demonstrate that procedures comply with a recognised industry standard such as ISO 22716:2007.

NAME...........................................................................................................

ADDRESS..................................................................................................

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TELEPHONE.................................................................................................

EMAIL..........................................................................................................
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Premises and equipment

The premises are maintained in good repair and are suitable for cosmetic production
Yes

There is adequate lighting and ventilation
Yes

Tools and equipment are suitable for the task and are cleaned and maintained properly and checked for defects before use
Yes

Cleaning and pest control procedures

Regular checks for pests are carried out and if necessary, corrective action taken
Yes

There are cleaning procedures in place
Yes

Aromantic’s Common Sense Hygiene Rules for Making Cosmetic Products are followed
Yes
Personnel

All those involved in the making of cosmetic products are aware of their obligation to comply with GMP

Yes

The following training has been undertaken by those involved in the making of cosmetic products (tick any that apply)

Aromantic Complying with Legal Requirements Course
Other Aromantic Courses
Aromantic Literature
Common Sense Hygiene Rules for making cosmetic products

Describe any other training or qualifications

All personnel are aware of the need to observe a high standard of personal hygiene and cleanliness

Yes

Appropriate protective clothing and equipment is available and used

Yes
The following types of protective clothing and equipment is available for use

- Head scarves
- Hairnets
- Aprons
- Masks
- Gloves

Describe any other protective clothing and equipment in use

Documents and Records

There is an appropriate system to record all batches of products produced, to enable batch traceability

Yes

There is an efficient stock control system

Yes

Ingredients are checked in and inspected for quality on arrival and documents filed

Yes

All processes (goods in, cleaning, production, testing, sales, complaints) are documented

Yes

All relevant documents are kept for the specified period of time

Yes
Production Processes and Procedures

The following checklist is followed when making a batch of products?

Protective clothing is worn and hair covered

Hands are washed using liquid soap

Surfaces are thoroughly cleaned before production

All required ingredients and equipment are gathered and checked before production begins

Ingredients are weighed and measured accurately

The recipe is followed correctly and each stage checked off

The finished product is checked for quality and signed off

All required documentation is completed and stored

Production area is thoroughly cleaned after production

A sample of each batch is retained to ensure continued compliance with the product specification
Storage and Handling

*Ingredients and products are stored correctly according to their specific needs*

Yes  

*Aromantic Best Practice Guide for the storage, handling and filling of containers is followed*

Yes  

*All stored containers are labelled for easy identification of contents*

Yes  

Packaging and Labelling

*All packaging used is suitable for what it is being used for*

Yes  

*The following types of packaging are used for products*

- Glass Jars  
- Plastic Jars  
- Glass Bottles  
- Plastic Bottles  
- Aluminium containers  

*Describe any other packaging*  


Waste packaging (Glass, Plastic, and Paper etc) is disposed of according to local and national regulations

Yes

Any defective packaging is returned to supplier or disposed of according to local and national regulations and is never used to contain ingredients or products

Yes

Products are labelled correctly with identity of product, INCI list of ingredients, name and address of manufacturer and any warnings or instructions for use

Yes

**Quality Control**

If an ingredient or product is not of the required standard the following action is taken:

- It is immediately withdrawn from use
- If applicable, the supplier is informed
- Information and action taken is recorded and documentation kept

Yes

If there is ever a need to recall products the following action is taken

- The item is immediately withdrawn from sale
- A report is written detailing the reason for the product recall
- The relevant authorities are informed
- Documentation is completed and kept on file
- Customers are contacted and arrangements made to return or dispose of the product and customers are reimbursed or offered a replacement

Yes
Complaints

There is a procedure in place for recording any adverse reactions to a product and the action taken

Yes

All complaints are dealt with in a timely manner and are properly documented including any action taken to resolve or settle any complaints

Yes
**GMP Statement**

- Premises are kept in good repair
- There is adequate ventilation and lighting
- Cleaning and pest control procedures are in place
- Equipment is checked for defects before use
- All personnel are properly trained
- Personal hygiene and cleanliness is of a high standard
- Appropriate protective clothing is available and used
- Ingredients are weighed and measured accurately
- There is no deviation from the recipe
- Only permitted ingredients are used
- Samples of each batch of product are kept and stored correctly
- There are written procedures outlining the production process
- A stock control system is in place
- All required documentation is completed and kept
- Ingredients and products are stored correctly
- All containers are labelled
- Only good quality ingredients are used
- All packaging (bottles, jars, etc) are suitable for the contents
- All products are labelled correctly
- A consistent quality is maintained for finished products
- Procedures are in place should the need ever arise to recall products
- Any complaints or adverse reactions are recorded

Signed ................................................................................ Date ..................................................
Common Sense Hygiene Rules for making Cosmetic Products

By Kolbjorn Borseth

1. Always keep very good hand hygiene: always spray your hands with alcohol spray (see 3 below) after a visit to the toilet, eating or touching animals, babies, etc even after washing them first in water. Never use solid soap for washing your hands, use liquid soap and then paper towels to dry hands.
2. Use a scarf, hairnet or hat to cover your hair when both handling containers and filling them. It's not nice for the customer to find hair in the product.
3. Fill a spray bottle with undiluted vodka and spray worktops and equipment/implements before making cosmetic products and/or using filling equipment and implements. Then wipe these surfaces off with clean kitchen paper towel. Do this every time you start to make or fill products even if you have already washed the implements/equipments in water before.
4. Wash your cosmetic making equipment in separate loads in your dishwasher to your normal household dishes - don't mix the two in the same wash/load.
5. For the making of water-based products, I always recommend using reputable bottled spring water. However, if you do use tap water, never use it to make non rinse-off products such as creams, gels and lotions, etc.
6. Use appropriate equipment that can be cleaned in a sterile way after use:
   • For example, if you use a plastic spatula, make sure that it is a single piece of plastic so that no contamination can occur between the head and the handle. You could also use wooden disposable spatulas that you can buy cheaply, for e.g. at Sally Beauty Supplies or Beauty Express. If you do use these wooden spatulas, one suggestion is to write on one end of the box ‘fingers’ and remember to only touch the spatulas on that end of the box with your fingers when you remove them from the box to use them - then you know that the other end of all the spatulas will always be sterile and that is the end of the spatulas you will use to stir your products, etc.
   • Steel whisks on which the wires are bent around into a multi-part handle can be a big contamination risk, so make sure you use one where this part of the whisk is sealed off properly so that no detritus can accumulate in the handle.
   • When using an electric stick blender, buy/use one that you can unscrew from the top/handle/motor; then you can clean the blade attachment part in the dishwashing machine.

   Note: if you are making products for the retail market, you can get current GMP (Good Manufacturing Practice) Guidelines from your safety assessor.

I confirm that I follow these guidelines:

Name:................................................................. Company name:.................................................................

Date:................................................................. Signature:.................................................................
Best Practice Guide to the Storage, Handling and Filling of Containers

Plastic Containers

1. If you are using plastic containers that have been purchased from Aromantic: Aromatic’s plastic bottles and jars are supplied to us in durable, airtight plastic packaging, inside sturdy carton boxes, which are sterile. Members of our staff will then use plastic gloves and repack the containers, if necessary, into the different quantities that we sell, before packing them into sealed plastic bags. When sent, they are safely wrapped in bubble wrap. It shouldn’t therefore be necessary to sterilise the plastic containers you buy from Aromantic. However, due to plastic's propensity for attracting dust, you may find some dust in the jars. If this happens then remove the dust hygienically using a hairdryer. Using preservatives correctly in your products along with usual hygiene standards will ensure that your products are packaged well, and will not prematurely grow fungus and bacteria.

2. When you are considering which plastic containers to use remember it is smart to use a container that will not be contaminated with fingers when using the product.
   There are 3 types of bottles/jars that you can use to avoid this contamination.
   a) Softer plastic containers that you can squeeze out the contents of.
   b) Bottles and Jars that you can add Pump or Spray caps onto.
   c) Using our Airless Pump Dispenser

   All of these will keep the products in the plastic container from being contaminated too soon/or challenging the preservation method by transferring bacteria or fungi into the product via fingers or hands.

3. As a general guideline when you are looking to use containers to squeeze out creams or lotions then it is best to use a Low Density Poly Ethylene (LDPE), PET, or PETG bottles. Other containers such as the High Density Poly Ethylene (HDPE) or the Poly Propylene (PP) will not be suitable.

4. Make sure that you don’t overfill your containers. If you do then when pressing the lid down it may cause the product to spill out from below the lid. If this happens then you need to use a clean paper towel and remove the excess product immediately otherwise this may cause growth of bacteria and fungus and contaminate the whole product.

5. When using strong products, like essential oils for example, it is best to use glass containers as the oils can react with the plastic. If your blend has up to 10% essential oils then a Poly Propylene (PP) Plastic bottle can be used.
Glass containers

1. All of our glass containers are supplied to us in sterile, airtight, durable plastic packaging. Members of our staff will then use plastic gloves and repack the containers, if necessary, into the different quantities that we sell, before packing them into sealed plastic bags. When sent, they are safely wrapped in bubble wrap. It shouldn't therefore be necessary to sterilise the glassware that you buy from Aromantic. Using preservatives correctly in your products along with usual hygiene standards will ensure that your products are packaged well, and will not prematurely grow fungus and bacteria. If you purchase a complete tray from us it will be supplied to you in its original sterile, airtight, durable plastic packaging ensuring your containers are at their ultimate cleanliness.

2. Our amber glass containers are the best choice for protecting products against sunlight and light oxidation and will help to prolong the shelf life of your products. The next container we would recommend using is our Blue Glass Bottles/Jars.

3. Make sure that you don't overfill your jars. If you do then when pressing the lid down it may cause the product to spill out from below the lid. If this happens then you need to use a clean paper towel and remove the excess product immediately otherwise this may cause growth of bacteria and fungus and contaminate the whole product.

4. The best way to avoid your customers contaminating your products is to add spray caps or pump caps to your glass bottles.
Best Practice Guide to the Storage, Handling and Filling of both plastic and glass Containers

General problems with plastic and glass jars and liners:

Wide neck plastic jars with plastic disc liners that cover the neck of the jar are used as protection for products however they could also compromise the microbiological integrity of a product. The covers allow water to condense on the surface which can encourage bacteria. The seal in the lid of glass jars is another microbial sponge just waiting to act as a growth medium. Following our recommended preservative regime will help to reduce this problem.

It is important to never touch the inside of the pot as this causes contamination. Always use spatulas to take cream from jars and never use your fingers, and ensure that you explain this process to your customers. Tubes, squeezable plastic bottles or bottles with pump/spray nozzle are the best option to reduce this risk.

It is likely that in these sealed and hygienic environments of these types of containers that your microbial challenge test will show your product has less chance of a growth in bacteria mould or yeast. This is because the consumer will never touch, and the air will never enter, the product.

1. When handling jars and containers make sure that you never touch inside them with your bare hands, always hold them from the outside of the container. This will stop contamination of your product.

2. Making cosmetics can be very similar to cooking, however making cosmetics requires extra care to avoid contamination as unlike many foods needing to last up to 24 hours only, a cream may need to last as long as 24 months. If you happen to touch the inside of your container then wipe it clean using the strongest vodka you can find.

3. Overfilling containers can cause spillages and create extra mess, which can encourage bacteria and fungus to form. If you do overfill your container, then spray your container with alcohol then wipe clean and let it dry before adding your label.

NB Filling any of our containers to the top will mean that you have overfilled it so it is important to remember to accurately pre-measure the correct volume you intend to pour into the container. A good tip is for you to keep a pre-measured bottle with coloured water to use for comparing levels when you are filling your products.

4. Pump Cap and Mist Spray Caps - The straw on our Pump Cap and Mist Spray Caps are too long in length for the containers so the straw needs to be cut at an angle, with scissors so that the tip just touches the bottom of the bottle you are inserting it into. There are hygiene considerations to be aware of when handling and cutting the straw.
   a) Use clean disposable gloves.
   b) Do not use your normal kitchen scissors, buy some cheap scissors to only be used for this purpose.
c) It is very important to store these Mist Spray Caps in clean, dust-free conditions and be careful to handle them with sterile gloves or a clean plastic bag acting as a glove - do not touch them with your bare hands unless you're making products for your own use.

5. When filling quite viscous/thick products that have required heating (e.g. balms, ointments or creams) you may find that it is difficult to fill them into a jar if the product has been cooled down to room temperature. If it is at room temperature you will most likely need to spoon it into a jar - the problem with this is that the products will not look smooth on the top and you can create spillage and mess which can increase the risk of contamination. To avoid this, fill your jars when the product is cooling down (approx. between 40 - 30 degrees Celsius. If that is not possible you can reheat the product until it becomes pourable. If the product is pourable it is best filled with a spouted beaker or jug.

6. The biggest contamination risk for bottles and jars is when they are stored in open packaging, meaning that although they were once sterile they are no longer. Ways to avoid this are:
   a) Seal them in bags with re-usable kitchen clips.
   b) If they are stored in trays make sure to re-seal the tray after removing any containers you need.

7. We no longer recommend that your customers return their used bottles so that you can refill them as the contamination risks are too high. We suggest that you ask your customers to take them to their local recycling centre.

8. To ensure our Aromantic customers use the optimum packaging for their products, earlier this year we upgraded all of our packaging information. Personally I don’t think any other company have such a vast amount of packaging information available.
   We now have full written descriptions for our plastic, glass, aluminium and make up containers, including the lids, tops and caps, which includes how to use them and what products they are most suitable for and not suitable for. You are also given the dimensions, best lids to use for your packaging, tips on how to fill your products, and advice on storing and handling them.

Please be aware that for your Cosmetic Product Safety Report (CSPR) the safety assessor will require information on the containers that you have used for each product.

It will not be enough to just say that your products are sold in plastic containers; the type of plastic has to be declared. (For e.g. HDPE - High Density Polyethane, LDPE – Low Density Polyethane, PP – Polypropylene)

If you are using containers from Aromantic, all the packaging information that you need is available from the website.

I confirm that I follow these guidelines:

Name:........................................................................ Company name:..............................................................

Date:........................................ Signature:........................................................................................................

Adverse Effects Form

Name of Product: ___________________________ Function: ___________________________

Product Code: ___________________________ Batch No: ___________________________

Date: ___________________________________

How was the adverse reaction notified?

Telephone [ ] in writing [ ] Email [ ] in Person [ ] via website [ ] other [ ]

Full Description of Adverse Effect:

Name and Contact Details of Complainant:

Action Taken:

Other information:

Name and Contact Details of Safety Assessor:

Name_______________________________ Signed_______________________________________
Complaints Form

Date: ________________________________

How complaint was notified

Telephone □ in writing □ Email □ in Person □ via website □ other □

Full Description of Complaint:

Name and Contact Details of Complainant:

Action Taken:

Other information:

Date Complaint Resolved: ________________________________

Name………………………………………………………

Signed…………………………………………………………
### Pest Control Check Form

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<th>Evidence identified</th>
<th>Action taken</th>
<th>Comments</th>
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<th>Signature</th>
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# Cleaning Log Form

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