GMP POLICY STATEMENT

BlueSky Solutions (UK) Ltd have adopted GOOD MANUFACTURING PRACTICE (GMP) standards across the business to comply with site accreditation, EU, and FDA standards.

These standards are in line with our Quality Management System and company goals and objectives and are reviewed regularly.

1/ BUILDING AND FACILITIES

A. Buildings used in the manufacture or storage of cosmetics are of suitable size, design, and construction to permit unobstructed placement of equipment, orderly storage of materials, sanitary operation, and proper cleaning and maintenance,
B. Floors, walls, and ceilings are constructed of smooth, easily cleanable surfaces and are kept clean and in good repair.
C. Fixtures, ducts, and pipes are installed to prevent drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment, or finished products in bulk.
D. Lighting and ventilation are sufficient for the intended operation and comfort of personnel.
E. Water supply, washing and toilet facilities, floor drainage and sewage system are adequate for sanitary operation and cleaning of facilities, equipment, and utensils, as well as to satisfy employee needs and facilitate personal cleanliness.

2/ EQUIPMENT

A. Equipment and utensils used in processing, holding, transferring, and filling are of appropriate design, material, and workmanship to prevent corrosion, build-up of material, or adulteration with lubricants, dirt, or sanitising agent
B. Utensils, transfer piping and cosmetic contact surfaces of equipment are well maintained and clean and are sanitised at appropriate intervals.
C. Cleaned and sanitised portable equipment and utensils are stored and located, and cosmetic contact surfaces of equipment are covered, in a manner that protects them from splash, dust or other contamination.

3/ PERSONNEL

A. Personnel supervising or performing the manufacture or control of cosmetics have the experience, skills, and training to perform the assigned functions.
B. Personnel coming into direct contact with cosmetic materials, finished products in bulk or cosmetic contact surfaces, to the extent necessary to prevent adulteration of cosmetic products, wear appropriate PPE including hair nets, beard snoods, laundered white coats, and where necessary disposable gloves. Personal Hygiene is monitored daily.

C. Consumption of food or drink, or use of tobacco is restricted to appropriately designated areas. (See also: Personal Hygiene Policy)

4/ RAW MATERIALS

A. Raw materials and primary packaging materials are stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.
B. Containers of materials are closed and bagged or boxed materials are stored off the floor.
C. Containers of materials are labelled with respect to identity, lot identification and control status.
D. Materials are sampled and tested or examined in conformance with procedures assuring the absence of contamination with foreign bodies, microorganisms, chemicals, or other extraneous substances to the extent necessary to prevent adulteration of finished products. Pay particular attention to materials of animal or vegetable origin and those used in the manufacture of cosmetics by cold processing methods with respect to contamination with foreign bodies or microorganisms.
E. Materials not meeting acceptance specifications are properly identified and controlled to prevent their use in cosmetics.

5/ PRODUCTION

A. The equipment for processing, transfer and filling the utensils, and the containers for holding raw and bulk materials are clean, in good repair and in sanitary condition.
B. Only approved materials are used.
C. Samples are taken, as appropriate, during and/or after processing, transfer or filling for testing for adequacy of mixing or other forms of processing, absence of hazardous microorganisms or chemical contaminants, and compliance with any other acceptance specification.
D. Weighing and measuring of raw materials is checked by a second person, and containers holding the materials are properly identified. Major equipment, transfer lines, containers and tanks are used for processing, filling, or holding cosmetics are identified to indicate contents, batch designation, control status and other pertinent information. Labels are examined for identity before labelling operations to avoid mix-up.
E. The equipment for processing, holding, transferring, and filling of batch is labelled regarding identity, batch identification and control status.
F. Packages of finished products bear permanent code marks.
G. Returned cosmetics are examined for deterioration or contamination.

6/ LABORATORY CONTROL

A. Raw materials, in-process samples and finished products are examined to verify their identity and determine their compliance with specifications for physical and chemical properties, microbial contamination, and hazardous or other unwanted chemical contaminants.
B. Reserve samples of approved lots or batches of raw materials and finished products are retained for the specified time period, are stored under conditions that protect them from contamination or deterioration and are retested for continued compliance with established acceptance specifications.
C. The water supply, particularly the water used as a cosmetic ingredient, is tested regularly for conformance with chemical-analytical and microbiological specifications.
D. Newly formulated and retained samples of finished products are tested for adequacy of preservation against microbial contamination which may occur user reasonably foreseeable condition of storage and consumer use.

7/ RECORDS

A. Raw materials and primary packaging materials, documenting disposition of rejected materials.
B. Manufacturing of batches, documenting the: 1/ Kinds, lots and quantities of material used, 2/ Processing, handling, transferring, holding, and filling, 3/ Sampling, controlling, adjusting, and reworking, 4/ Code marks of batches and finished products.
C. Finished products, documenting sampling, individual laboratory controls, test results and control status.
D. Distribution, documenting initial interstate shipment, code marks and consignees.

8/ LABELLING

Check whether the labels of the immediate and outer packaging have:

A. In addition to the name of the product, the statements of identity and net contents, the statement "Warning--The safety of this product has not been determined" if the safety of the respective product has not adequately been substantiated. Determine whether and what toxicological and/or other testing the firm has conducted to substantiate the safety of its products. See 21 CFR 740.10.
B. The list of ingredients (only on outer container) if intended for sale or customarily sold to consumers for consumption at home.
C. The warning statement(s) required at 21 CFR 740.11, 740.12 and 740.17. v Any other warning statement necessary or appropriate to prevent a health hazard. Determine the health hazard or their basis for a warning statement. vi Any direction for safe use of product.

D. In hair dye products, the caution statement of Sec. 601 (a) of the Act and appropriate directions for preliminary patch testing. This warning only applies to coal-tar hair dyes which, if so labelled, are then exempted from the adulteration provision of the Act.

9/ COMPLAINTS

A. The kind and severity of each reported injury and the body part involved.

B. The product associated with each injury, including the manufacturer and code number.

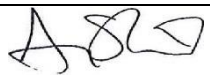
C. The medical treatment involved, if any, including the name of the attending physician.

D. The name(s) and location(s) of any poison control centre, government agency, physician's group etc., to whom formula information and/or toxicity data are provided.

GMP COMPLIANCE CONFIRMATION

I understand that it is a requirement under regulation EC 1223/2009 to produce cosmetic products according to Good Manufacturing Practice, the law does not require GMP certification, only to demonstrate that procedures comply with a recognised Industry standard and certification e.g., ISO 22716:2007, BRCGS Personal Care and Household.

On behalf of BlueSky Solutions (UK) Ltd

Name	Sign	Position
Lorraine Gregory		Quality & Environmental Manager
Danny Shiels		Head of Operations