Drugs & Cosmetics Act-1940 and Rules-1945

Provisions Relating to Manufacture of Cosmetics

Presentation By

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Definition of Cosmetic

Section 3(aaa): Any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic

*Words “but does not include Soaps” omitted w.e.f 1-2-1983*
PART XIV of D&C Rules
MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-137:- Manufacture on more than one set of premises

Rule-138:- Application for licence to manufacture cosmetics

Rule-138A :- Application for loan licence to manufacture cosmetics

Rule-139:- Conditions for the grant or renewal of a licence in Form 32:
  ◦ The factory premises shall comply with the requirements and conditions specified in Schedule M-II.
PART XIV of D&C Rules
MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-139A:- Form of licence to manufacture cosmetics for sale or for distribution

Rule-139AA:- Inspection before grant or renewal of licence

Rule-139AB:- Report by Inspector

Rule-139AC:- Grant or refusal of licence
PART XIV of D&C Rules

MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-130AD:- Further application after rejection

Rule-139AE:- Appeal to the State Government

Rule-139-B:- Form of loan licence to manufacture cosmetics for sale or for distribution

Rule-140:- Duration of licence
PART XIV of D&C Rules
MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-141: Certificate of renewal

Rule-141A: Certificate of renewal of a loan licence

Rule-141AA: Duration of a loan licence

Rule-142: Conditions of licence
PART XIV of D&C Rules
MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-142A :- Additional information to be furnished by an applicant for licence or a licensee to the Licensing Authority

Rule-142B:- Conditions of licence in Form 32-A

Rule-143:- Cancellation and suspension of licence

Rule-144:- Prohibition of manufacture of cosmetics containing colours other than those prescribe
PART XIV of D&C Rules

MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-144A:- Prohibition of manufacture of cosmetics containing Hexachlorophene

Rule-145:- Use of Lead and Arsenic compounds for the purpose of colouring cosmetics prohibited

Rule-145A:- Form of intimation for purpose of taking samples of cosmetics

Rule-145AA:- Form of receipt of samples of cosmetics where fair price tendered is refused
PART XIV of D&C Rules
MANUFACTURE OF COSMETIC FOR SALE OR FOR DISTRIBUTION

Rule-145B:- Form of receipt for seized cosmetics

Rule-145BA:- Manner of certifying copies of seized documents

Rule-145C:- Form of order not to dispose of stocks of cosmetics

Rule-145D:- Prohibition of manufacture of cosmetics containing mercury compounds
PART XV of D&C Rules
LABELLING, PACKING AND STANDARDS OF COSMETICS

Rule-146: Prohibition of sale or distribution

Rule-147: Exemption of cosmetics not manufactured for consumption or sale in India from the provisions of this Part: bear a code number

Rule-148: Manner of labelling

Rule-148A: Prohibition against altering inscriptions on containers, labels or wrappers of cosmetic

Rule-148B: Prohibition against false or misleading claims
PART XV of D&C Rules
LABELLING, PACKING AND STANDARDS OF COSMETICS

Rule-149:- Labelling of Hair dyes containing Dyes, Colours and Pigments:
  ◦ Caution—This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying direction should first be made. This product should not be used for dyeing the eye-lashes or eye-brows; as such a use may cause blindness.

Rule-149A:- Special provisions relating to toothpaste containing fluoride: not be more than 1000 ppm

Rule-150:- Report of result of test or analysis of cosmetics: in Form 34

Rule-150A:- Standard for cosmetics: Subject to the provisions of these rules, the standards for cosmetics shall be such as may be prescribed in Schedule S.
The following cosmetics in finished form shall conform to the Indian Standards specifications laid down from time to time by the Bureau of Indian Standards (BIS):

1. Skin Powders
2. Skin Powder for infants
3. Tooth Powder
4. Toothpaste
5. Skin Creams
6. Hair Oils
7. Shampoo, Soap-based
8. Shampoo, Synthetic-Detergent based
9. Hair Creams
10. Oxidation hair dyes, Liquid
11. Cologne
12. Nail Polish (Nail Enamel)
13. After Shave Lotion
14. Pomades and Brilliantines
15. Depliators chemicals
16. Shaving Creams
17. Cosmetic Pencils
18. Lipstick
19. Toilet Soap
20. Liquid Toilet Soap
21. Baby Toilet Soap
22. Shaving Soap
23. Transparent Toilet Soap
24. Lipsalve IS: 10284
25. Powder Hair Dye IS: 10350
26. Bindi (Liquid) IS: 10998
27. Kum Kum Powde IS: 10999
28. Henna Powder IS: 11142
SCHEDULE M-II

REQUIREMENT OF FACTORY PREMISES FOR MANUFACTURE OF COSMETICS

I. GENERAL REQUIREMENTS
A. Location and surroundings
B. Buildings
C. Water supply
D. Disposal of water
E. Health, clothing and sanitary requirements of the staff
F. Medical Services
G. Working benches
H. Adequate facilities shall be provided for washing and drying
SCHEDULE M-II

II. REQUIREMENT OF PLANT AND EQUIPMENT

A. Powders- Face powder, cake make-up, compacts, face packs, masks and rouges, etc

Equipment- mixer, blender, Ball mill, Trays, Filling & Sealing equipment with dust extractor, weighing & measuring devices, storage tanks

An area of 15 square meters is recommended. The section is to be provided with adequate exhaust fans.
SCHEDULE M-II

B. Creams, lotions, emulsions, pastes, cleansing milks, shampoos, pomade, brilliantine, shaving creams and hair-oils

Equipment- Mixing and storage tanks, Heating kettle, agitator, Colloidal mill, Filling and sealing equipment, Weighing and measuring devices.

An area of 25 square meters is recommended.
SCHEDULE M-II

C. Nail Polishes and Nail lacquers

1. Equipment- Mixer, Storage tanks, Filling machine, Weighing and Measuring devices. An area of 15 square meters is recommended. The section shall be provided with flame proof exhaust system.

2. Premises:
   (a) It shall be suited in an industrial area.
   (b) It shall be separate from other cosmetic-manufacturing areas by metal/brick partition up to ceiling.
   (c) Floors, walls, ceiling and doors shall be fireproof.
   (d) Smoking, cooking and dwelling shall not be permitted and no naked flame shall be brought in the premises.
   (e) All electrical writing and connections shall be concealed and main electric switch shall be outside the manufacturing area.
   (f) All equipment, furniture and light fittings in the section shall be flameproof.
   (g) Fire extinguisher like foam and dry powder and sufficient number of buckets containing sand shall be provided.
   (h) All doors of the section shall open outwards.
C. **Nail Polishes and Nail lacquers**

3. **Storage.** - All explosive solvents and ingredients shall be stored in metal cupboards or in a separate enclosed area.

D. **Lipsticks and Lip-gloss, etc:**

Equipment - Vertical mixer, Jacketted kettle, Mixing vessel, Triple roller mill/Ball mill, Moulds with refrigeration facility, Weighing and measuring devices.

An area of 15 square meters is recommended.

E. **Depilatories.**

Equipment - Mixing tanks, Mixer, Triple roller mill or homogeniser, Filling and sealing equipment, Weighing and measuring devices, Moulds.

An area of 10 square meters is recommended.
SCHEDULE M-II

F. **Preparations used for Eyes** - Such preparations shall be manufactured under strict hygienic conditions to ensure that these are safe for use.

Equipment for Eyebrows, Eyelashes, Eyeliners, etc - Mixing tanks, mixer, Homogeniser, Filling and sealing equipment, Weighing and measuring devices.

An area of 10 square meters is recommended.

Other requirements - False ceiling, fly proof, airlock, utensils shall be of stainless steel, hand gloves

G. **Aerosols**

Equipment - Air-compressor, Mixing tanks, propellant filling and crimping equipments, Liquid filling unit, Leak testing equipment, Fire extinguisher, filtration equipment, Weighing and measuring devices.

An area of 15 square meters is recommended.

Other requirements - No objection certificate from the Local Fire Brigade Authorities shall be furnished.
SCHEDULE M-II

H. Alcoholic Fragrance Solutions.
Equipment - Mixing tanks, Filtering equipment, Filling and sealing equipment, Weighing and measuring devices,
An area of 15 square meters is recommended.

I. Hair Dyes.
Equipment - Stainless steel tanks, Mixer, Filling Unit, Weighing and measuring devices, Masks, gloves and goggles.
An area of 15 square meters with proper exhaust is recommended.
J. Tooth powders and toothpastes, etc.

1. Tooth-powder in General.
   Equipment- Weighing and measuring devices, Dry mixer, Stainless steel sieves, Powder filling and sealing equipments.
   An area of 15 square meters with proper exhaust is recommended.

2. Toothpastes.
   Equipment- Weighing and measuring devices, Kettle, Planetary mixer with de-aerator system, Stainless steel tanks, Tube filling equipment, Crimping machine.
   An additional area of 15 square meters with proper exhaust is recommended.
SCHEDULE M-II

K. Toilet Soaps.

Equipment- Kettles/pans for saponification, Suitable heating arrangement, stirring arrangement, Storage tanks or trays, Driers, Amalgamator/chipping machine, Mixer, Triple roller mill, Granulator Plodder, Cutter, Pressing, stamping and embossing machine, Weighing and measuring devices

A minimum area of 100 square meters is recommended for the small-scale manufacture of toilet soaps.
Note No. I. The above requirements of the Schedule are made subject to modification at the direction of the Licensing Authority, if he is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter them in the circumstances of a particular case.

Note No. II. The above requirements do not include requirements of machinery, equipments and premises required for preparation of containers and closers of different categories of cosmetics. The Licensing Authority shall have the discretion to examine the suitability and adequacy of the machinery, equipments and premises for the purpose of taking into consideration of the requirements of the licence.
Note No. III. Schedule M-II specifies equipments and space required for certain categories of cosmetics only. There are other cosmetics items, viz. Attars, perfumes, etc., which are not covered in the above categories. The Licensing Authority shall, in respect of such items or categories of cosmetics have the discretion to examine the adequacy of factory premises, space, plant and machinery and other requisites having regard to the nature and extent of the manufacturing operations involved and direct the licensee to carry on necessary modification in them.

Note No. IV. Areas for formulations meant for external use and areas for formulations meant for internal use shall be separately provided to avoid mix - up even though they are from the same category of formulations
16. Cosmetics: The provisions of Chapter IV of the Act and the Rules made thereunder, which require them to be covered by a licence for sale provided that the cosmetics sold, if of Indian origin, are manufactured by licenced manufacturers.
Thank You All