

### GOVERNMENTAL REGULATIONS

Our business and operations are subject to certain laws and regulations, including laws and regulations specifically relating to cosmetic products and rules covering general consumer protection and product safety. Compliance with the applicable laws and regulations is monitored by governmental and regulatory authorities.

#### **Laws and regulations specific to the cosmetics industry**

Some countries in which we operate have passed laws and regulations directly relating to the cosmetics industry and which are applicable to us. The principal objective of these regulations is to ensure that cosmetic products placed on the market are safe. The principal regulations to which we are subject in the major markets in which we operate, namely the European Union, the United States and Japan, are summarised below.

#### ***European Union***

Our business and operations in those countries which are Member States of the European Union are subject to the regulatory framework set out by the European Union's Council Directive 76/768/EEC, as amended (the *Cosmetics Directive*). The Cosmetics Directive is the main regulatory framework for finished cosmetic products sold in the European Union, and lays down rules on the composition, labelling and packaging of cosmetic products. This Cosmetics Directive will be replaced by the new EU Cosmetics Regulation (EC) 1223/2009, adopted on November 30, 2009, which will only enter into force on 11 July 2013, with the exception of specific articles which will already enter into force on 1 December 2010 and 11 January 2013. The key provisions mentioned in these two texts applicable to us are summarised below:

- **Composition and presentation.** The Cosmetics Directive requires that a cosmetic product sold in the European Union must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer, distributor or retailer of such product. The provision of warnings to cosmetics products shall not exempt any person from compliance with the other requirements laid down in the Directive. The Cosmetics Directive further sets out a list of substances which cannot — or only under certain restrictions and conditions — be included in the composition of cosmetic products. It also contains a list of colourings, preservatives and UV filters permitted in cosmetic products.
- **Labelling and packaging.** Pursuant to the Cosmetics Directive, the container and packaging of cosmetic products marketed in the European Union are generally required to bear, in indelible, easily legible and visible lettering, certain specified information, including the name and address of the manufacturer or distributor, the nominal content of the product at the time of packaging given by weight or by volume, the date of minimum durability, particular precautions for use and a list of the ingredients.

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### **United States**

In the United States we are subject to the Federal Food, Drug and Cosmetic Act (the **FDCA**), the Fair Packaging and Labeling Act (the **FPLA**) and certain regulations published by the Food and Drug Administration (the **FDA**), which are codified in Title 21 of the Code of Federal Regulations (**21 CFR**). The key provisions which are applicable to us are summarised below:

- **FDCA.** Under the FDCA, the introduction or delivery for introduction into interstate commerce of adulterated or misbranded cosmetics is prohibited and may result in regulatory action by the FDA. A cosmetic is “adulterated” if it contains or its container is made of any poisonous or noxious substance which will injure a user who follows the instructions stated thereon or uses the cosmetic under customary or usual conditions, if it contains any filthy, putrid or decomposed substance, if it has been prepared, packed or held in unsanitary conditions or if it contains a prohibited colour additive. A cosmetic is “misbranded” if its labelling is false or misleading, required words or statements are not prominently displayed, or if its package does not contain a label stating the manufacturer’s name and place of business and an accurate statement of the quantity of contents. Cosmetics and their ingredients are not subject to pre-market approval by the FDA (with the exception of colour additives) but they must be tested to assure safety, otherwise a specific warning is required.
- **FPLA.** The FPLA requires that any consumer commodity, which includes cosmetics, has a label stating the identity of the commodity and the name and place of business of the manufacturer, packer or distributor. The label should also clearly and accurately state the net quantity of the contents with no qualifying words or phrases. If these requirements are not followed, the cosmetics will be deemed to be misbranded under the FDCA.
- **21 CFR.** The provisions of 21 CFR which are relevant to our business contains a number of requirements. They detail certain ingredients which, if included in cosmetics, would mean that those cosmetics are considered adulterated under the FDCA, as well as requirements for packaging of certain types of cosmetics to avoid them being considered adulterated under the FDCA. Further detail on the labelling requirements under the FDCA are outlined, including prominence of statements, declaration of ingredients, exemptions, requirements of what to include on the principal display panel of a package, product warnings and the fact that a misleading label will render a cosmetic misbranded.

### **Japan**

In Japan, we are subject to the Standards for Cosmetics (Ministry of Health and Welfare Notification No. 331 of 2000) established by the Ministry of Health, Labour and Welfare in accordance with the Pharmaceutical Affairs Law (Law No. 145 of 1960) and Drug Notification No. 44 “Enforcement of the Pharmaceutical Affairs Law” as revised by the Revisions to the scope of efficacy of cosmetics issued by the Ministry of Health, Labour and Welfare on 28 December 2000 (**Drug Notification No. 44 (as revised)**). The key provisions under these regulations which are applicable to us are summarised below:

- **Standards for Cosmetics.** The Standards for Cosmetics require that cosmetic ingredients should not contain anything that may cause infection or otherwise make the use of cosmetics a potential health hazard. The Standards for Cosmetics also list ingredients that cannot be

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included in cosmetics, impose limitations on the amounts of certain ingredients that can be included (depending on the type of products), and publish a negative list of ingredients like preservatives, UV absorbers etc.

- **Drug Notification No. 44 (as revised).** These limit what can be detailed on cosmetic labels to 55 claims of what the effect of the product is, such as “moisturise the scalp and hair” or “keep the skin healthy”.

### **General consumer protection and product safety and environmental protection regulations**

In addition to the cosmetics industry-related rules, we are subject to general consumer protection, product safety and environmental protection rules in the jurisdictions we operate in. These are rules which generally apply to a business involving the manufacturing and distribution of consumer products and which are not specific to the cosmetics industry. The principal general product safety and environmental protection regulations to which we are subject in the major markets in which we operate, namely the European Union, the United States and Japan, are summarised below.

#### ***European Union***

There is extensive European Union legislation governing consumer protection, product safety and product liability implemented at national level in all Member States. For example, the General Product Safety Directive 2001/95/EC (the GPSD) is designed to apply a high level of product safety for all products. The GPSD provides that producers are obliged to place only safe products on the market. In determining whether a product is considered safe under the GPSD, various factors are taken into account including the following: (i) national safety standards, (ii) guidelines from the European Commission on product safety, (iii) product safety codes of good practice in force in the sector concerned, (iv) the state of the art and technology and (v) reasonable consumer expectations concerning safety. The GPSD further provides that national governments must appoint local authorities to carry out market surveillance to ensure that safety standards are implemented.

Our manufacturing facilities in France need to comply with Directive 2008/01/EC on integrated pollution prevention and control (IPPC Directive), which has been incorporated into French law by Article L511-1 of the French Environmental Code and is known as the “classified installations regime”. Classified installations must obtain an environmental permit by submitting a declaration or an authorisation file to the DRIRE (*Directions Regionale de l’Industrie, de la Recherche et de l’Environnement*) that includes an environmental impact study and a risk assessment study as well as further studies and analysis as required by the DRIRE. Analysis and supervision measures relating to environmental concerns must take place during the operation of the site and the results must be sent to environmental inspectors.

Our manufacturing facilities will need to comply with the Good Manufacturing Practices (GMP), which follow ISO norm EN ISO 22716 published in 2007 and expected to become mandatory throughout the European Union in 2013 for the cosmetics industry, with the objective of enhancing the protection of the consumer. In France, compliance with this norm will be audited by the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS), a governmental body.

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### **United States**

The FDCA and 21 CFR cover general consumer protection and product safety as detailed above. As we do not engage in any manufacturing activities in the United States, we believe regulations relating to environmental protection in the United States are generally not applicable to our manufacturing activities in France.

### **Japan**

General consumer protection legislation is laid out in the Pharmaceutical Affairs Law as amended by ministerial ordinances numbers 134 and 135 on the safety control of production and sale of drugs, non-regulated drugs, cosmetics and medical instruments issued by the Ministry of Health, Labour and Welfare on 22 September 2004. These require us to appoint a safety control manager to supervise safety maintenance work and establish a procedure for safety control work after production and sale. Safety information must be collected and reports must be made and retained to ensure that the safety control procedure is appropriate and runs smoothly.

As we do not engage in any manufacturing activities in Japan, regulations relating to environmental protection in Japan are generally not applicable to us.

### **Compliance monitoring**

Authorities in certain jurisdictions in which we operate monitor our compliance with applicable regulations. The authorities which monitor our compliance with relevant regulations in the major markets in which we operate, namely the European Union, the United States and Japan, are summarised below.

### **European Union**

Each Member State of the European Union disposes of its own authorities to ensure compliance with regulations relating to the cosmetics industry. The Minister of Health in France is primarily responsible for incorporating European Union legislation into French law, and we and our products are subject to regulation by the Minister of Health (the *direction generale de la santé*), the Minister of Industry (the *direction generale des entreprises*), the French Agency for the Safety of Health Products (the *Agence française de sécurité sanitaire des produits de santé* or *AFSSaPS*) and the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (the *Direction generale de la concurrence, de la consommation et de la repression des frauds* or *DGCCRF* and together with the *AFSSaPS*, the French Authorities). Our products are not subject to pre-market approval by the French Authorities but we are obliged to conduct tests on our products and ingredients. The French Authorities monitor compliance of our products through periodic visits and audits of our factory site in Provence and have the authority to confiscate cosmetic products and to control consignments and activities at the manufacturing facilities. In compliance with the provisions of the Cosmetics Directive we keep a file which contains various details of each finished product, including the ingredients used.

### **United States**

In the United States, we are monitored by the US Food and Drug Administration (the **FDA**), which oversees both cosmetic products imported into the United States as well as those produced there. Our products are not subject to pre-market approval but the FDA may conduct examinations and investigations on products and products can be subject to examination and/or sampling by the US Customs Service at the time of entry into the country. Cosmetics that appear to be adulterated or

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misbranded may be refused entry, and shipments that do not comply with US laws and regulations are subject to detention until they are brought into compliance, destroyed or re-exported. To prevent further shipments of adulterated or misbranded products, the FDA may request a federal district court to issue a restraining order against the manufacturer or distributor of the cosmetics, or may initiate a criminal action.

### ***Japan***

In Japan, we are monitored by the Ministry of Health, Labour and Welfare which operates a system of “in market control” where responsibility for imported products falls on the distributor or importer in Japan. There is, again, no requirement for pre-market registration of the products.

### **All jurisdictions — no material non-compliance**

There were no findings notified to us by any regulating authority in the jurisdictions in which we operate of any material non-compliance with any rule, regulation or law to which our business is subject, or any irregularities as a result of periodic visits and audits, during the Track Record Period.

### **ORGANIC CERTIFICATION**

In order to label and market products manufactured by us in Europe as “organic”, we need to obtain a certification from an independent testing organisation recognised in France that certifies that the products are truly organic in nature.

For example, ECOCERT is a French control and certification organisation whose activities are in line with the current legislation and the public authorities in France. ECOCERT’s approval enables us to label and market our products as organic in France under the condition that in particular the specific labeling requirements of ECOCERT are met. The respect of these requirements enables us to continue receiving our certification.

Currently there is no international organic certification organisation. Due to this lack of a centralised certification body, our products that are classified as “organic” by ECOCERT in France may not be classified as such in other countries in which we sell our products such as the United States.