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化妆品
法规服务

Intertek天祥专家服务部（化妆品）致力于为客户提供化妆品的风险评估和法规咨询服务，使其产品能够满足中国、欧盟、美国、东盟和其它国家和地区的法规要求。同时为企业提供化妆品法规培训、咨询及化妆品新原料注册服务。

我们的服务类型主要包括：

- **毒性风险评估**
  评估产品中每种成分的毒理特性和成品中这些成分混合后的毒理特性，以及产品在使用过程中暴露的特性和风险，同时考虑各个国家化妆品法规中对于产品安全的要求。

- **产品通告**
  欧盟化妆品法规（EC）No 1223/2009中规定化妆品必须在其官方网站上进行通告后（e-Notification）方能进入欧盟市场，加拿大化妆品法规第30条要求生产商和进口商必须在首次销售某一化妆品10天之内，按要求进行化妆品通告。

- **化妆品安全评估报告**
  欧盟化妆品法规在2013年7月11日正式实施后，进入到欧盟市场的所有化妆品必须提供产品安全报告。

- **化妆品组分/原材料毒理学档案**
  欧盟化妆品法规附录一第8条规定化妆品中使用的所有成分/原材料须提供其单独的毒理学档案。

- **化妆品信息档案**
  欧盟化妆品法规（EC）No 1223/2009规定了欧盟境内销售的化妆品必须制定一套产品的资料档案（Product Information File，PIF），并随时供官方当局查询。该资料档案包含产品、生产厂商和责任人的全部信息且须时时更新。

- **中国化妆品新原料注册和备案**
  2021年4月27日，中国国家药监局关于发布《已使用化妆品原料目录（2021年版）》的公告（2021年 第62号），不在此目录内的原料，即被认为属于化妆品新原料，新原料需要注册和备案后才可使用到化妆品中。

- **化妆品标签审核**
  化妆品产品标签须满足各个国家或地区中对产品标签的规定和要求，其中有欧盟化妆品法规（EC） No 1223/2009和美国Federal Food, Drug, and Cosmetic Act（FD&C Act）。通过该服务帮助企业审核和完善产品标签，满足法规所列要求。服务适用的国家和地区包括：中国、欧盟、美国、加拿大、东盟、澳大利亚等。

- **化妆品成分审核**
  对客户提供的产品配方进行审核和评估，根据各个国家和地区对于化妆品成分的要求来检查是否有禁用或限用物质。服务适用的国家和地区包括：中国、欧盟、美国、加拿大、东盟、澳大利亚等。

- **进口/国产化妆品备案或注册**
  针对不同类型的产品，药品监督管理局采取不同的监管方式：
  - 进口/国产非特殊用途化妆品备案制；
  - 进口/国产特殊用途化妆品行政许可审批制。

- **化妆品原料报送**
  根据中国法规要求，化妆品成品在进行注册备案时需提交原料安全信息。根据客户提供的信息，进行账户创建和原料报送。

如有疑问，请联系我们：
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Cosmetic Regulatory Services

Intertek Assuris (Cosmetics) is committed to providing risk assessment and regulatory consulting for cosmetic products compliance in China, European Union, United States, ASEAN and other countries or regions. Simultaneously, it provides cosmetics regulatory training, consulting and new cosmetic ingredient registration for enterprises.

Our service includes:

- **Toxicological Risk Assessment (TRA)**
  TRA was carried out based on toxicological properties of each ingredient in the product and after mixing these ingredients, taking consider of the exposure, risks of the product during use, and specific regulation to determine whether or not a product poses a potential risk for consumers.

- **Notification**
  EU Cosmetics Regulation (EC) No 1223/2009 states that cosmetics must be notice on their official website (e-Notification) before they can enter the EU market. Article 30 of the Canadian Cosmetics Regulation requires manufacturers or importers must submit a cosmetic notification to Health Canada within 10 days of the first sale in Canada.

- **Cosmetic Product Safety Report (CPSR)**
  Cosmetics Regulation (EC) No 1223/2009 was officially implemented on July 11, 2013, all cosmetics entering the EU market must provide a Cosmetic Product Safety Report.

- **Toxicological Profile of the Substances (TPS)**
  Article 8 of Appendix I to the EU Cosmetics Regulations requires that all ingredients/ raw materials used in cosmetics be provided with their separate toxicological profile.

- **Product Information File (PIF)**
  EU Cosmetics Regulation (EC) No 1223/2009 stipulates that cosmetics sold in the EU must have Product Information File (PIF) and are readily available for inspection by official authorities. This profile contains all information on the product, manufacturer and responsible person and must be updated timely.

- **China new cosmetic ingredient registration and notification**
  On April,27,2021, the NMPA (National Medical Products Administration issued IECIC (2021), The ingredients not listed in inventory are considered to be new ingredients of cosmetic, and it is mandatory to process registration or notification before putting them into China market.

- **Cosmetics labeling review**
  Cosmetic product labels must meet relevant requirements under regulations in various countries, including the EU Cosmetics Regulation (EC) No 1223/2009 and the US Federal Food, Drug, and Cosmetic Act (FD&C Act). This service helps companies review and refine product labels to meet regulatory requirements. The countries and regions where the service is applicable including China, EU, USA, Canada, ASEAN, Australia, etc.

- **Cosmetics ingredient review**
  Intertek offers ingredient review base on the prohibited and restricted ingredients list. The countries and regions where the service is applicable include: China, EU, USA, Canada, ASEAN, Australia, etc.

- **Imported / domestic cosmetics record-keeping system/Approval system**
  The NMPA takes different regulatory approaches for different category:
  - Imported / domestic Non-special use cosmetics: Record-keeping system;
  - Imported / domestic special Use Cosmetics: Approval system.

- **Cosmetic Raw Material Safety Data Submission**
  According to Chinese regulations, the safety information of raw materials should be submitted when the finished cosmetics are registered/notified. Intertek will create accounts and submit raw materials according to the information provided by customers.

Please contact us: Intertek Assuris 021-5339 7991 hers@intertek.com