CUSTOMS FILE

REGULATION REPUBLIC OF CHINA

Amendments as regards the labelling of infant formula and trade-related news have been brought to the import documentation for the P.R. of China. The following changes have been made:

Labelling of Infant Formula

Additional information on the labelling of infant formula has been included in the chapter on Packaging, Marking and Labelling Requirements of this import report. Please see said section for particulars.

Other Changes

For current trade-related News, please see the following section.

News

Increased Time Limits for Renewal of Cosmetics Registrations

Starting from 1 September 2017, renewals for cosmetics registrations must be applied for at the China Food and Drug Administration (CFDA) of the P.R. of China at least six months prior to expiry. Before this date, an application for renewal four months in advance of expiry is sufficient. If the registration is additionally to be amended in the course of the renewal, application is to be made even ten months before the registration expires. For more information on the importation of cosmetics, please see the section on Cosmetics below and the documents mentioned therein.

EU Gateway to China Programme

The EU Gateway to China Programme was launched in Beijing in March 2017. The project is funded by the European Union (EU) and aims at promoting collaborations between EU and Chinese companies in diverse sectors. The first sector targeted by the project is clean technlogy, including green energy technologies, solid waste and wastewater treatment technologies. As a next step, health care technology will be in focus.

Mutual Recognition Arrangements (MRAs) between New Zealand and the P.R. of China

On 27 March 2017, New Zealand and the P.R. of China signed a Mutual Recognition Arrangement (MRA) which aims at facilitating trade between the two countries and ensures the mutual recognition of the countries' trusted trader programmes. The agreement is believed to lead

to a faster cargo clearance, reduced document checks and fewer examinations. The arrangement is effective from 1 July 2017. The Chinese and New Zealand customs authorities also recently launched a Joint Electronic Verification System, which automatically sends New Zealand's Certificate of Non-Preferential Origin to the Chinese customs authorities to facilitate authenticity assurance of goods. A similar arrangement with Australia is also under way. For particulars, e.g. further countries with which the P.R. of China has arrangements to this effect, please turn to the chapter on Registration in this import report.

The P.R. of China and New Zealand also signed an MRA on organic product certification. Accordingly, the two parties confirm the equivalence of their respective organic products certification systems and mutually recognise organic certification results form the other country. The MRA is to become effective in summer 2017.

Trade Talks

The twelfth round of trade talks on a trilateral free trade agreement (FTA) between the P.R. of China, Japan and South Korea was held in Tokyo from 10 to 13 April. In this round of negotiations, areas such as trade in goods and services and investment, amongst others, were discussed. The three parties will work towards holding the 13th round of negotiations in South Korea.

General Information

- **Conventional long form of country name:** People's Republic of China
- **ISO Country Code:** CN
- **Population:** 1,373.54 million (July 2016 est.)
- **Area:** 9,596,960 sq km
- **Population density:** 143 inhabitants per sq km
- **Capital:** Beijing
- **Major ports:** Dalian, Guangzhou, Ningbo, Qingdao, Qinhuangdao, Shanghai, Shenzhen, Tianjin
- **Currency:** 1 Yuan Renminbi = 10 Jiao = 100 Fen
- **ISO Currency Code:** CNY

Note

The tariff codes correspond to the current Customs Import and Export Tariff of the People's Republic of China, which is based on the Harmonized System (HS) 2017; the P.R. of China applies the HS on the basis of the HS Convention (for further general information on the Harmonized System, please turn to the section thereon below).

Sanctions

Due to the European Council Declaration of 27 June 1989, an arms embargo on China is in force. However, China is not an embargo state in the sense of Art. 4 (2) of the Regulation (EC) No. 1334/2000 of 22 June 2000 (EC-Dual-Use-Regulation) in its currently valid version. For the

assessment of export licences not covered by the scope of this embargo, the EU Code of Conduct on Arms Exports applies.

International Agreements

China is a member of the following organisations and has signed the agreements listed below:

- Asia-Pacific Economic Cooperation (APEC)
- Asia-Pacific Trade Agreement (APTA), previously named Bangkok Agreement
- Customs Convention on the A.T.A. Carnet for the Temporary Admission of Goods (A.T.A. Convention), please refer to the document Carnet A.T.A. for further details
- International Convention on the Harmonized Commodity Description and Coding System (HS Convention)
- International Convention on the Simplification and Harmonization of Customs Procedures (as amended) (Revised Kyoto Convention)
- Organization for Economic Co-operation and Development (OECD) - enhanced engagement country status
- World Customs Organization (WCO)
- World Trade Organization (WTO).

Preferential Treatment

Besides the Most Favoured Nations (MFN) preferential rate, the Chinese customs grants preferential rates for numerous goods originating in various countries, namely in the member states of the Asia-Pacific Trade Agreement (APTA, i.e. Bangladesh, India, Laos, South Korea, Sri Lanka) and the member states of the ASEAN-China Free Trade Area (ACFTA, i.e. Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam). Furthermore, preferential rates are granted for goods originating in Australia (China-Australia Free Trade Agreement - ChAFTA), Chile, Costa Rica, Iceland, New Zealand (New Zealand-China Free Trade Agreement - NZCFTA), Pakistan, Peru, Singapore (China-Singapore Free Trade Agreement - CSFTA), South Korea and Switzerland. In addition, mainland China has concluded two Closer Economic Partnership Arrangements (CEPAs) with both special administrative regions, referred to as the Mainland and Hong Kong CEPA, and the Mainland and Macau CEPA, respectively. Furthermore, an Economic Cooperation Framework Agreement (ECFA) is in force between the People's Republic of China and Taiwan, which is, de facto, a free trade agreement (FTA).

Goods which are originating products in the sense of the agreements above or which are included in special rules may benefit from preferential treatment in China.

Export Controls

Besides the stipulations of the country of importation, export control provisions may have to be observed in international movements of goods and services. The subject of such provisions may be particular commodities, countries of (final) destination and legal or natural persons involved in the respective transactions. These persons may comprise, but are not limited to, the following legal entities or individuals:

- exporters and consignors
- importers and consignees
- end users
- freight forwarders and their agents
- banks and financial institutions.

The listed entities may include governmental agencies in the country of (final) destination, too.

Countries may even partially or completely interdict external trade with another country. However, goods may also be exempt from such embargoes if exported for humanitarian or special reasons.

In general, the following types of merchandise (as well as related services and maintenance) are regulated in the framework of export control laws:

- arms and ammunition
- military equipment
- designated explosive substances
- strategic goods (e.g. encryption technology for communications equipment)
- dual-use goods, i.e. commodities which may be used for military and civil purposes alike (including software and technologies)
- goods which could be used for torture, capital punishment or similarly inhuman treatment.

In principle, the competent authorities of the exporting country regulate the scope of goods to be controlled upon their exportation and in respect of the parties and countries involved in the transactions. Following the examination of the relevant documentation, export authorisations may be issued. The export control authorities may also require documents from the respective bodies in the country of destination in order to control the goods and monitor their delivery chains. Such documents may comprise, e.g., international import certificates, end-user certificates or delivery verification certificates.

In addition, specific import requirements may apply to the abovementioned goods as well.

As regards controls of dual-use goods in the framework of the European Union (EU), the basic legal stipulation is Council Regulation (EC) No 428/2009 of 5 May 2009, setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items. The responsibility for the execution of the so-called Dual-Use Regulation lies, however, with the competent authorities of each individual Member State.

Exporters should be aware of the fact that they may be held legally responsible for respective foreign trade transactions, comprising all different aspects of transboundary movements of goods and services. This individual responsibility is usually not transferable to other persons. Advice should be sought from the competent authority in the exporting country.

For additional details of applicable measures for the P.R. of China, please turn also to the section on Sanctions above.

Customs Procedures

The Chinese customs authorities mainly differentiate between the following types of customs procedures for imports:

- release for free circulation
- temporary importation
- re-export
- customs warehousing
- processing of dutiable goods
- customs transit.

Customs Regulations

In analogy with the Framework of Standards to Secure and Facilitate Global Trade issued by the WCO, Decree No. 172 of the General Administration of Customs of the P.R. of China lays down Measures for Manifest Administration for Inbound and Outbound Means of Transportation of the P.R. of China. These measures on registration requirements for all means of transportation used in international trade and on compulsory summary declarations to be provided in form of lists containing passengers, freight and other effects (Automated Manifest Rule) became operative on 1 January 2009. Please refer to the documents entitled Registration with the Chinese Customs Authorities and Cargo Manifest for further details.

According to the Customs Law of the People's Republic of China, goods to be imported into the country are to be declared to the customs authorities and import formalities are to be conducted within 14 days of arrival. Please refer to the following documents for further details:

- Customs Import Declaration
- Commercial Invoice
- Packing List
- Certificate of Non-Preferential Origin
- Air Waybill
- Rail Waybill Conforming to both COTIF and SMGS Agreements
- Bill of Lading
- Insurance Certificate.

Importers may, moreover, apply for a Pre-Classification for Imported Goods which may accelerate customs clearance procedures.

Certain products require a permit or approval prior to their actual importation. The Chinese Government issues a list of prohibited imports which comprises import prohibitions regarding both, prohibitions on a general level and certain second-hand machinery and equipment in specific. Please refer to the documents Import Prohibition and Prohibition to Import Certain Used Machinery and Electrical Equipment. In addition, a number of commodities is subject to a general Commodity Inspection Certificate or a specific Inspection Certificate for Medicines issued by the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ). The conformity of product labels, e.g. for imported foodstuffs or cosmetics, will be

checked upon arrival of the products in the framework of the Commodity Inspection Certificate. The inspection certificates will include a note on the compliance of the labels ("audited labels are found to meet the standards").

In order to prevent the introduction of highly pathogenic viruses and contagious diseases into the country, the Chinese authorities may require additional measures to be carried out prior to the shipment of goods and/or at the time of entry into the country, e.g. as a consequence of the outbreak of such in the country of provenance. By way of example, vehicles and containers may be required to have been subjected to specific treatments and proof thereof may accordingly be required to be submitted to the quarantine authorities at the point of entry and the goods themselves might also be subject to quarantine under the supervision of the competent Chinese authorities.

Licences and quota regulations may also apply. Please see the section on Import Regulations below.

Free Trade Zones and Warehousing

In China, there are 15 free trade zones or bonded zones (economic and technological development zones) under the administration of the State Department, which are located in Tianjing, Shantou, Guangzhou, Shatoujiao and Futian (both in the Shenzhen special economic zone), Zhuhai, Xiamen, Fuzhou, Haikou, Dalian, Qingdao, Zhangjigang, Shanghai, Xiangyu and Ningbo. Six of these free zones are classified as special economic zones: Hainan, Pudong, Shenzhen, Shantou, Zhuhai and Xiamen.

The customs authorities provide for bonded warehousing, which is free of charge for commodities intended for transit or dutiable goods processing. These goods may be stored in a warehouse for up to one year (which, under certain conditions, could be extended for a second year). However, a range of steel products may no longer be processed in bonded warehouses free of charge with effect from 31 July 2014, i.e. customs duties and import taxes are payable in this case.

Any treatment of warehoused goods is subject to customs supervision. Goods intended for free circulation are not permitted under bonded warehousing.

The China (Shanghai) Pilot Free Trade Zone, including Shanghai Waigaoqiao Bonded Zone, Waigaoqiao Bonded Logistics Zone, Yangshan Bonded Port and Shanghai Pudong Airport Free Trade Zone, was inaugurated in September 2013. The zone is intended as a testing ground for market opening and administrative reforms; accordingly, areas such as facilitation of trade and investment, the convertibility of the Yuan Renminbi (CNY) as well as methods for the efficient supervision of goods will be explored in this framework over a period of two or three years. Further free trade zones modelled after the China (Shanghai) Pilot Free Trade Zone have been established in Fujian, Guangdong and Tianjin. Which kinds of foreign investment are not permissible in the respective free trade zone has been stipulated by means of a negative list.

Customs Value

The customs value of imported goods is determined by their transaction value, which is usually based on the CIF value. Rules on determining the customs value are applied by the customs authorities according to the Agreement on Implementation of Article VII (Customs Valuation) of the General Agreement on Tariffs and Trade (GATT 1994). If the customs value cannot be determined on the basis of the transaction value of the imported goods, the following values are to be applied successively as a basis for its calculation:

- the transaction value of identical imported goods
- the transaction value of similar imported goods
- the deductive value
- the computed value
- the value deduced by way of an appropriate fall-back method.

Registration

According to the Foreign Trade Law, all economic operators must register with the Registration Bureau of the State Administration for Industry and Commerce (SAIC), which is subordinate to the Ministry of Commerce of the P.R. of China (MOFCOM), or with one of the local record registration organs which come under the Ministry. Registration is generally conducted within two weeks and results in a Business Licence, which must be renewed periodically. Importers must, moreover, obtain an Import and Export Business Licence and a Customs Registration. For further details, please see the quoted documents.

In addition, all importers, exporters and customs agents residing in the P.R. of China are subject to an Enterprise Categorisation. All such enterprises are divided into five different categories (AA, A, B, C and D). Whereas business entities with an effective compliance management would be classified as AA or A and may expect certain facilitations, those classified as C or D may be subject to more elaborated inspections. Newly registered companies will be classified as category B. Please refer to the quoted document for procedural details of the classification and possible upgradings. The categorisation became effective in April 2008 and transposes the World Customs Organization (WCO) SAFE Framework of Standards, which aims at securing and facilitating global trade. The classification as an AA enterprise is equivalent to obtaining the status as authorised economic operator (AEO) in the framework of similar schemes conducted in other countries. Mutual recognition agreements (MRAs) with regard to their respective schemes have been signed with the European Union (EU), Hong Kong, New Zealand and Singapore. Since 3 November 2015, foreign trade participants recognised as AEO in the EU and in China may benefit from mutual advantages as regards security controls and customs clearance procedures.

Resident offices must also be registered with SAIC. This registration is to be renewed annually via the submission of a report containing information on the business performance and expenditures of the resident office as well as evidence for the existence of the foreign enterprise it represents. Upon registration of the resident office, evidence must be presented that the foreign enterprise has been in existence for at least two years. Furthermore, no more than four representatives, including one chief representative, may be designated by the foreign enterprise. A resident office of a foreign enterprise in the P.R. of China may not engage in commercial activities, but may carry out activities related to products and services of the represented foreign

enterprise, e.g. market surveys, displays and campaigns, liaison activities, service providing and domestic procurement and investment.

Trademarks intended to be used are to be registered at the China Trademark Office (CTMO) of the SAIC. Please refer to the document entitled Trademark Registration for details.

Government Procurement

The so-called "Buy Chinese" policy, based on the Chinese Government Procurement Law, stipulates that government agencies and related entities must preferably purchase goods produced or manufactured in the P.R. of China. Said goods may only be imported if they are unreasonably priced or not available in sufficient quantities in China, if the domestic goods are of unsatisfactory quality, or if the imported goods are to be used outside the P.R. of China.

Foreign Investment

In order to encourage foreign investments in China, the Chinese Government has gradually set up a relatively complex legal basis and constituted a foreign investment policy system. The main legislation applying to this field are the Company Law of the P.R. of China, the Law on Chinese-Foreign Equity Joint Ventures and the Measures for the Administration of Foreign Investment in Commercial Fields. The three main forms of foreign direct investment provided for in China are Chinese-foreign equity joint ventures, Chinese-foreign contractual joint ventures and wholly foreign-owned enterprises. Other investment forms include share companies with foreign investment, foreign investment holdings, joint exploitations and build-operate-transfer models.

Anti-Dumping and Anti-Subsidy

The Chinese legislation provides for anti-dumping measures in case of importation of commodities at low prices which cause a threat to domestic industries. Provisional anti-dumping duties may be raised or securities like bonds or deposits may be asked for. Anti-subsidy measures, e.g. in the form of anti-subsidy taxes or guarantees, may be taken if imported products are subsidised and have caused material injury or threaten to cause such injury to domestic industries.

Import Regulations

Import regulations of the People's Republic of China are still based on the quota and licence system to some extent. The Quota and Licence Administrative Bureau of the Ministry of Commerce (MOFCOM) is the authority responsible for the administration of these measures. As to licensing procedures, please see the documents Import Licence, Automatic Import Licence and Automatic Import Licence for New and Used Mechanical and Electronic Appliances for further details. Automatic import licences are considered as granted if the authority does not reject the application within 10 days. The quota system has been gradually reduced during the last years in order to cope with the World Trade Organization (WTO) requirements. Please see the document Customs Quota Certificate for Agricultural Products for further details.

Sanitary and Phytosanitary (SPS) Measures and General Importability of Goods Subject Thereto

Sanitary and Phytosanitary (SPS) measures may be applied within the territory of a country to protect the life and health of its population, fauna and flora from one or more of the following risks:

- diseases carried by animals
- plant pests (e.g. insects, bacteria, viruses)
- toxins or disease-causing organisms in foods, beverages or feedstuffs
- additives
- contaminants (e.g. heavy metals, residues of pesticides or veterinary drugs, extraneous matter).

SPS measures may be included in the relevant laws, decrees, regulations, requirements and procedures of a country or an economic community.

The Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization (WTO), also referred to as SPS Agreement, sets out the rules that the WTO member states are obliged to follow when they implement SPS measures governing food and feed safety, animal health and plant health. Said Agreement applies to all SPS measures which may, directly or indirectly, affect international trade. Every WTO member has the right to take respective measures to pursue the abovementioned protection goals. Under the WTO rules, countries are allowed to set their own standards, but their regulations are required to be based on scientific evidence and international standards, i.e. the imposed measures must be transparent and comprehensible. WTO members are to notify the content of a proposed sanitary or phytosanitary regulation, whether new or not substantially the same as the content of an international standard, guideline or recommendation, and the covered products to the WTO in advance.

International organisations working towards an international harmonisation of SPS measures include the World Organisation for Animal Health (OIE, former Office International des Epizooties, for animal health), the International Plant Protection Convention (IPPC, for plant health) and the Codex Alimentarius Commission (a joint Commission of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO), for food safety). In addition, the SPS Agreement offers technical assistance to developing countries with regard to capacity building and programmes concerning food safety, animal and plant health.

SPS measures must be in proportion to the potential risk involved and must be equally applied to national and imported goods. These measures may take various forms, such as requiring products to come from disease-free areas, specific treatment or processing of products, prescribing an inspection of products, quarantine regulations, setting the allowable maximum levels for pesticide residues, or permitting the use of only certain additives in food.

For any merchandise potentially bearing SPS risks, comprehensive risk assessment measures usually apply in order to ascertain whether the good is importable or not. This holds true in particular for animal or plant species or products which have previously not been traded between two countries. In the course of establishing the health standards to be met for a certain good,

specific conditions under which the particular item will be importable are usually defined, e.g. the mandatory fumigation treatment of designated plant produce or the vaccination of particular animal species against their characteristic diseases. Such terms are then reflected in the respective health certificate (i.e. those certificates mentioned in the chapters on animals, plants and products thereof in this overview).

Animals and Products of Animal Origin

Consignments of animals and products of animal origin are subject to a Commodity Inspection Certificate at the customs point of entry and are to be accompanied by either a Veterinary Health Certificate for Live Animals or a Veterinary Health Certificate for Animal Products. For the importation of live animals, a Permit to Import Live Animals and Plants Subject to Quarantine to be applied for at the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) is mandatory. Animal products may require a Certificate of Analysis. A Clearance Certificate for Products of Lawfully Captured Fish is required for the importation of designated fish and fish products. Said document is to be obtained from the Bureau of Fisheries under the Ministry of Agriculture.

For the importation of endangered animal species, please turn to the chapter on Endangered Species of Wild Fauna and Flora below.

With regard to issues concerning Sanitary and Phytosanitary (SPS) Measures, amongst others (please also refer to the same-named section above), the authority responsible for veterinary controls of live animals and animal products in the P.R. of China may be contacted as follows: Ministry of Agriculture of the P.R. of China, Veterinary Bureau, 11 Nongzhanguan Nanli, Chaoyang District, CN-100125 Beijing, phone numbers: +86 10 59191428, 59191492, fax number: +86 10 59191428.

Importers should note that specific temporary protective measures may be imposed on the import of animals or products of animal origin, e.g. as a consequence of the outbreak of contagious diseases. For further information on the animal health status of the country of origin, the World Animal Health Information System (WAHIS), a service provided by the World Organisation for Animal Health (OIE), may be consulted. Exporters are also advised to contact the importer, freight forwarder or the abovementioned authority for updated and detailed information concerning possible import prohibitions.

Pest Risk Analysis (PRA)

The P.R. of China applies pest risk analysis (PRA). On the national level, PRA is regulated by the Law of the People's Republic of China on the Entry and Exit Animals and Plants Quarantine and its implementing regulations. The International Standard for Phytosanitary Measures (ISPM) No. 2 setting the Framework for Pest Risk Analysis agreed upon in the scope of the International Plant Protection Convention (IPPC) provides the framework for PRA which has been accepted by the signatory countries.

A PRA is to be conducted on plants, plant products or other regulated articles by the National Plant Protection Organization (NPPO), i.e. the Plant Protection Office, if the risk associated with

their importation is unknown. This is usually the case if goods are imported to the country for the first time or if they are imported from a new area of origin. A PRA may also be required in further cases, e.g. if the goods are to be imported for a new intended use or if the phytosanitary legislation of the country of export has undergone changes. Moreover, the revision of an already existing PRA may be required, e.g. if a change in susceptibility of a plant to a pest or a change in the virulence or aggressiveness or host range of a pest has been identified. Depending on the outcome of the PRA, the NPPO develops and stipulates the specific phytosanitary requirements for the importation of the product in question as risk management measures.

In general, the PRAs are conducted following a process of mutual data exchange between the NPPOs in the countries of origin and destination. A stakeholder, e.g. plant exporter, importer or trader, would thus need to approach his NPPO to initiate a PRA. Usually, the PRA is to be applied for by the national stakeholder at the Chinese NPPO. According to Article XI of the Provisions for the Administration of Risk Analysis on Entry Plant and Plant Products of the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ), the relevant domestic units or individuals may submit an application and provide the necessary technical information. The NPPO may request further information from the NPPO in the country of export for the purpose of conducting the PRA.

There is currently no comprehensive list of completed PRAs available. However, the Ministry of Agriculture of the P.R. of China (MOA) published an Entry Quarantine Pest List in 2007 which is being updated if and as appropriate on the basis of newly completed PRAs.

PRAs are furthermore regulated by the national standards GB/T 20879-2007 ("Technical requirement of pest risk analysis for import and export plant and plant product") and GB/T 21658-2008 ("Guideline for pest risk analysis of import and export plant and plant product"), which may be obtained from the Standardization Administration of the P.R. of China (SAC), 9 Madian East Road, Haidian District, CH-100088 Beijing, phone number: +86 10 82262609.

The authority responsible for PRAs in the P.R. of China may be contacted as follows: Ministry of Agriculture of the P.R. of China (MOA), Plant Protection Office, 11 Nongzhanguan Nanli, Chaoyang District, CN-100125 Beijing, phone number: +86 10 59191451. For forest seeds and seedlings, the following competent body may be contacted: State Forestry Administration of the P.R. of China (SFA), He Ping Li East Road 18, CN-100714 Beijing, phone number: +86 10 84239104, fax number: +86 10 84238883.

In terms of commodity inspections, the authorities work in close cooperation with the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ), 9 Ma Dian East Rd., Hai Dian District, CN-100088 Beijing, phone number: +86 10 82262114, fax number: +86 10 82260011.

Plants and Plant Products

The importation of plants and plant products requires a Permit to Import Live Animals and Plants Subject to Quarantine and the goods are to be accompanied by a Phytosanitary Certificate. Goods subject to phytosanitary control will be scrutinised by a commodity inspection at the customs office of entry (pleaser refer to the document entitled Commodity Inspection Certificate for

further details). Certain plants and plant products used in agriculture fall under the quota regulations. Please see the document Customs Quota Certificate for Agricultural Products for further details. Manufactured products of plant origin may be subject to a Certificate of Analysis.

Crop seeds and seedlings may only be imported by holders of a Seed Business Licence for Import and Export issued by the General Office for Administrative Examination and Approval under the Ministry of Agriculture. Moreover, an Examination and Approval of Crop Seeds or Seedlings for Import and Export must be obtained. Breeders may apply for a Registration of New Plant Varieties, which entitles them to exclusively produce or sell the variety in question for commercial purposes and/or to licence other parties to do so.

For details of the requirement of a Pest Risk Analysis (PRA), please turn to the previous section.

Information on the importation of endangered species of wild flora may be obtained from the following section.

The authority responsible for phytosanitary control in the P.R. of China may be contacted as follows, inter alia concerning issues of Sanitary and Phytosanitary (SPS) Measures (please also turn to the same-named section above): Ministry of Agriculture of the P.R. of China, Plant Protection Office, 11 Nongzhanguan Nanli, Chaoyang District, CN-100125 Beijing, phone number: +86 10 59191451.

Endangered Species of Wild Fauna and Flora

In the framework of China's membership to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES - also referred to as Washington Convention), a Permit to Import Endangered Species and Products Thereof is to be obtained from the State Forestry Administration of the P.R. of China prior to international movements of said species into the country or accross its territory. Additional documentation must be enclosed in order to prove that the species or products are moved in accordance with the provisions of the Convention. Please turn to the quoted document for additional information.

Foodstuffs and Related Goods

The National Health and Family Planning Commission develops, where appropriate in conjunction with further responsible authorities, e.g. the Ministry of Agriculture or the China Food and Drug Administration (CFDA), mandatory national food safety standards. These concern threshold values (e.g. for pathogenic microorganisms, residues of pesticides and veterinary drugs, biotoxins and contaminants), approved food additives, their dosage and permissible application, requirements for nutritional ingredients of particular foodstuffs, labelling, hygienic and quality requirements as well as methods and procedures for food testing. Novel foodstuffs, new food additives and other food-related products, whether locally produced or imported, must undergo safety assessment by the Commission. Upon successful assessment, the Commission will issue a licence which allows for the production or importation, as applicable, of the goods in question.

Moreover, importers of foodstuffs and food additives are required to keep records on the importation and sale of such goods with regard to the product name, specification, quantity, production date, production or import batch number, shelf life (if applicable), name and contact information of the exporter and buyer and the delivery date. Said records and related documents are to be kept for at least six months after expiry of the shelf life of the product in question, or for at least two years after the transaction in case the product does not have a definite shelf life.

Foodstuffs in general may only be imported from exporters who are registered with the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ). Said registration takes place on an intergovernmental level and is administered by the Certification and Accreditation Administration of the P.R. of China (CNCA). For the purpose of this registration, the exporter's compliance with the relevant requirements is to be certified by the competent authority in the country of export. The latter is, moreover, to submit the national legislation on sanitary and related issues and further documentation for evaluation. A registration number will ultimately be assigned to the exporter, which is to be displayed on the product label of the respective goods. The registration is valid for four years.

Moreover, importers of foodstuffs and exporters of foodstuffs other than dairy products are required to register with the Filing Management System for Exporters/Agents and Consignees of Imported Food of the AQSIQ, while exporters of dairy products must register with the CNCA instead.

For details, please see the following documents:

- Registration of Foreign Exporters of Particular Foodstuffs
- Registration of Foreign Exporters of Dairy Products
- Registration of Importers of Foodstuffs.

Infant formula milk powders must be registered with the CFDA in order to be imported and marketed in the country. A manufacturer may register up to three product series of nine different recipes. Every series shall include the following stages: formulas for infants of 0-6 months (stage 1), 6-12 months (stage 2) and 12-35 months (stage 3). For further details of the registration, please turn to the document entitled Registration of Infant Formula Products. In addition, particular labelling requirements apply for infant formula. Please see the respective chapter below.

Processed foodstuffs are to be accompanied by a Certificate of Analysis, documenting the sanitary status of the product. Currently, a new Export Certificate for Foodstuffs, also including a prescribed sample form, is being implemented by the AQSIQ for all types of foodstuffs, including health food products and special dietary food, pastry and cookies, confectionary, flavourings, drinks, alcoholic beverages, preserved and canned fruit. However, a grace period until the end of September 2017 has been granted. Please turn to the quoted document for further particulars.

The labelling of imported foodstuffs will be checked by the AQSIQ at the customs point of entry upon the arrival of the shipment. Please see the document entitled Commodity Inspection Certificate for further details. Upon the release of the goods, they will be subject to a quality

control. A Registration of Health Food to be Imported is, in addition, required for foodstuffs with health claims.

There are regulations concerning the duration of storage for certain foodstuffs: The residual shelf life of these products must be at least half of the entire shelf life at the time of importation. For unprocessed food, the regulations detailed in the preceding two chapters on animal and plant products apply.

With regard to automatic import licences, which are required for tobacco products and few foodstuff items such as poultry meat and certain oils of plant origin, please refer to the section on import regulations in this overview. Imported and locally produced cigarettes may only be sold in China if the smoke of a cigarette does not contain more than 12 mg of tar.

Please refer also to the section on Packaging, Marking and Labelling Requirements below for the labelling requirements regarding pre-packaged foodstuffs intended for direct sale.

Genetically Modified Organisms (GMOs)

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD) is an international agreement which aims to ensure the safe handling, transport and use of modified organisms resulting from modern biotechnology which may have adverse effects on biological diversity, taking also into account risks to human health. The Protocol differentiates between five risk classes ranging from no-risk to high-risk GMOs, which are defined in the respective lists. The P.R. of China is a member of the Cartagena Protocol on Biosafety. Non-parties to the Protocol may nevertheless impose measures for the importation, placement on the market and use of GMOs. For member states, a facilitated procedure may be available in the form of an advanced informed agreement (AIA) on designated products.

In the scope of the Cartagena Protocol, the Biosafety Clearing House (BCH) is a platform for the exchange of scientific, technical, environmental and legal information on, and experience with, modified organisms. It also assists parties to implement the Protocol and has local branches in various countries. Further information may be obtained from the Biosafety Clearing House (BCH), 413, St. Jacques Street, Suite 800, CA-Montreal, Quebec, H2Y1N9, phone number: +1 514 2882220, fax number: +1 514 2886588.

The BCH in the P.R. of China is the Ministry of Environmental Protection, Department of Nature and Ecology Conservation, Division of Biodiversity Conservation (Office of Bio-Safety Management), 115 Xi Zhi Men South Road, Xi Cheng District, CN-100035 Beijing, phone number: +86 10 66556308.

Products containing GMOs must be labelled in accordance with the national labelling regulations; please refer also to the section on Packaging, Marking and Labelling Requirements below.

Pharmaceutical Products and Medical Devices

Medical devices and pharmaceutical products must be registered with the China Food and Drug Administration (CFDA). Manufacturing sites of medicinal products intended for human or veterinary use and their manufacturing methods must comply with the requirements of good manufacturing practice (GMP). A corresponding certification is therefore mandatory for the registration of human and veterinary medicines.

Medical devices are categorised as follows: while class I medical devices (low risk) are only registered for the record, class II (medium risk), class III (high risk) and not yet classified medical devices must undergo an evaluation process and the registration thereof is subject to approval by the CFDA. As of January 2016, such classes are defined according to whether the device is considered active or passive and whether or not it comes into direct contact with the human body. A large number of medical devices of classes II and III are exempt from the requirement of a prior clinical evaluation. For further information on such products and said procedure, please contact the Center for Medical Devices Evaluation of the China Food and Drug Administration (CFDA), 3-5/F, Tower B3, Five Buildings, 9 Chegongzhuang Street, Xicheng District, CN-1000442 Beijing, phone number: +86 10 68390606, fax number: +86 10 68390706.

The responsible authority for veterinary drugs is the Veterinary Drugs Department of the Ministry of Agriculture of the P.R. of China, Administration, Examination and Approval Office.

Psychotropic and narcotic drugs as well as substances that may be used for their manufacture require licences and permissions to be issued by the National Health and Family Planning Commission or the Quota and Licence Administration Bureau, respectively.

All commodities treated in this chapter will be inspected upon their actual importation. Imported medicinal products and drugs must be accompanied by appropriate certificates determining their specifications.

Please refer to the following documents for details on these procedures:

- Registration of Medicines
- Registration of Veterinary Drugs
- Registration of Medical Devices
- Licence to Import Dual Use Goods
- Permit to Import Narcotic Drugs and Psychotropic Substances
- Customs Release Certificate for Veterinary Drugs
- Inspection Certificate for Medicines
- Commodity Inspection Certificate
- Free Sale Certificate
- Certificate of Analysis
- Certificate of a Pharmaceutical Product
- Certificate of Good Manufacturing Practice
- Material Safety Data Sheet.

Within the framework of the country's healthcare reforms, a number of medical devices and pharmaceutical products are subject to price control measures in the P.R. of China.

For specific labelling requirements for pharmaceutical products and medical devices, please see the section on Packaging, Marking and Labelling Requirements.

Cosmetics

Cosmetic products must be registered with the China Food and Drug Administration (CFDA) of the P.R. of China. The authority differentiates between general cosmetics and special-purpose cosmetics. Moreover, new ingredients are to be registered with said authority before they may be used in cosmetic products. Please refer to the following documents related to the registration procedures:

- Registration of General Cosmetics
- Registration of Special-Purpose Cosmetics
- Registration of New Cosmetic Ingredients
- Certificate of Analysis
- Free Sale Certificate.

Imported cosmetics are subject to inspection conducted by the China Inspection and Quarantine Services (CIQ) of the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ) upon arrival.

Non-Agricultural Chemical Substances

The importation of chemical substances is supervised by the Ministry of Environmental Protection of the P.R. of China (MEP). New chemical substances must be registered with the Ministry's Chemical Registration Center (CRC-MEP) before they are placed on the market for the first time. Please refer to the following documents:

- Registration of New Chemical Substances (Regular Declaration)
- Registration of New Chemical Substances (Simplified Declaration)
- Material Safety Data Sheet.

The responsible authority will decide, whether a regular declaration is required or a simplified declaration is sufficient. A different registration procedure is necessary for new chemical substances intended for scientific research. Please contact the responsible authority for further information.

For certain chemicals, MEP requires a Registration of Environmental Management on Import/Export of Toxic Chemicals. In addition, an Environmental Control Release Notice for Toxic Chemicals is necessary for each actual importation of these substances.

Certain ozone-depleting substances (ODS) may only be imported if an Import Quota for Ozone-Depleting Substances has been allotted to the importer. An Import Licence is also required for ODS. China runs a phase-out programme for ODS. The production and consumption of chlorofluorocarbons (CFCs), as well as Halon, CFC-13 and CTC (carbon tetrachloride) have been prohibited since 2010. The importation and exportation of CFCs as a refrigerant in

compressors and related products for the refrigeration industry had already been forbidden since March 2006. Trichloroethane (TCA) was phased out by 2015.

Paint products to be imported must be inspected and subsequently be registered with the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ). Please see the document entitled Registration of Paint to be Imported for further details.

For specific labelling requirements for hazardous substances, please refer to the section on Packaging, Marking and Labelling Requirements below.

Agricultural Chemical Substances

Specific measures apply to chemical substances for agricultural application. Namely, pesticides to be imported must be registered with the Institute for the Control of Agrochemicals, Ministry of Agriculture of the P.R. of China (ICAMA). The General Administration of Customs and the Ministry of Agriculture have launched an electronic network verification system to manage and supervise the import and export of pesticides. The system, which enables an inter-departmental exchange of data and thus facilitates customs clearance procedures, allows enterprises registered with the system to submit applications for the Registration of Pesticides via the internet, to check the application status and also to receive certification online.

Please note that a registration with the CRC-MEP as described in the section on Non-Agricultural Chemical Substances above may nevertheless also be required.

Please turn to the chapter on Packaging, Marking and Labelling Requirements for specific labelling requirements for pesticides.

Hazardous Goods

China is a member of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, commonly known as the Rotterdam Convention. This Convention undertakes to ensure that exports of designated chemical substances may only take place with the consent of the importing party. By means of the prior informed consent (PIC) procedure, information is gathered and disseminated as to whether an importing party wishes to receive future shipments of a certain chemical and to ensure the compliance with that decision by the exporting party. The treaty further requires all parties to notify the Convention Secretariat about any national legal changes with regard to a ban or a severe restriction of a chemical. In terms of the actual shipment of a product, information about the characteristics of the chemical must be provided, labelling requirements adhered to and stipulations such as the indication of the HS Code in the shipping documents met, thus guaranteeing the sound handling of such substance.

In case a company is seeking to export chemicals which are covered by the Convention (i.e. the pesticides and industrial chemicals listed in Annex III of the Convention) or which are subject to national regulatory action (i.e. bans or severe restrictions in the importing country's own

territory), an export notification must be sent to the Designated National Authority (DNA) of the importing country nominated to this effect in order to obtain prior consent. For further information, please refer to the document entitled Export Notification for Goods Coming under the Rotterdam Convention.

In addition to the Rotterdam Convention, China is also party to the Stockholm Convention on Persistent Organic Pollutants (also referred to as the POP Convention), a treaty designed to curb and eventually abolish the production, use and trade of toxic, long-lasting chemicals by requiring its signatories to take measures to eliminate or restrict the production and use of POPs and to minimise any possible unintentional releases of such substances into the environment. Exemptions, i.e. the continued use and/or production of one or more chemicals covered by the treaty for a certain period of time, may be applied for by the member states. Furthermore, amendments to the treaty (lastly done so in 2009 with the addition of nine more chemicals to the original list of twelve chemicals) are subject to the approval and ratification of each signatory state, thereby allowing the country time to implement the measures required to adhere to the new stipulations. As a consequence, imports and exports of the chemicals covered by the Stockholm Convention may be subject to prohibitions or severe restrictions. Importers are also advised to contact the responsible authority for issues of nature protection, i.e. the Official Contact Point (OCP). The OCP in the P.R. of China is the Ministry of Environmental Protection, Foreign Economic Cooperation Office, Office of the National Coordination Group for Stockholm Convention Implementation, No. 5, Hou Ying Fang Lane, Xi Cheng District, CN-100035, Beijing, phone number: +86 10 82268810, fax number: +86 10 82200510.

Standardisation

Goods imported into China must comply with the applied Chinese standards. Mandatory certification is required for a wide range of products subject to regular reviews. Please see the document China Compulsory Certification (CCC) for further details. The submission of a Declaration of Conformity is a prerequisite for the certification and may also be required for customs clearance and market access of goods not subject to CCC.

Small amounts of goods subject to compulsory certification according to the catalogue may qualify for a Special Processing Programme (SPP). This holds especially true for products which would not obtain the CCC mark, due to diverging norms, if the importer can accredit that these products are needed for special purposes in the P.R. of China (as an example, spare parts for pieces of equipment required in manufacturing processes may be granted access to the Chinese market through SPP). Certain special equipment, such as boilers and pressure vessels, are not subject to compulsory certification but require a separate Special Equipment Manufacture Licence.

Regarding the content of certain hazardous substances in electrical and electronic appliances, designated products intended for the Chinese market must be accompanied by a Certificate on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS-Certificate) and/or a corresponding declaration or disclosure put up in Standard Chinese. This measure corresponds to procedures initiated by the RoHS (Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment) Directive 2002/95/EC. Please refer to the quoted document for further details.

Efforts towards the harmonisation of Chinese standards with international standards and cooperations with standardisation authorities in other countries are under way, e.g. in the framework of the German-Chinese Standardization Cooperation Commission and the Europe-China Standardization Information Platform. The latter provides general information on a number of Chinese standards, e.g. with regard to electrical equipment, medical devices, machinery, environmental protection, aerosol containers, packaging, textile products, toys and child care articles and leather, and may be accessed at: https://webgate.ec.europa.eu/cesip. It should be noted that the actual standard documents are to be purchased from the Standardization Administration of the P.R. of China (SAC), 9 Madian East Road, Haidian District, CN-100088 Beijing, phone number: +86 10 82262609.

Radio Transmission Equipment

A Type Approval for Radio Transmission Equipment is to be obtained from the State Radio Regulatory Commission (SRRC) under the Ministry of Industry and Information Technology of the P.R. of China (MIIT) to ensure that said equipment conforms to the relevant standards and norms. The type approval is also a prerequisite for the Permit to Import Radio Transmission Equipment, which is to be applied for at the same authority. Please refer to the quoted documents for details.

Motor Vehicles

Motor vehicles to be imported into the P.R. of China fall into two categories. On the one hand, the importation of certain used machinery is forbidden; please refer to the document Prohibition to Import Certain Used Machinery and Electrical Equipment. On the other hand, in general, an Automatic Import Licence for New and Used Mechanical and Electronic Appliances is necessary and additional standardisation requirements are to be met. Upon the release of the goods, they will be subject to a commodity inspection, which is also required for particular motor vehicle parts. Please refer to the document entitled Commodity Inspection Certificate.

Industrial Technologies

The importation of certain kinds of technologies into the P.R. of China is prohibited or restricted, as stipulated in the catalogues released by the Ministry of Commerce of the P.R. of China (MOFCOM). Technologies the importation of which is restricted require a licence, which is to be applied for at the Department of Scientific and Technological Development and Trade in Technology under the MOFCOM. Other kinds of technologies are freely importable, but nevertheless require a registration of the respective technology import contract with the same authority. Please refer to the following documents for further information:

- Licence to Import and Deal in Technology
- Registration of Technology Import Contract.

Waste

China is a member of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal. Furthermore, China has ratified and implemented the Decision III/1 on an amendment to the Basel Convention. The so-called Ban Amendment, which has not entered into force as an international treaty to date, aims at prohibiting all transboundary movements of waste from OECD countries, EU Member States and Liechtenstein to other, especially developing, countries. China is thus not an importer of hazardous wastes as defined by the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal.

The Chinese authorities differentiate between three categories of waste: prohibited waste, automatically permitted solid waste and restricted solid waste. Designated waste materials (e.g. human hair, waste petroleum products, pharmaceutical waste, sugar cane molasses, mica waste, waste of silicone content, scrap of vulcanised rubber, wastes of leather) are prohibited from importation; please refer to the document entitled Import Prohibition for further information.

Permissible waste imports may not be intended for final disposal. Such waste may only be imported as raw materials for recovery purposes. The National Center of Solid Waste Management, which is subordinate to the Ministry of Environmental Protection, issues two different types of import permits, depending on the type of waste:

- Automatic Permit to Import Solid Waste
- Permit to Import Restricted Solid Waste.

Exporters must, in addition, apply at the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ) for a Registration as an Overseas Supplier of Rubbish Material. Please refer to the quoted documents in this section for further details of the said procedures.

Please refer also to the document entitled Pre-Shipment Inspection Certificate for Scrap Material and the section on Pre-Shipment Inspection (PSI) below.

Designated non-hazardous waste may be eligible for importation into China, e.g. tungsten carbide scrap or wastes of animal hair. The Organisation for Economic Co-operation and Development (OECD) provides a guideline for the international trade in said goods by virtue of its Decision of the Council concerning the Control of Transboundary Movements of Wastes Destined for Recovery Operations. A corresponding OECD guidance manual has been developed.

The OECD control system is based on two types of control procedures (please note that waste exported outside the OECD area, whether for recovery or final disposal, does not benefit from this control system):

- green control procedure: for wastes that present a low risk for human health and the environment and, therefore, are not subject to any other controls than those normally applied in commercial transactions
- amber control procedure: for wastes presenting sufficient risk to justify their control accordingly.

By way of example, the European Union (EU) approved the aforementioned Decision. Therefore, consignments of waste being exported from the EU are subject to the basic Regulation (EC) No 1013/2006 on shipments of waste and its amendments. In order to assist countries outside the OECD to ensure that these import only the types of waste they agree to, exports of non-hazardous waste for recovery purposes to such countries are regulated. Potential destination countries therefor provide information on permissible waste by completing respective questionnaires for non-hazardous waste and for mixtures of waste. China has already replied to said questionnaires and various types of waste have consequently been classified as follows:

- prohibited waste (e.g. worn clothing and other worn textile articles)
- waste subject to prior written notification and consent as described in Article 35 of Regulation (EC) No 1013/2006; to be controlled by the customs authorities of the EU Member State from which the waste is exported (China has not yet notified materials which may come under this category)
- waste not subject to specific control measures (China has not yet notified materials which may come under this category)
- control procedures, which are to be followed in China under its applicable national laws (e.g. the above-mentioned tungsten carbide scrap and wastes of animal hair); usually subject to the formalities listed further above and to be controlled by the Chinese customs authorities at the time of the importation of the waste into China.

The applicable legal basis is Regulation (EC) No 1418/2007 (as amended). As the waste codes set out by the Basel Convention and the Harmonized System (HS) codes may only be compared on a rough level, the Chinese authorities should be consulted prior to the importation of materials coming under the last point on the list above.

More information, the applicable legal stipulations and completed questionnaires may be found on the following website: http://ec.europa.eu/trade/import-and-export-rules/export-from-eu/waste-shipment.

Used Goods

A number of used goods, including certain used machinery and second-hand electrical products, are banned from being imported into the P.R. of China by order of the Ministry of Commerce (MOFCOM). For other second-hand goods, e.g. used mechanical and electronic appliances, an automatic import licence must be applied for by the importer at the same authority. Such goods must also be registered with the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ). Please refer to the documents listed below for further information:

- Registration of Used Machinery and Electrical Equipment
- Automatic Import Licence for New and Used Mechanical and Electronic Appliances
- Prohibition to Import Certain Used Machinery and Electrical Equipment.

Please refer also to document entitled Pre-Shipment Inspection Certificate for Used Machinery and Electrical Equipment and the section on Pre-Shipment Inspection (PSI) below.

Pre-Shipment Inspection (PSI)

A number of commodities, e.g. metal, plastic and paper scrap as well as certain used machinery and electrical equipment require a pre-shipment inspection (PSI) in the country of export. The inspection is to be applied for by the exporter at a local branch of the Certification and Inspection (Group) Company (CCIC), an inspection company authorised by the Certification and Accreditation Administration of the P.R. of China (CNCA) under the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ). Please refer to the following related documents for further information:

- Pre-Shipment Inspection Certificate for Scrap Material
- Pre-Shipment Inspection Certificate for Used Machinery and Electrical Equipment.

Please refer also to the sections on Waste and Used Goods above.

Commercial Samples

In general, commercial samples and advertising material with or without commercial value is subject to the same requirements as commercial consignments. Commercial samples of a value below 50 CNY may be imported duty-free in accordance with the Chinese customs legislation. For this purpose, the goods are to be accompanied by a Pro Forma Invoice including the statement "no commercial value". In case of express deliveries of samples, the Customs Registration number of the importer is to be additionally stated.

Harmonized System

As a multipurpose international product nomenclature, the Harmonized Commodity Description and Coding System (HS), commonly referred to as Harmonized System, constitutes a universal economic language and code for goods.

Developed and continuously enhanced by the World Customs Organization (WCO), the HS consists of over 1,200 four-digit headings grouped in 97 chapters, which are arranged into 21 sections. Most of the headings are further subdivided into five-digit or six-digit subheadings. In total, the Harmonized System comprises about 5,000 commodity groups, each identified by a six-digit code (HS Code). HS Codes are identical in different countries, provided the latter apply the same version of the HS. The classification of goods into HS-based nomenclatures generally follows the same principles. In trade practice, however, it may not be necessarily the same.

In an interval of usually five years, the Harmonized System is kept up to date reflecting changes in technology or in international trade volumes. The sixth revision of the HS becomes effective in 2017, replacing the former version referred to as HS 2012. Although intended for the beginning of 2017, the implementation of the new HS version as well as the adaptation of related non-tariff measures may take place at varying points in time in different countries.

Requirements for Import Formalities

Import documents may be presented in any language, but it is advisable to submit them in either English or Chinese, or to enclose an appropriate translation. In general, application forms should be completed in the same language as used therein.

Not only in view of the periodic amendments of the HS, commodity codes and related descriptions included in commercial documents should always contain a reference to the nomenclature basis, e.g. HS 2012 or HS 2017 (please refer to the section on the Harmonized System above). In case the commodity codes indicated go beyond the six-digit level of the HS and refer to the tariff nomenclature of the destination country, these codes should be adjusted with the importer.

Exporters should bear in mind that besides officially required documentation, additional necessities may result from contractual agreements with the importer. If a sales contract or a letter of credit (L/C) stipulates that particular documents are to be supplied by the exporter, their provision constitutes an obligation, regardless of official requirements. Moreover, customs or further authorities may request additional documentation if they consider the information given in the customary documentation as insufficient or doubtable. Besides necessities of the authorities, importers or forwarders, requirements for import documentation are also influenced by trade practice.

Incoterms®

Responsibilities of sellers and buyers concerning the delivery of goods under international sales contracts are frequently defined by the so-called Incoterms®. These International Commercial Terms, created by the International Chamber of Commerce (ICC), constitute authoritative rules for the allotment of costs and risks to the parties of sales contracts. Because of the determination of how costs are allocated to the parties, Incoterms® are also used for purposes of customs valuation. It is generally advisable to refer to a specific edition (e.g. Incoterms® 2010) when Incoterms® are included into contracts or trade documents. If no explicit reference to a version is made, the use of the current 2010 edition will be assumed.

The current edition of the Incoterms® 2010 stipulates the following eleven rules:

- **... for sea transport (and inland waterways):**
  - **Free alongside Ship:** FAS
  - **Free on Board:** FOB
  - **Cost and Freight:** CFR
  - **Cost, Insurance and Freight:** CIF
- **... for any mode(s) of transport:**
  - **Ex Works:** EXW
  - **Free Carrier:** FCA
  - **Carriage paid to:** CPT
  - **Carriage and Insurance paid to:** CIP
  - **Delivered at Terminal:** DAT
  - **Delivered at Place:** DAP
  - **Delivered Duty paid:** DDP

If the DDP rule is used, the exporter is responsible for the customs and import clearance of the goods. The importer, however, is required to assist the exporter in obtaining official authorisations where applicable. Therefore, this term should not be used if the exporter is not in the position to either directly or indirectly arrange for the clearance of the commodities.

Legalisation of Documents

All supporting documentation prepared by the exporter is to be legalised by the Embassy or Consular Section of China in the country of export. Prior to this legalisation, the documents are to be certified by either a chamber of commerce or by a notary, depending on the nature of the particular documents. The official full name of the country in which the documents will be presented is usually required to feature on the document (People's Republic of China), i.e. the denomination "China" is not sufficient.

Translations, where required, are usually to be prepared by sworn translators and regularly necessitate an additional certification by the competent authority, e.g. the respective court. The Embassy may moreover set supplementary conditions, e.g. that photocopies of original documents are to be enclosed for the archives of the representation, or that all documents to be legalised are to be enlisted in a specific form.

Currency and Payments

The most widely used mode of payment for imports is the Letter of Credit (L/C). L/Cs with a longer term duration (in general more than 90 days) require a prior permit by the State Administration of Foreign Exchange (SAFE). The customs authorities must confirm the commercial papers if the total value of the transaction exceeds 100,000 USD. A bank guarantee is required for any deposit payment exceeding 30,000 USD. As these limits may be subject to adjustment by the Chinese authorities, please contact the Chinese importer for the currently valid limits. Short-term trade transactions may also be regulated via documentary collections. For most import procedures, a copy of the business contract is required.

The Yuan Renminbi (CNY) is the official currency of the P.R. of China (1 CNY = 10 Jiao = 100 Fen). The exchange rate is regulated by the Chinese Government. The CNY (also commonly referred to as RMB) is not yet fully convertible. To achieve its aims of full convertibility and a cautious internationalisation of its currency, the Chinese Government has implemented a programme on cross-border settlements of payments in CNY. The programme has expanded to be operable worldwide apart from its initial restriction to trade activities with Hong Kong, Macau and the ASEAN member states (i.e. Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand, Vietnam). Starting from 2011, the Central Bank of China has enabled Chinese importers and exporters to transact in CNY. A number of foreign banks already enables exporters to open accounts in CNY for cross-border trade settlement.

Country of Origin Labelling

Country of origin labelling is not legally required for all goods. It is, however, a prerequisite to market designated commodities in the P.R. of China, especially merchandise intended for the local consumer, as indicated in the following section. In general, it is advisable to mark

consignments with the country of origin, as the Chinese customs authorities examine imported goods to this effect. If no such information is marked on the packages, the customs authorities may disregard the origin of the goods in terms of any preferential treatment, if applicable, and an additional surcharge may be payable.

The country of origin labelling on the merchandise and/or its packaging should correspond to the origin stated on the commercial documents. It should be borne in mind that any indication of a country on the commodity itself may be valued as a declaration of origin. In case of any doubts, it is advisable to contact the importer.

Packaging, Marking and Labelling Requirements

Marking

The correct wording for the destination marking of consignments intended to be exported to China is "People's Republic of China" (P.R. of China). The denomination "China" alone is not sufficient. The marking of consignments intended to be exported to China must be clearly printed in inerasable letters in English and Chinese.

The following details must be marked on consignments to be imported into the P.R. of China in accordance with the applicable national standard GB/T 6388-1986 in Chinese and English:

- classification symbol as prescribed by the standard
- contract number
- sequential number of the consignment
- specifications (product name or HS Code, indication of the model, size, colour etc.)
- quantity contained in the consignment
- gross and net weight
- date of manufacture (year/month/day)
- name of the manufacturer
- volume of the consignment
- best before date (month/year), if applicable
- place of destination
- name of the consignee
- name of the consignor
- transport number
- shipping number.

General product labelling

For most products intended to be sold to the final consumer without re-packaging, e.g. foodstuffs and cosmetic products, labelling in Chinese is mandatory. The minimum content of the labels comprises:

- name and address of the manufacturer
- name, address, and contact information of the local agent

- registration number/product licence number in China
- kind of product (and function, if applicable)
- brand name
- list of ingredients and their quantities
- generic names of food additives, if applicable
- net weight
- conditions of storage
- date of manufacture
- expiry date, if applicable
- lot numbers and product codes
- product standard code, if applicable
- country of origin
- description of the way of preparation, if applicable.

Labelling of foodstuffs

The foreign exporter's registration number assigned by the Certification and Accreditation Administration of the P.R. of China (CNCA) must be displayed on the product label of foodstuffs.

Nutritional labelling is compulsory for certain foodstuffs. The nutrition label is an integral part of the foodstuffs label and must be designed to provide the consumer with a clear description of all nutritional components of the foodstuff and their respective values. A catalogue of foodstuff varieties which are subject to mandatory nutritional labelling is published by the National Health and Family Planning Commission; please contact the Commission for further information: Xi Zhi Men Wai South Rd. 1, CN-100044 Beijing, phone number: +86 10 68792114, fax number: +86 10 68792024.

Irradiated or genetically modified foodstuffs must be labelled accordingly. Infants' foods must, in addition, bear the following details:

- nutrients and nutritional value
- method of preparation
- intended age group
- name and address of the Chinese importer.

Additional requirements apply to infant formula, which is to be labelled in accordance with the Chinese standard GB 10765-2010 and further stipulations by the China Food and Drug Administration (CFDA). The Chinese requirements for the labelling of infant formula are based on the respective standard by the Codex Alimentarius. The following information is to be provided:

- product name
- clear statement of the source of protein (e.g. based on cows' milk/goat's milk/whey), percentage of the sources of protein, if more than one
- list of ingredients, including the names of edible vegetable oil in decreasing order of weight

- declaration of nutritive value, stating the amount of energy, protein, fat, carbohydrate, vitamins, minerals and optional ingredients
- specific source or country of origin (statements such as "imported milk" or similar are not permissible)
- date marking and storage instructions
- instructions for use
- Registration of Infant Formula Products number.

Labels of infant formula must not contain information which express or imply that the product may be used for the prevention or treatment of diseases or that it has any health effects. Phrasing as to what the product does not contain are neither permissible (e.g. "does not contain ..."). Content which violates scientific principles, is false, exaggerated or inconsistent with the product registration is also prohibited.

A sample of the intended product label and of the instructions for use must be submitted to the CFDA for the purpose of the Registration of Infant Formula Products, together with supporting material. Consignments of infant formula may not be relabelled upon arrival.

The following information is required for wine in addition to the general labelling requirements for foodstuffs listed above:

- alcoholic strength by volume
- product standard numbers
- quality level.

Labelling of pharmaceuticals and medical devices

Labels of pharmaceutical products must be approved by the China Food and Drug Administration (CFDA) and are to contain the following information:

- common name of the pharmaceutical product
- indication or function
- specifications
- list of ingredients
- application and dosage form
- possible adverse reactions
- contraindications
- dates of manufacture and expiry
- lot number
- contact details of the manufacturer (name, address, postal code, phone number, country of origin)
- storage conditions.

In case of particular medicines, e.g. anesthetics, radioactive or toxic medicines, a specific sign must be printed or attached to the product package.

Labels of medical devices are to provide information as follows:

- product name
- type
- size
- name, address and contact details of the registrant or his agent
- Registration of Medical Devices number
- name, address and contact details of the manufacturer and his production licence number
- date of manufacture
- period of use or expiry date
- conditions for power supply and input power, if applicable
- callout graphic of the device
- warning and precautions, if applicable
- instructions for storage and use
- graphic or verbal warning that the device is harmful to the environment or emits radiation, if applicable.

If the size of the label of a medical device is small, at least the following information must be provided: product name, type, size, date of manufacture, period of use or expiry date and an indication towards further instructions.

Labelling of hazardous substances

Specific labelling requirements also apply for hazardous substances. Information as follows is to be displayed on the labels of such goods:

- name of the hazardous substance in Chinese and English
- main hazardous ingredient, its content and concentration
- molecular formula
- dangerous goods code (UN number)
- respective pictograms and signal words
- indication of the dangerous character of the hazardous substance (inflammable, explosive etc.) and associated harmful effects on human and animal health and the environment
- safety precautions
- production date
- lot number
- contact details of the manufacturer (name, address, postal code, phone number, country of origin)
- emergency phone number or chemical accident and emergency inquiry phone number located in the P.R. of China
- prompt to refer to the relevant Material Safety Data Sheet (MSDS)
- measures to be taken in case of accidents.

Labelling of pesticides

The following details are to be provided on the labels of pesticides:

- registered product name
- list of ingredients
- Registration of Pesticides number
- evidence that the manufacturer is an approved producer of pesticides
- applied product standard code
- net weight
- dates of manufacture and expiry
- lot number
- contact details of the manufacturer (name, address, postal code, phone number, country of origin)
- contact details of the manufacturer's Chinese agency, if applicable
- toxicity category and the respective signal word
- handling conditions for transportation and storage
- first-aid measures in case of poisoning.

Samples of pesticides labels must be submitted to the Ministry of Agriculture for approval before they may be used.

Labelling of electrical and electronic consumer goods

Energy efficiency labelling is compulsory for a number of consumer goods, such as household electrical appliances (e.g. refrigerators, freezers, air conditioners, air compressors, ventilators, household cookers, rice cookers, microwave ovens, water heaters, washing machines, self-ballasted lamps, high-pressure sodium lamps, DC switches, transformators), industrial devices (e.g. electric motors, cooling systems) as well as IT equipment and similar goods (e.g. computer monitors, copiers, flat-screen television sets, printers, fax machines, digital TV receivers, microcomputers). The following information must be provided on the energy efficiency label:

- name or shortened form of the producer
- specification/type of the product
- grading of energy efficiency
- energy consumption
- implemented standard code for energy efficiency
- quick response (QR) code, allowing the consumer to consult the appropriate energy efficiency information online.

Prior to the marketing of the goods, modified labels - including those for which a QR code has been introduced for the first time - must be presented to the China Energy Label Center (CELC) for approval. Manufacturers and importers of goods subject to compulsory energy efficiency labelling must submit an annual report on their use of such labels in the previous year to the CELC before 15 March of the following year.

Labelling of goods subject to China Compulsory Certification (CCC)

All goods subject to China Compulsory Certification (CCC) must bear the CCC mark.

Packaging

Hay and straw may be used as packaging materials if accompanied by a Phytosanitary Certificate. They will be subject to a phytosanitary inspection.

China has been applying the International Standard for Phytosanitary Measures (ISPM) No. 15 for wood packaging material (WPM) since 2006. All WPM must bear the ISPM No. 15 compliant mark and thus must have been treated with the appropriate quarantine sanitisation treatment methods. Coniferous wood as packaging material must additionally be free of bark. Although, according to China Announcement No. 2002/58 and Notices No. 11 and 32/2005, a Phytosanitary Certificate is not required for such WPM, problems in getting shipments cleared without a Phytosanitary Certificate have been reported. Previously required fumigation or disinfection certificates should not be required by the Chinese authorities any longer. If non-wooden packaging materials are used, it is recommended to enclose a Declaration of Non-Wood Packaging Material to be provided by the exporter.

It should be considered that packages are often stored in the open. Consequently, they should be water-resistant. As transportation is at times difficult, packages may be subject to rough treatment and should thus be shock-proof and extremely hard-wearing. Instructions on the proper handling of packages should be given in Chinese. Exporters are advised to consult the importer for more specific information on product labelling and packaging.

Codes douaniers

29411000 PENICILLINE

30067000 GEL POUR OPERATION CHIRURGICALE

PENICILLINE

Registration of Medicines

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 2941:

Only required for 2941.10.11, 2941.10.12, 2941.10.19, 2941.10.91, 2941.10.92, 2941.10.94, 2941.10.95, 2941.10.96, 2941.10.99, 2941.20.00.11, 2941.20.00.90, 2941.30.11, 2941.30.12, 2941.30.20, 2941.40, 2941.50, 2941.90.10, 2941.90.20, 2941.90.30, 2941.90.40, 2941.90.52, 2941.90.53, 2941.90.54, 2941.90.55, 2941.90.56, 2941.90.57, 2941.90.58, 2941.90.59.10, 2941.90.59.90, 2941.90.60, 2941.90.70, 2941.90.90.11, 2941.90.90.12, 2941.90.90.90

A document certifying that medicines are registered with the China Food and Drug Administration (CFDA).

Required for market access and customs clearance.

Chinese name of the document = 进口药品注册申请表或医药产品注册申请表 (Jin Kou Yao Pin Zhu Ce Shen Qing Biao)

The registration is to be applied for by the importer at the respective provincial department of the China Food and Drug Administration (CFDA), 26 Xuanwumen Xidajie, CN-100053 Beijing, phone number: +86 10 68313344, fax number: +86 10 68310909.

The application is to be completed in both Chinese and English as indicated.

To be submitted in duplicate as a hard copy and in an electronic format.

The processing time is approximately six months.

The processing fee is 45,300 CNY.

The period of validity of the registration is three years.

1. Information to be provided:
    1. China Food and Drug Administration
    2. application for the Registration of Medicines
    3. original code
    4. application code
    5. application details
    6. application classification: import medicines
    7. registration classification: Chinese traditional medicines – chemical medicines – organic products for treatment – organic products for prevention – other
    8. additional application details: non-prescription drugs – reducing or free of clinical research – international multicentre clinical research – other
    9. description of the medicine
    10. designation of the medicine
    11. English/Latin name

12. Pinyin
13. chemical name
14. other designation
15. commodity name: not used – used, Chinese name: ... English name: ...
16. source of the designation of the medicine: National Drug Standards – National Pharmacopoeia Commission – literature – self-design
17. non-preparations: active pharmaceutical ingredient (API) – Chinese crude drugs – prepared slices of Chinese crude drugs – effectual ingredients – preparation intermediate – other
18. preparations: type, strength
19. belongs to: preparation type in the Chinese Pharmacopoeia – new type, English name:
20. packing standard
21. minimum durability in months
22. medicinal active ingredients in the preparation and dosage
23. dosage of excipients in the preparation
24. origin of chemical drug substances in the preparation: manufacturer in China – import registration – not registered – another application (original code: ...)
25. name of the manufacturing company
26. address of the manufacturing company
27. Chinese crude drugs standard in the preparation: all legal – including illegal, name of the drug: ...
28. drug standard accords to: Chinese Pharmacopoeia Edition: – published by the CFDA Volume – self-designed standard – registered standard and code – name and edition of the foreign pharmacopoeia
29. indications or functions
30. usage, dosage
31. relevant information
32. special control drugs: no – yes: narcotic drugs – psychotropic substances – toxic drugs for medial use – radioactive pharmaceuticals
33. patent: Chinese patent, including medical patent – technical patent – other patent
34. patent open to public inspection
35. patent authorised, patentee:
36. expiry date
37. patentee's approval of application obtained: yes – no
38. foreign patent, patentee:
39. drugs protection in the same variety: administrative protection, expiry date – Chinese traditional medicine protection, expiry date – new medicine protection, expiry date
40. drugs protection applied for previously
41. control period for new drugs in the same variety: no – yes, period from ... to ...
42. this application is: first application
43. reapplication, and treatment for first application is:
44. withdrawn, reason
45. refused, date and reason
46. allowed free sale in foreign countries: no – not clear – yes, name of country/region and date

47. applicant
48. organisation 1 (company)
49. organisation is responsible for payment
50. Chinese name
51. English name
52. legal representative
53. position
54. registered/manufacture address
55. country/region
56. person responsible for the application
57. signature
58. position
59. telephone number
60. fax number
61. e-mail address
62. organisation 2 (manufacturer)
63. organisation 3 (packaging factory abroad): no – yes
64. organisation 4: none
65. organisation 5: none
66. agency for the registration of drugs
67. this agency is responsible for payment
68. name of the agency
69. organisation code
70. legal representative
71. position
72. registered address
73. postal code
74. contact person
75. position
76. telephone number (including area code and extension number)
77. fax number
78. e-mail address
79. declaration
80. We assure that: 1) this application abides by the relevant laws and regulations, such as: Drug Administration Law of the People's Republic of China, implement statute of Drug Administration Law of the People's Republic of China, provisions for medicine registration; 2) the information in this form and the enclosed materials and samples are legitimate, legal and do not infringe upon the rights and interests of others. The methods and data of examination and research stem from the relevant drugs to be applied for; 3) the content of the electronic application form is completely in accordance with the content of the printed one. We bear all legal responsibilities for any untrue information.
81. other supplementary information
82. name, seal, signature of the legal representative of each organisation and date
83. name, seal, signature of the legal representative of the agency for drug registration and date
84. to be completed by the CFDA official

85. After examination we confirm that this application form is completed according to our requirements.
86. examination organisation
87. signature of the examiner
88. date: year, month, day
89. The applicant must use this form designed by the CFDA and fill in, modify and print it through software. The filled contents of the application form should not be altered. Checkback data code: ... .

2. Documents to be enclosed:
    - Free Sale Certificate
    - evidence of the manufacturer's adherence to WHO production standards (e.g. Certificate of Good Manufacturing Practice, certificate of good laboratory practice, Certificate of a Pharmaceutical Product, Material Safety Data Sheet)
    - Certificate of Analysis
    - samples of the medicine
    - samples of the label and package leaflet of the medicine
    - samples of packages

国家药品监督管理局 1

药品注册申请表 2

021202

原始编号：3
申请编号：4

申请事项

1. 申请分类：○ 进口药品
2. 注册分类：○ 中药____类 ○ 化学药品____类 ○ 治疗用生物制品____类
○ 预防用生物制品____类 ○ 其他：-
3. 附加申请事项：□ 非处方药 □ 减或者免临床研究 □ 国际多中心临床研究 □ 其他：

药品情况

4. 药品名称：
5. 英文名/拉丁名：
6. 汉语拼音：
7. 化学名：

8. 其他名称：
9. 商品名称：○ 不使用 ○ 使用，中文： 英文：
10. 药品名称来源：○ 国家药品标准 ○ 国家药典委员会 ○ 文献 ○ 自拟

11. 非制剂：○ 原料药 ○ 中药材 ○ 中药饮片 ○ 有效成份 ○ 制剂中间体 ○ 其他：
12. 制剂：剂型： 规格：
属于：○ 《中国药典》剂型 ○ 新剂型，英文：
13. 包装规格：
14. 药品有效期： 个月
15. 处方内药物活性成份或者中药药味(均含处方量)：

16. 处方内辅料(含处方量)：

17. 制剂中化学原料药来源：○ 境内生产 ○ 进口注册 ○ 未注册 ○ 另行申报(原始编号：)
生产企业名称：
生产企业地址：
18. 制剂中的中药材标准：○ 全部法定 ○ 含非法定者，药材名称：

19. 药品标准依据：○ 《中国药典》_____版 ○ 局颁_____第____册
○ 自拟标准 ○ 注册标准及标准编号： ○ 国外药典及版次：

20. 主要适应症或者功能主治：

21. 给药途径及特殊用法：

相关情况

22. 是否特殊管理药品：○ 否 ○ 是：□ 麻醉药品 □ 精神药品 □ 医疗用毒性药品 □ 放射性药品
23. 专利： □ 有中国专利：□ 药物专利 □ 工艺专利 □ 其他专利：
34 ○ 已公开 35 已授权 专利权人：
36 专利到期日期： 37 本申请是否得到专利权人的实施许可： ○ 是 ○ 否
38 □ 有外国专利： 专利权人：
39 24. 同品种药品保护：□ 药品行政保护 保护截止日期：
□ 中药品种保护 保护截止日期： 40 □ 已知有申请者
□ 原新药保护 保护截止日期：
41 25. 同品种新药监测期：● 无 ○ 有，起始日期： 终止日期：
26. 本次申请为：○ 首次申请 42 ○ 再次申请，其首次申请：□ 曾经撤回，原因：43 44
□ 曾被退审(或者退回)，日期： 原因：
45

46 27. 境外是否获准上市：○ 否 ○ 不详 ○ 是，国家(地区)： 日期：

本表必须使用国家药品监督管理局制发的申请表填报软件填写、修改和打印，不得涂改。 数据核对码：

47 申请人

48 28. 机构1（公司）：

49 □ 本机构负责缴费

中文名称： 50

英文名称： 51

法定代表人： 52　　职位： 53

注册地址： 54　　国家或地区： 55

注册申请负责人： 56　　签名： 57　　职位： 58

电　　话： 59　　传真： 60

电子信箱： 61

62 29. 机构2（生产厂）：

中文名称： 50

英文名称： 51

法定代表人： 52　　职位： 53

生产地址： 54　　国家或地区： 55

注册申请负责人： 56　　签名： 57　　职位： 58

电　　话： 59　　传真： 60

电子信箱： 61

63 30. 机构3（国外包装厂）：　● 无　○ 有

中文名称： 50

英文名称： 51

生产地址： 54　　国家或地区： 55

注册申请负责人： 56　　签名： 57　　职位： 58

电话： 59　　传真： 60

电子信箱： 61

64 31. 机构4：　●无

65 32. 机构5：　●无

66 药品注册代理机构

67 □ 本机构负责缴费

68 33. 机构名称：

组织机构代码：69

法定代表人：70　　职位：71

注册地址：72　　邮政编码：73

联系人：74　　职位：75

电话(含区号及分机号)：76　　传真：77

电子信箱：78

79 申　明

80 34. 我们保证：①本申请遵守《中华人民共和国药品管理法》、《中华人民共和国药品管理法实施条例》和《药品注册管理办法》等法律、法规和规章的规定；②申请表内容及所提交资料、样品均真实、来源合法，未侵犯他人的权益，其中试验研究的方法和数据均为本药品所采用的方法和由本药品得到的试验数据；③一并提交的电子文件与打印文件内容完全一致。

如查有不实之处，我们承担由此导致的一切法律后果。

81 35. 其他特别申明事项：

82 36. 各申请机构名称、公章、法定代表人签名、签名日期：

83 37. 药品注册代理机构名称、公章、法定代表人签名、签名日期：

84 官方填写

经审查，本表填写符合形式审查要求。85

审查机关：86　　审查人签名：87　　日期：88　年　月　日

89 本表必须使用国家药品监督管理局制发的申请表填报软件填写、修改和打印，不得涂改。数据核对码：

Last updated: 26 Jun 2017

Inspection Certificate for Medicines

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 2941:

Only required for 2941.10.11, 2941.10.12, 2941.10.19, 2941.10.91, 2941.10.92, 2941.10.94, 2941.10.95, 2941.10.96, 2941.10.99, 2941.20.00.11, 2941.20.00.90, 2941.30.11, 2941.30.12, 2941.30.20, 2941.40, 2941.50, 2941.90.10, 2941.90.20, 2941.90.30, 2941.90.40, 2941.90.52, 2941.90.53, 2941.90.54, 2941.90.55, 2941.90.56, 2941.90.57, 2941.90.58, 2941.90.59.10, 2941.90.59.90, 2941.90.60, 2941.90.70, 2941.90.90.11, 2941.90.90.12, 2941.90.90.90

A document certifying that medicines have been inspected and that their importation has been approved.

Required for customs clearance.

Chinese name of the document = 进口药品报验单 (Jin Kou Yao Pin Bao Yan Dan)

The certificate is to be applied for by the importer at the China Food and Drug Administration (CFDA), 26 Xuanwumen Xidajie, CN-100053 Beijing, phone number: +86 10 68313344, fax number: +86 10 68310909. In addition, the CFDA has offices in major ports.

The application is to be completed in Chinese.

To be submitted in duplicate as a hard copy and in an electronic format.

The processing time varies.

The processing fee varies depending on the value of the goods to be imported.

The certificate is valid for a single importation only.

1. Information to be provided:
    1. application form for an Inspection Certificate for Medicines
    2. first importation, yes/no (please check correct box)
    3. name of the medicinal product
    4. in Chinese
    5. in English
    6. brand name
    7. in Chinese
    8. in English
    9. form of the drug
    10. specification of the drug
    11. pattern of packaging
    12. expiry date of the drug
    13. number of Registration of Medicines
    14. contract number
    15. inspection standard
    16. period of compensation claim
    17. quantity of goods
    18. value of goods
    19. batch/lot number
    20. Bill of Lading number
    21. port of dispatch
    22. date of dispatch
    23. means of transportation
    24. competent customs office
    25. port of destination
    26. date of arrival
    27. place of storage
    28. name of the manufacturer
    29. country
    30. name of the consignor
    31. information on the consignee
    32. name
    33. address
    34. responsible contact person(s)
    35. phone number
    36. seal of the consignee, date (year, month, day)
    37. information on the applicant
    38. licence number for drug manufacture or drug supply
    39. documents to be attached
2. Documents to be enclosed (in duplicate):
    - Registration of Medicines in the original or as a copy
    - business contract
    - copy of Commercial Invoice
    - Packing List
    - copy of Bill of Lading or Air Waybill
    - Certificate of Analysis

- Free Sale Certificate
- Certificate of Non-Preferential Origin
- specific specimens of the packaging, the labels and leaflets

1 进 口 药 品 报 验 单

HS 商品编码： 2 首次品种：是□ 否□

1.药品名称 3	中文： 4 英文： 5			2.商品名 6	中文： 7 英文： 8		
3.剂型	9	4.规 格	10	5.包装规格	11	6.药品有效期	12
7.注册证号	13	8.合同号/唛头	14	9.检验标准	15	10.索赔期	16
11.货物数量	17	12.货值	18	13.批号/件数	19	14.提运单号	20
15.发货港（地）	21	16.发货日 期	22	17.运输工具（航/班次）	23	18.负责海关	24
19.到岸港（地）	25	20.到岸日 期	26	21.存货地点	27		
22.生产厂家	28					国 家	29
23.发货单位	30					国 家	29
24.收货单位 31	名 称 32						
	地 址 33					（公 章） 年 月 日 36	
	联系人 34		电 话	35			
25.报验单位 37	名 称 32					药品经营或生产许可证证号	38
	地 址 33					（公 章） 年 月 日 36	
	联系人 34		电 话	35			
26.所附资料	39						

Last updated: 26 Jun 2017 Top

Certificate of Analysis

China

Last updated on 26 Jun 2017

A document confirming that microbiological and physical/chemical tests have been carried out by an appropriate laboratory in the country of export.

Required for customs clearance and market access.

Chinese name of the document = **分析**证书 (Fen Xi Zheng Shu)

The Chinese authorities will accept the certificates issued by an appropriate and duly accredited laboratory in the country of export if all relevant information is provided.

To be prepared in Chinese or English.

No specific form required.

- Minimum content:
  - date of the analyses
  - name, address and stamp of laboratory which has carried out the analyses
  - name, commercial name and description of the samples and their features, including batch numbers, if applicable
  - test methods and maximum levels allowed
  - results of the physical/chemical tests
  - results of the microbiological tests, if applicable
  - name and signature of the responsible official of the concerned laboratory

Please note:

The specific conditions for the Certificate of Analysis depend on the country of export and the particular product. For example, in case of wine to be imported into the P.R. of China, the certificate must state the content of sulphur dioxide and sulphites to ensure that the relevant threshold values are adhered to.

For a sample of a Certificate of Analysis for China, see the following document:

CERTIFICATE OF ANALYSIS

NAME OF PRODUCT: SILICON DIOXIDE BATCH NO.: 99104
REPORT DATE: JAN 6, 1999

ITEMS	STANDARDS	RESULTS
CHARACTERISTICS:	WHITE COMFORTABLE POWDER	PASS
IDENTIFICATION:	AS STIPULATED	PASS
PH:	5.0 – 7.5	6.5
CHLORIDE:	0.5% MAX.	PASS
NON-VOLATILE SUBSTANCES IN HF:	5.0% MAX.	2.2%
LOSS ON DRYING:	5.0% MAX.	3.6%
IRON SALT:	0.02% MAX.	PASS
HEAVY METALS:	0.005% MAX.	PASS
As:	0.0005% MAX.	PASS
BACTERIAL NUMBER:	1000/G MAX.	PASS
MOULD NUMBER:	100/G	PASS
LARGE INTESTINE BACILUS:	N.D.	PASS
ACTIVE MITE:	N.D.	PASS
CONCLUSION:	CONFORMS	

Last updated

Free Sale Certificate

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 2941:

Only required if intended for pharmaceuticals

A document confirming that the goods in question are freely sold in the country of export.

May be required for customs clearance and market access. The document is usually a prerequisite for the registration of medicinal and related products, e.g. cosmetics.

Chinese name of the document = 自由销售证明 (Zi You Xiao Shou Zheng Ming)

In general, the certificate is issued by an appropriate authority or another institution in the country of export, e.g. the chamber of commerce.

The Free Sale Certificate may be prepared in any language. However, a translation into English or Chinese is recommended.

1. Minimum content:
    - name and address of the manufacturer
    - name and properties of the product
    - place and date of issue
    - signature and seal of the issuing authority/institution
2. For a sample of a Free Sale Certificate, see the document below:

韓國 (Korea)

식품의약품안전청
Korea Food & Drug Administration

Korea Food And Drug Administration

5 Nokbun-dong, Eunpyung-Ku, Seoul, 122-704, Republic of Korea
Tel: +82-2-380-1690, Fax: +82-2-388-6394

CERTIFICATE OF FREE SALES

┌ No. of Certificate :
├ Exporting (certifying) country :
└ Importing (requesting) country :

The Korea Food and Drug Administration, certifies that the following firm is authorized to manufacture medical devices under The Medical Device Law and the following item(s) is permitted to be freely sold in domestic and overseas markets.

o Applicant
Name :
Address :
Registered No. :

Name of product	Model	No . And date of product-license, comments
	See Attachment	

Commissioner
Korea Food and Drug Administration

Last updated

Certificate of Good Manufacturing Practice

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 2941:

Only required for 2941.10.11, 2941.10.12, 2941.10.19, 2941.10.91, 2941.10.92, 2941.10.94, 2941.10.95, 2941.10.96, 2941.10.99, 2941.20.00.11, 2941.20.00.90, 2941.30.11, 2941.30.12, 2941.30.20, 2941.40, 2941.50, 2941.90.10, 2941.90.20, 2941.90.30, 2941.90.40, 2941.90.52, 2941.90.53, 2941.90.54, 2941.90.55, 2941.90.56, 2941.90.57, 2941.90.58, 2941.90.59.10, 2941.90.59.90, 2941.90.60, 2941.90.70, 2941.90.90.11, 2941.90.90.12, 2941.90.90.90

A document certifying that a manufacturing site of medicinal products intended for human or veterinary use to be imported and its manufacturing methods comply with the requirements of good manufacturing practice (GMP).

Required for customs clearance and market access.

The competent authority for pharmaceuticals intended for human use is the China Food and Drug Administration (CFDA), 26 Xuanwumen Xidajie, CN-100053 Beijing, phone number: +86 10 68313344, fax number: +86 10 68310909.

For veterinary medicinal products, the responsible body is the Ministry of Agriculture of the P.R. of China, Administration, Examination and Approval Office, Veterinary Drugs Department, 11 Nong Zhan Nan Li Road, CN-100125 Beijing, phone number: +86 10 59191812, fax number: +86 10 59192048.

The certificate is to be issued by a competent authority in the country of export.

No specific form required. The certificate is to contain the details shown in the model below.

The certificate may be prepared in any language. However, a translation into English or Chinese is recommendable.

- For a sample of a Certificate of Good Manufacturing Practice as recommended by the World Health Organization (WHO), see the following document:

Letterhead of regulatory authority

Model Certificate of Good Manufacturing Practices

This one-page certificate conforms to the format recommeded by the World Health Organization (general instructions and explanatory notes attached).[1]

Certificate No: _____

On the basis of the inspection carried out on ____ [date] ____ we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1. Name and address of site:

_____

2. Manufacturer's licence number:

_____

3. Table 1:

Dosage form(s)	Category(ies)	Activity(ies)

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until ____ [date] ____ It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Address of certifying authority:

_____

Name and function of responsible person:

_____

Email: _____ Telephone no.: _____ Fax no.: _____

Signature: Stamp and date:

_____

[1] This model certificate for GMP is not part of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Explanatory notes

(1) This certificate, which is in the format recommeded by WHO, certifies the status of the Site listed in point 1 of the certificate.

(2) The certification number should be traceable within the regulatory authority issuing the certificate.

(3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in case where there is no legal framework for the issuing of a licence.

(4) Table 1

List the dosage forms, starting materials, categories and activities. Examples give below.

Example 1

Pharmaceutical Product(s)[2]	*Category(ies)*	*Activity(ies)*
Dosage form(s):		
Tablets	Cytotoxic	Packaging
	Hormone	Production, packaging, quality control
	Penicillin	Repackaging and labelling
Injectables	Cefalosporin	Aseptic preparation, packaging, labelling

Example 2

Pharmaceutical Product(s)[2]	*Category(ies)*	*Activity(ies)*
Starting material(s):[3]		
Paracetamol	Analgesic	Synthesis, purification, packing, labelling

[2] Pharmaceutical Products: Any medicine intended for human use or veterinary product administered to food-producing animals, presented in its finished dosage for or as a starting material for use in such a dosage form, that is subject to control by pharmaceutical legislation in both the exporting state and the importing state.

[3] Starting Materials: Any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

Use, whenever available, International Nonproprietary Names (INNs) or otherwise national nonproprietary names.

(5) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.

(6) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in *Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2*, 1999. World Health Organization, Geneva and subsequent updates.

Last updated: 26 Jun

Certificate of a Pharmaceutical Product

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 2941:

Only required for 2941.10.11, 2941.10.12, 2941.10.19, 2941.10.91, 2941.10.92, 2941.10.94, 2941.10.95, 2941.10.96, 2941.10.99, 2941.20.00.11, 2941.20.00.90, 2941.30.11, 2941.30.12, 2941.30.20, 2941.40, 2941.50, 2941.90.10, 2941.90.20, 2941.90.30, 2941.90.40, 2941.90.52, 2941.90.53, 2941.90.54, 2941.90.55, 2941.90.56, 2941.90.57, 2941.90.58, 2941.90.59.10, 2941.90.59.90, 2941.90.60, 2941.90.70, 2941.90.90.11, 2941.90.90.12, 2941.90.90.90

A document certifying that pharmaceuticals to be registered conform to internationally acknowledged standards as stipulated by the World Health Organization (WHO).

May be required for the registration of pharmaceuticals.

No specific form required.

The certificate is usually prepared in English. A translation into Chinese may, however, be required.

The Chinese authorities accept certificates issued by an appropriate laboratory in the country of export if all relevant information is provided.

To be submitted in the original.

- For a sample of a Certificate of a Pharmaceutical Product, please see the following document:

Model Certificate of a Pharmaceutical Product

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

No. of certificate

Exporting (certifying country):

Importing (requesting country):

---

1. Name and dosage form of the product:

Active ingredient(s)[2] and amount(s) per unit dose[3]:
For complete composition including excipients, see attached [4]:

1.2. Is this product licensed to be placed on the market for use in the exporting country?[5]
(*Key in as appropriate*)

1.3 Is this product actually on the market in the exporting country?
(*Key in as appropriate*)

yes ***no*** ***unknown***

If the answer to 1.2. is yes, continue with section 2A and omit section 2B. If the answer to 1.2 is no, omit section 2A and continue with section 2B[6]:

2.A.1. Number of product licence[7] and date of issue:

2.A.2. Product licence holder (name and address):

2.A.3. Status of product licence holder[8]:

(Key in appropriate category as defined in note 8)

2.A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

2.A.4. Is a summary basis for approval appended?[10]

(*Key in as appropriate*)

yes ***no***

2.A.5. Is the attached, officially approved product information complete and consonent with the licence?[11]

(*Key in as appropriate*)

yes ***no*** ***not provided***

2.A.6. Applicant for certificate, if different from licence holder (name and address)[12]:

2.B.1. Applicant for certificate (name and address):

2.B.2. Status of applicant:

(*Key in appropriate catergory as defined in footnote 8)*

2.B.2.1. For categories (b) and (c) the name and address of the manufacturer producing the dosage form is:[9]

2.B.3. Why is marketing authorization lacking?

(*Key in as appropriate*)

not required ***not requested***

under consideration ***refused***

2.B.4. Remarks[13]:

---

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced

(*Key in as appropriate*)

If not or not applicable, proceed to question 4.

yes ***no*** ***not applicable***

3.1. Periodicity of routine inspections (years):

3.2. Has the manufacture of this type of dosage form been inspected?

(*Key in as appropriate*)

yes ***no***

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

(*Key in as appropriate*)

yes ***no*** ***not applicable***

---

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product[16]: *(Key in as appropriate)*

If No, explain:

yes ***non***

Address of certifying authority:

Telephone

Fax

Name of authorized person:

Signature/Firma /Signature:

General instructions

Please refer to the guidelines for full instructions on how to complete this form and information on the implementation of the Scheme.

The forms are suitable for generation by computer. They should always be submitted as hard copy, with responses printed in type rather than handwritten.

Additional sheets should be appended, as necessary, to accommodate remarks and explanations.

Explanatory notes

[1] This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.

[2] Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.

[3] The formula (complete composition) of the dosage form should be given on the certificate or be appended.

[4] Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.

[5] When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.

[6] Sections 2A and 2B are mutually exclusive.

[7] Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.

[8] Specify whether the person responsible for placing the product on the market:

(a) manufactures the dosage form;

(b) packages and/or labels a dosage form manufactured by an independent company; or

(c) is involved in none of the above.

[9] This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information.

It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.

[10] This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.

[11] This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)

[12] In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.

[13] Please indicate the reason that the applicant has provided for not requesting registration.

(a) the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;

(b) the product has been reformulated with a view to improving its stability under tropical conditions;

(c) the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;

(d) the product has been reformulated to meet a different maximum dosage limit for an active ingredient;

(e) any other reason, please specify.

[14] Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.

[15] The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).

[16] This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.

Last updated: 26 Jun

Material Safety Data Sheet

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 2941:

Only required for 2941.10.11, 2941.10.12, 2941.10.19, 2941.10.91, 2941.10.92, 2941.10.94, 2941.10.95, 2941.10.96, 2941.10.99, 2941.20.00.11, 2941.20.00.90, 2941.30.11, 2941.30.12, 2941.30.20, 2941.40, 2941.50, 2941.90.10, 2941.90.20, 2941.90.30, 2941.90.40, 2941.90.52, 2941.90.53, 2941.90.54, 2941.90.55, 2941.90.56, 2941.90.57, 2941.90.58, 2941.90.59.10, 2941.90.59.90, 2941.90.60, 2941.90.70, 2941.90.90.11, 2941.90.90.12, 2941.90.90.90

A document containing details of chemical substances or products with regard to their potential hazards and providing instructions for the handling of the goods.

May be required for customs clearance and market access.

No specific form required.

The data sheet is to be prepared by the manufacturer, supplier or importer in Chinese or English.

For a sample of a Material Safety Data Sheet, please see the document below:

Material Safety Data Sheet

Hydrogen chloride, 1 - 2N solution in diethylether

Section 1 - Chemical Product and Company Identification

MSDS Name: Hydrogen chloride, 1 - 2N solution in diethylether
Catalog Numbers: 36846-0000, 36846-1000, 36847-0000, 36847-1000
Synonyms: Muriatic acid

Company Identification:

Company Identification: (USA)

For information in the US, call:
For information in Europe, call:
Emergency Number, Europe:
Emergency Number US:
CHEMTREC Phone Number, US:
CHEMTREC Phone Number, Europe:

Section 2 - Composition, Information on Ingredients

CAS#	Chemical Name:	%	EINECS#	Hazard Symbols:	Risk Phrases:
60-29-7	Diethylether	96.4%	200-467-2	F+ XN	12 19 22 66 67
7647-01-0	Hydrogen chloride	3,6-7,2%	231-595-7	C T	23 35

Text for R-phrases: see Section 16

Hazard Symbols: XN F+

Risk Phrases: 12 19 22 66 67

Section 3 - Hazards Identification

EMERGENCY OVERVIEW

Extremely flammable. May form explosive peroxides. Harmful if swallowed. Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness and dizziness.Hygroscopic (absorbs moisture from the air).Light sensitive.Air sensitive.

Potential Health Effects

Eye: May cause eye irritation. May cause painful sensitization to light.

Skin: May cause skin sensitization, an allergic reaction, which becomes evident upon re-exposure to this material. Prolonged and/or repeated contact may cause defatting of the skin and dermatitis.

Ingestion: Harmful if swallowed. May cause irritation of the digestive tract. Causes gastrointestinal irritation with nausea, vomiting and diarrhea. May cause systemic toxicity with acidosis. May cause liver and kidney damage. May cause circulatory system failure. May cause central nervous system

depression, characterized by excitement, followed by headache, dizziness, drowsiness, and nausea. Advanced stages may cause collapse, unconsciousness, coma and possible death due to respiratory failure.

Inhalation: May cause severe irritation of the respiratory tract with sore throat, coughing, shortness of breath and delayed lung edema. May cause drowsiness, unconsciousness, and central nervous system depression. Vapors may cause dizziness or suffocation. Exposure to the mist and vapor may erode exposed teeth.

Chronic: Prolonged or repeated skin contact may cause dermatitis. Prolonged or repeated skin contact may cause defatting and dermatitis. Repeated exposure may cause erosion of teeth. Prolonged or repeated exposure can cause psychic abnormalities such as anxiety, depression and excitability.

Section 4 - First Aid Measures

Eyes: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical aid immediately.

Skin: Get medical aid immediately. Immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

Ingestion: Do not induce vomiting. If victim is conscious and alert, give 2-4 cupfuls of milk or water. Get medical aid immediately.

Inhalation: Get medical aid immediately. Remove from exposure and move to fresh air immediately. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Notes to Physician: Treat symptomatically and supportively.

Section 5 - Fire Fighting Measures

General Information: As in any fire, wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. Vapors may form an explosive mixture with air. Vapors can travel to a source of ignition and flash back. Extremely flammable liquid and vapor. May form explosive peroxides. Containers may explode when heated.

Extinguishing Media: Use water spray to cool fire-exposed containers. Use dry chemical, carbon dioxide, or alcohol-resistant foam.

Section 6 - Accidental Release Measures

General Information: Use proper personal protective equipment as indicated in Section 8.

Spills/Leaks: Remove all sources of ignition. Absorb spill using an absorbent, non-combustible material such as earth, sand, or vermiculite. Do not use combustible materials such as sawdust. Use a spark-proof tool. Provide ventilation.

Section 7 - Handling and Storage

Handling: Use only in a well-ventilated area. Use spark-proof tools and explosion proof equipment. Contents may develop pressure upon prolonged storage. Do not breathe dust, vapor, mist, or gas. Do not get in eyes, on skin, or on clothing. Take precautionary measures against static discharges. Use only in a chemical fume hood. If peroxide formation is suspected, do not open or move container. Use caution when opening. Keep from contact with moist air and steam.

Storage: Keep away from heat, sparks, and flame. Keep away from sources of ignition. Do not store in direct sunlight. Store in a tightly closed container. Keep under a nitrogen blanket. Store in a cool, dry, well-ventilated area away from incompatible substances. Flammables-area.

Section 8 - Exposure Controls, Personal Protection

Engineering Controls:

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. Use adequate ventilation to keep airborne concentrations low.

Exposure Limits

CAS# 60-29-7:

United Kingdom, WEL - TWA: 100 ppm TWA; 310 mg/m3 TWA United Kingdom, WEL - STEL: 200 ppm STEL; 620 mg/m3 STEL

United States OSHA: 400 ppm TWA; 1200 mg/m3 TWA

Belgium - TWA: 100 ppm VLE; 308 mg/m3 VLE Belgium - STEL: 200 ppm VLE; 616 mg/m3 VLE

France - VME: 100 ppm VME; 308 mg/m3 VME France - VLE: 200 ppm VLE; 616 mg/m3 VLE

Germany: 400 ppm TWA; 1200 mg/m3 TWA

Japan: 400 ppm OEL; 1200 mg/m3 OEL

Malaysia: 400 ppm TWA; 1210 mg/m3 TWA

Netherlands: 200 ppm STEL; 616 mg/m3 STEL Netherlands: 100 ppm MAC; 308 mg/m3 MAC

Russia: 300 mg/m3 TWA (vapour)

Spain: 100 ppm VLA-ED; 308 mg/m3 VLA-ED Spain: 200 ppm VLA-EC; 616 mg/m3 VLA-EC

CAS# 7647-01-0:

United Kingdom, WEL - TWA: 1 ppm TWA (aerosol mist and gas); 2 mg/m3 TWA (aerosol mist and gas) United Kingdom, WEL - STEL: 5 ppm STEL (aerosol mist and gas); 8 mg/m3 STEL (aerosol mist and gas)

United States OSHA: ; 5 ppm Ceiling; 7 mg/m3 Ceiling

Belgium - TWA: 5 ppm VLE; 8 mg/m3 VLE Belgium - STEL: 10 ppm VLE; 15 mg/m3 VLE

France - VLE: 5 ppm VLE; 7.6 mg/m3 VLE

Germany: 8 mg/m3 TWA

Japan: 5 ppm Ceiling; 7.5 mg/m3 Ceiling

Malaysia: 5 ppm Ceiling; 7.5 mg/m3 Ceiling

Netherlands: 10 ppm STEL; 15 mg/m3 STEL Netherlands: 5 ppm MAC; 8 mg/m3 MAC

Spain: 5 ppm VLA-ED; 7.6 mg/m3 VLA-ED Spain: 10 ppm VLA-EC; 15 mg/m3 VLA-EC

Personal Protective Equipment

Eyes: Wear chemical splash goggles.

Skin: Wear appropriate protective gloves to prevent skin exposure.

Clothing: Wear appropriate protective clothing to prevent skin exposure.

Respirators: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Section 9 - Physical and Chemical Properties

Physical State: Clear liquid

Color: colorless

Odor: Not available

pH: Not available

Vapor Pressure:	Not available
Viscosity:	Not available
Boiling Point:	Not available
Freezing/Melting Point:	Not available
Autoignition Temperature:	Not available
Flash Point:	-40 deg C (-40.00 deg F)
Explosion Limits: Lower:	Not available
Explosion Limits: Upper:	Not available
Decomposition Temperature:	Not available
Solubility in water:	Soluble
Specific Gravity/Density:	0.731
Molecular Formula:	HCl
Molecular Weight:	36.46

Section 10 - Stability and Reactivity

Chemical Stability:	Prolonged exposure to air and sunlight may form unstable peroxides.
Conditions to Avoid:	Mechanical shock, incompatible materials, light, ignition sources, temperatures above 150°C, exposure to moist air or water.
Incompatibilities with Other Materials	Strong oxidizing agents, bases.
Hazardous Decomposition Products	Hydrogen chloride, carbon monoxide, carbon dioxide.
Hazardous Polymerization	Will not occur.

Section 11 - Toxicological Information

RTECS#:

CAS# 60-29-7: KI5775000
CAS# 7647-01-0: MW4025000 MW4031000

LD50/LC50:

RTECS:
CAS# 60-29-7: Draize test, rabbit, eye: 100 mg Moderate;
Inhalation, mouse: LC50 = 31000 ppm/30M;
Oral, mouse: LD50 = 1760 mg/kg;
Oral, rat: LD50 = 1215 mg/kg;
Skin, rabbit: LD50 = >20 mL/kg;
.
RTECS:
CAS# 7647-01-0: Inhalation, mouse: LC50 = 1108 ppm/1H;
Inhalation, mouse: LC50 = 20487 mg/m3/5M;
Inhalation, mouse: LC50 = 3940 mg/m3/30M;
Inhalation, mouse: LC50 = 8300 mg/m3/30M;
Inhalation, rat: LC50 = 3124 ppm/1H;
Inhalation, rat: LC50 = 60938 mg/m3/5M;
Inhalation, rat: LC50 = 7004 mg/m3/30M;
Inhalation, rat: LC50 = 45000 mg/m3/5M;
Inhalation, rat: LC50 = 8300 mg/m3/30M;
Oral, rabbit: LD50 = 900 mg/kg;
.

Carcinogenicity: Diethylether - Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65.
Hydrogen chloride - IARC: Group 3 (not classifiable)

Other: The toxicological properties have not been fully investigated. See actual entry in RTECS for complete information.

Section 12 - Ecological Information

Other: Do not empty into drains.

Section 13 - Disposal Considerations

Dispose of in a manner consistent with federal, state, and local regulations.

Section 14 - Transport Information

	IATA	IMO	RID/ADR
Shipping Name:	FLAMMABLE LIQUID, CORROSIVE, N.O.S.*	FLAMMABLE LIQUID, CORROSIVE, N.O.S.	FLAMMABLE LIQUID, CORROSIVE, N.O.S.
Hazard Class:	3 (8)	3 (8)	3 (8)
UN Number:	2924	2924	2924
Packing Group:	I	I	I

USA RQ: CAS# 60-29-7: 100 lb final RQ; 45.4 kg final RQ
USA RQ: CAS# 7647-01-0: 5000 lb final RQ; 2270 kg final RQ

Section 15 - Regulatory Information

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: XN F+

Risk Phrases:

R 12 Extremely flammable.

R 19 May form explosive peroxides.

R 22 Harmful if swallowed.

R 66 Repeated exposure may cause skin dryness or cracking.

R 67 Vapours may cause drowsiness and dizziness.

Safety Phrases:

S 9 Keep container in a well-ventilated place.

S 16 Keep away from sources of ignition - No smoking.

S 29 Do not empty into drains.

S 33 Take precautionary measures against static discharges.

WGK (Water Danger/Protection)

CAS# 60-29-7: 1

CAS# 7647-01-0: 1

Canada

CAS# 60-29-7 is listed on Canada's DSL List

CAS# 7647-01-0 is listed on Canada's DSL List

US Federal

TSCA

CAS# 60-29-7 is listed on the TSCA Inventory.

CAS# 7647-01-0 is listed on the TSCA Inventory.

Section 16 - Other Information

Text for R-phrases from Section 2

R 12 Extremely flammable.

R 19 May form explosive peroxides.

R 22 Harmful if swallowed.

R 23 Toxic by inhalation.

R 35 Causes severe burns.

R 66 Repeated exposure may cause skin dryness or cracking.

R 67 Vapours may cause drowsiness and dizziness.

MSDS Creation Date: [redacted]
Revision #2 Date [redacted]

Revisions were made in Sections: General revision.

Last updated: 26 Jun 2017

GEL POUR OPERATION CHIRURGICALE

Registration of Medicines

Commodity Inspection Certificate

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 3006:

Only required for 3006.20, 3006.30

A document certifying that commodities have been inspected and that their importation has been approved. Depending on the kind of commodities, the certificate may be a prerequisite for further inspection and customs procedures.

Required for customs clearance.

Chinese name of the document = **入境**货物报检单 (Ru Jing Huo Wu Bao Jian Dan)

The certificate is to be applied for by the importer at the General Administration for Quality Supervision, Inspection and Quarantine of the P.R. of China (AQSIQ), 9 Ma Dian East Rd., Hai Dian District, CN-100088 Beijing, phone number: +86 10 82262114, fax number: +86 10 82260011.

The application is to be completed in Chinese.

To be submitted in the original.

The processing time varies.

The processing fee varies depending on the type of goods to be imported. For certain goods a fixed charge per item or unit is payable, in other cases a product-specific ad valorem rate applies.

The certificate is valid for a single importation only.

1. Information to be provided and documents to be enclosed:
    1. application form for Commodities Inspection Certificate
    2. full name of the applicant (stamp)
    3. code number
    4. registration number of the applicant
    5. contact person
    6. phone number
    7. date of application
    8. year, month, day
    9. consignor's full name
    10. in Chinese
    11. in English
    12. consignee's full name
    13. name of the goods (in Chinese/English)
    14. HS Code numbers
    15. country of origin
    16. quantity/weight
    17. total value
    18. category and quantity of packages
    19. name and number of the means of conveyance
    20. mode of trade
    21. depository of goods
    22. contract number
    23. letter of credit (L/C) number
    24. application/intended use
    25. date of consignment
    26. country (region) of destination
    27. licence/authorisation number
    28. port of loading
    29. port of entry
    30. registration number of manufacturer
    31. specification of the container, quantity and code
    32. specific terms and requirements of the contract
    33. marks and numbers
    34. enclosed documents (Mark where applicable. If some special documents are not listed, fill them in the blank.)
    35. business contract
    36. L/C
    37. Commercial Invoice
    38. voucher of changing documents
    39. Packing List
    40. inspection document, issued by factory

41. result document of packing capability
42. licence or approval
43. certificates required for the application (the appropriate certificates are to be marked, giving clear indication of the quantity of originals and duplicates required. If the name of the certificate is not given, fill it in the blank)
44. quality certificate (number of originals/duplicates)
45. weight certificate (number of originals/duplicates)
46. quantity certificate (number of originals/duplicates)
47. Veterinary Health Certificate for Live Animals or Veterinary Health Certificate for Animal Products (number of originals/duplicates)
48. health certificate (number of originals/duplicates)
49. sanitary certificate (number of originals/duplicates)
50. animal quality certificate (number of originals/duplicates)
51. Phytosanitary Certificate (number of originals/duplicates)
52. fumigation/disinfection certificate (number of originals/duplicates)
53. voucher of changing documents for exported goods
54. customs clearance form
55. expenses for inspection and quarantine
56. total amount (in CNY)
57. calculator
58. collector
59. I, the applicant, hereby declare that 1) I am authorised to apply for inspection; 2) the information provided above is true and correct, the goods are not counterfeit nor do they make use of any other company's name, logo or certificate symbol.
60. signature of the applicant
61. receipt of the certificate
62. date of receipt
63. signature of recipient

2. Additional documents to be enclosed:
    - Certificate of Analysis, if applicable
    - Certificate of Non-Preferential Origin, if applicable
    - Export Certificate for Foodstuffs, if applicable

1 入境货物报检单

报检单位（加盖公章）：2　　*编号：3

报检单位登记号：4　　联系人：5　　电话：6　　报检日期：7　　年　月　日 8

发货人 9	（中文）10	
	（外文）11	
收货人12	（中文）10	
	（外文）11	

货物名称(中/外文)	H.S.编码	产地	数量/重量	货物总值	包装种类及数量
13	14	15	16	17	18

运输工具名称号码	19		贸易方式	20	货物存放地点		21
合同号	22		信用证号	23		用途	24
发货日期	25	输往国家（地区）	26		许可证/审批号	27	
启运地	28	到达口岸	29		生产单位注册号	30	
集装箱规格、数量及号码	31						

合同订立的特殊条款以及其他要求	标记及号码	随附单据（划“√”或补填）34	
32	33	□合同 35	□ 包装性能结果单 41
		□ 信用证 36	□ 许可/审批文件 42
		□ 发票 37	□
		□ 换证凭单 38	□
		□装箱单 39	□
		□厂检单 40	□

需要单证名称（划“√”或补填）43				检验检疫费 55	
□品质证书 44	_正_副	□植物检疫证书 51	_正_副	总金额（人民币元）56	
□重量证书 45	_正_副	□熏蒸/消毒证书 52	_正_副		
□数量证书 46	_正_副	□出境货物换证凭单 53		计费人 57	
□兽医卫生证书 47	_正_副	□通关单 54			
□健康证书 48	_正_副	□		收费人 58	
□卫生证书 49	_正_副	□			
□动物卫生证书 50	_正_副	□			

报检人郑重声明：59

1.本人被授权报检。

2.上列填写内容正确属实，货物无伪造或冒用他人的厂名、标志、认证标志，并承担货物质量责任。

签名：60

领取证单 61	
日期 62	
签名 63	

注：有*号栏由出入境检验检疫机关填写

Last updated: 26 Jun 2017

Inspection Certificate for Medicines

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 3006:

Only required for 3006.30, 3006.60.10, 3006.60.90

A document certifying that medicines have been inspected and that their importation has been approved.

Required for customs clearance.

Chinese name of the document = 进口药品报验单 (Jin Kou Yao Pin Bao Yan Dan)

The certificate is to be applied for by the importer at the China Food and Drug Administration (CFDA), 26 Xuanwumen Xidajie, CN-100053 Beijing, phone number: +86 10 68313344, fax number: +86 10 68310909. In addition, the CFDA has offices in major ports.

The application is to be completed in Chinese.

To be submitted in duplicate as a hard copy and in an electronic format.

The processing time varies.

The processing fee varies depending on the value of the goods to be imported.

The certificate is valid for a single importation only.

1. Information to be provided:

1. application form for an Inspection Certificate for Medicines
2. first importation, yes/no (please check correct box)
3. name of the medicinal product
4. in Chinese
5. in English
6. brand name
7. in Chinese
8. in English
9. form of the drug
10. specification of the drug
11. pattern of packaging
12. expiry date of the drug
13. number of Registration of Medicines
14. contract number
15. inspection standard
16. period of compensation claim
17. quantity of goods
18. value of goods
19. batch/lot number
20. Bill of Lading number
21. port of dispatch
22. date of dispatch
23. means of transportation
24. competent customs office
25. port of destination
26. date of arrival
27. place of storage
28. name of the manufacturer
29. country
30. name of the consignor
31. information on the consignee
32. name
33. address
34. responsible contact person(s)
35. phone number
36. seal of the consignee, date (year, month, day)
37. information on the applicant
38. licence number for drug manufacture or drug supply
39. documents to be attached

2. Documents to be enclosed (in duplicate):
    - Registration of Medicines in the original or as a copy
    - business contract
    - copy of Commercial Invoice
    - Packing List
    - copy of Bill of Lading or Air Waybill
    - Certificate of Analysis
    - Free Sale Certificate

- Certificate of Non-Preferential Origin
- specific specimens of the packaging, the labels and leaflets

1 进 口 药 品 报 验 单

HS 商品编码：　　2　　首次品种：是□　　否□

1.药品名称 3	中文：4 英文：5			2.商品名 6	中文：7 英文：8		
3.剂型	9	4.规　格	10	5.包装规格	11	6.药品有效期	12
7.注册证号	13	8.合同号/唛头	14	9.检验标准	15	10.索赔期	16
11.货物数量	17	12.货值	18	13.批号/件数	19	14.提运单号	20
15.发货港（地）	21	16.发货日　期	22	17.运输工具（航/班次）	23	18.负责海关	24
19.到岸港（地）	25	20.到岸日　期	26	21.存货地点	27		
22.生产厂家	28					国　家	29
23.发货单位	30					国　家	29
24.收货单位 31	名　称	32					
	地　址	33				（公　章） 年　月　日 36	
	联系人	34	电　话	35			
25.报验单位 37	名　称	32				药品经营或生产许可证证号	38
	地　址	33				（公　章） 年　月　日 36	
	联系人	34	电　话	35			
26.所附资料	39						

Last updated

Import Prohibition

China

Last updated on 26 Jun 2017

Specific applicability conditions for product under HS code 3006:

Only prohibited for 3006.92

Certain commodities are subject to a general import prohibition.

Chinese name = **禁止**进口商品 (Jin Zhi Jin Kou Shang Pin)

For further information, please contact the Ministry of Commerce of the P.R. of China (MOFCOM), Dong Chang'an Avenue 2, CN-100731 Beijing, phone number: +86 10 65197420, fax number: +86 10 65197952.

Please note:

As regards import prohibitions of designated waste products, MOFCOM acts in close cooperation with the Ministry of Environmental Protection, National Center of Solid Waste Management, 6th Floor, A Building, 1 Yu Hui South Road, Chao Yang District, CN-100029 Beijing, phone number: +86 10 84636376, fax number: +86 10 84653059, which is the responsible authority for the issue of the relevant catalogues.

Depending on the type of products, further temporary or permanent prohibitions may be decided upon by the Ministry of Environmental Protection. The following items or type of goods are subject to an import prohibition, and may not be classified in terms of exact codes pertaining to the Chinese customs tariff:

- waste electrical and electronic equipment of chapters 84, 85 and 90 of the Chinese customs tariff, as well as waste electronic games coming under heading 9504
- waste fluorescent tubes and similar waste lighting equipment
- industrial and household waste containing chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE) or similar toxic substances

- designated gypsum waste (flue gas) coming under the customs heading 2520
- waste asbestos coming under the customs heading 2524 in both dust and fibre form, as well as waste mineral fibre, slag wool, rock wool and similar mineral cotton, ceramic fibre with similar physical and chemical properties as asbestos
- certain household and agricultural waste (such as plastic containers or films), used fishing nets and municipal refuse, as well as used plastic bags or sacks that contained such waste
- waste paints.

- Certificate of Analysis
- Free Sale Certificate
- Certificate of Good Manufacturing Practice
- Certificate of a Pharmaceutical Product
- Material Safety Data Sheet

OTHERS

EU rules

https://www.ema.europa.eu/en/human-medicines-regulatory-information