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# Regulations and Requirements for the clearance of medicines, pharmaceutical products, medical devices and supplies, and food products that arrive for pilgrims' use

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Version 2.1

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# **Regulations and Requirements for the clearance of medicines, pharmaceutical products, medical devices and supplies, and food products that arrive for pilgrims' use**

Version 2.1

Saudi Food & Drug Authority

For inquiries and suggestions 19999

[CEC@sfda.gov.sa](mailto:CEC@sfda.gov.sa)

For more information visit the official website

<https://www.sfda.gov.sa/ar/regulations?tags=2>

## Saudi Food & Drug Authority

### Vision and mission

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#### Vision

To be a leading international science-based regulator to protect and promote public health.

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#### Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

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## Documentation

version	Date	Publisher	Note
1	1/10/1439	Ports directorate in drug sector	Initiation
2	11/10/1442	Inspection support executive directorate	update
3	11/10/1443	Inspection support executive directorate	update

- The update in this version

Title	update
<ul style="list-style-type: none"><li>• Change the email to the central clearance section.</li><li>• Change the letter for clearance to email</li></ul>	<ul style="list-style-type: none"><li>• Create a new email to receive clearance application <a href="mailto:Hajj@sfda.gov.sa">Hajj@sfda.gov.sa</a></li><li>• Change the email to <a href="mailto:Hajj@sfda.gov.sa">Hajj@sfda.gov.sa</a></li></ul>

## Index

	Page
<b><u>Section One:</u></b> Imported products such as medicines, medical devices and supplies that are in the possession of Pilgrim Affairs Offices or official government agencies coming to the Kingdom for the use by patients of the mission.	7-10
<b><u>Section Two:</u></b> Products such as medicines, pharmaceutical products or medical devices and supplies that arrive with doctors accompanying Hajj campaigns coming through air, sea or land ports for emergency use by pilgrims during the period of travel to reach the holy sites.	11
<b><u>Section Three:</u></b> Products such as medicines, medical devices and supplies, and food items that arrive and are in the possession of pilgrims for personal use.	12-15
<b><u>Section Four:</u></b> Forms, Pledge and Lists	15-24

**Section One: Imported products such as medicines, medical devices and supplies that are in the possession of Pilgrim Affairs Offices or official government agencies coming to the Kingdom for the use by patients of the mission and impediments to the supply of food items.**

**First: Conditions and Rules:**

- 1- Compliance with the supply of medicines, medical equipment and supplies via the accredited airports. (King Abdul Aziz International Airport in Jeddah and Prince Mohammed bin Abdul Aziz Airport in Madinah) during the period from 15 Shawwal to 30 Dhu al-Qa'da Clearance **of anything that arrives outside this period shall not be approved** in accordance with the conditions contained in the booklet of instructions governing Hajj affairs issued by the Ministry of Hajj and Umrah, and the supply otherwise shall not be approved.
- 2- Hajj Affairs Offices must submit official documents and details on medicines, medical devices and supplies to the Ministry of Hajj and Umrah at least fifteen (15) days prior to the arrival date of the shipment, and also send an electronic copy of the documents set forth in the second paragraph (Documents Required) via email ([Hajj@sfda.gov.sa](mailto:Hajj@sfda.gov.sa))
- 3- The import of medicines and medical devices relating to Pilgrim Affairs Offices arriving via King Abdul Aziz International Airport in Jeddah shall be by airfreight only and under a bill of lading in order for the formal customs procedures to be applied for the clearance of medicines and medical devices.
- 4- The staff of the Hajj Affairs Office shall have a licensed medical team and the required medicines shall be under the supervision and responsibility of the head of the medical team.
- 5- The supply of medical devices and supplies containing radioactive materials shall not be permitted.
- 6- It is prohibited to import the medicines and pharmaceutical products containing substances that fall within the banned lists locally and internationally .
- 7- The contents of the packing statement of the attached list of products to be imported and submitted for clearance must be verified in accordance with the actual content of shipments received through the port, with the provision that the lists and cartons shall be numbered in such a way as to facilitate the procedures of inspection and checking of items.

8- All Pilgrim Affairs Offices upon leave must do:

- re-export the remaining quantities of medicines and medical devices upon departure of the mission from the Kingdom, under a customs declaration.
- A copy of the statement of what was dispensed, what is remaining and what was damaged must be submitted.

due to non-compliance of some of Hajj Affairs Offices to the submitted Commitments in pervious Hajj seasons, the responsible person will not be able to leave the kingdom until the submitted Commitments are fulfilled and all the remaining quantities are re-exported and receiving a letter from SFDA directed to border control.

- 9- The distribution of excess or unnecessary quantities of medicines, medical devices and supplies to any entity shall not be permitted. They shall not be allowed to be kept in the residential premises after the end of the Hajj season and must be re-exported so as not to be damaged.
- 10- The mission must import the necessary medicines, medical devices and supplies only for the use of the personnel of the mission by estimating the annual consumption based on what was consumed during the previous years, and it must not supply large quantities in excess of the need. The SFDA has the right to reject any product or quantity that it deems to be in excess of the need of the mission.
- 11- The supply of food items to the Pilgrim Affairs Offices for the purpose of catering shall not be permitted, as this is provided by the catering operators in accordance with the booklet of instructions regulating Hajj affairs and the memorandum of agreement between the Ministry of Hajj and the Pilgrim Affairs Office.
- 12- The import of food items from the list of countries from which import is prohibited as published on the Authority's website shall not be permitted.
- 13- The import of food items listed in the list of food items prohibited for import shall not be permitted to be imported according to the customs terms published on the Authority's website (List attached).



## **Second: Documents Required for Clearance:**

- a. EMAIL addressed to [Hajj@sfda.gov.sa](mailto:Hajj@sfda.gov.sa) asking for clearance, indicating the name of the responsible personal for the imported medicines, pharmaceutical products, medical devices and supplies and the re-export of the remaining quantities, the record number of the transaction at the Ministry of Hajj, attached to which shall be a copy of the concluded memorandum of agreement with the total number of pilgrims, and a table with the following data:

Total number of pilgrims - according to the memorandum of agreement	Name of the head of the mission and contact number	Name and number of pharmacist / physician responsible for the drugs and custody of narcotic and psychotropic substances	Number of medical facilities in Makkah	Number of medical facilities in Madinah

- b. A pledge to limit the use of the medicines, medical devices and supplies to the personnel of the mission only and under their responsibility, that these shall not be sold or disposed of in any manner whatsoever, and that the remaining amounts thereof shall be returned together with the mission when it returns; also submitting a statement of what was dispensed , what is remaining and what was damaged, prior to the mission's departure from the Kingdom to the branch of the Food and Drug Authority at the customs port; a pledge to delete contract with an accredited company to dispose medical waste (Attached is the form for the pledge that is required to be submitted with the Pilgrim Affairs Offices or the official missions).
- c. Packing statement of:
- controlled and narcotic drugs.
  - (non-controlled) drugs.
  - medical devices and supplies.
- approved by the competent authority in the mission's country (Ministry of Health) and endorsed by the Saudi Embassy.**

For controlled, non-controlled and narcotic drugs statement containing:

- the scientific name
- pharmaceutical form
- concentration
- size
- required quantity
- number of cases treated

For medical devices and supplies statement containing:

- the name of the item or device.
- the required quantity.

together with filling out the attached form and providing it in an electronic format in Excel, and attaching the invoices showing the quantity, weight and value, with the need to ensure that they conform to the quantities and items approved within the lists with the shipment received and that the lists and cartons contain explanatory numbers to facilitate inspection procedures.

•Note:

The E-track electronic system of ministry of hajj and umrah, is under development to include clearance submitting, and all request shall be submitted via the E-track if it's completed before the submission date.

**Section Two: Products such as medicines, pharmaceutical products or medical devices and supplies that arrive with doctors accompanying Hajj campaigns coming through air, sea or land ports for emergency use by pilgrims during the duration of travel to reach the holy sites and impediments to the supply of food items.**

**First: Conditions and Rules:**

- 1- The medicines and medical supplies that arrive with the doctor must be for emergency cases only and in quantities that will cover the needs of the members of campaign accompanying the doctor for their personal use during the journey and the transfer to the residential premises or holy sites and until they are connected to the Pilgrim Affairs Office later.
- 2- The supply of narcotic or controlled drugs with the doctor for the use of pilgrims during the period of movement up to the holy sites shall be prohibited.
- 3- The supply of products containing substances that fall within the banned lists locally and internationally shall be prohibited.
- 4- The supply of medical devices and supplies containing radioactive materials shall not be permitted.
- 5- The supply of food items to Hajj campaigns and offices shall be prohibited and there is no need to transport them with the doctor accompanying the campaign.
- 6- The medicines and medical supplies must be under the responsibility of the doctor accompanying the campaign, and he must re-export the remaining quantities thereof when departing from the Kingdom.

**Second: Documents Required for Clearance:**

- 1- A letter from the Ministry of Health of the doctor accompanying the campaign stating that he is charged with accompanying the campaign to provide the necessary emergency treatment services during the journey of the campaign until it reaches the holy sites.
- 2- In the event that the above-mentioned letter is not available, medical reports / prescriptions indicating the need of the patients accompanying the doctor shall be attached to the emergency products during the period of transfer to the premises.
- 3- A pledge from the doctor stating his responsibility for the medicines and medical supplies, that they will only be dispensed to pilgrims of the campaign, and that the remaining amounts shall be re-exported when leaving the Kingdom in accordance with the undertaking form required to be submitted by the doctor accompanying the campaign.

**Section Three: Products such as medicines, medical devices and supplies, and food items that arrive and are in the possession of pilgrims for personal use.**

**❖ First: Controlled and narcotic drugs and non- controlled drugs and pharmaceutical products:**

**● Regulations and Requirements:**

- Clearance of controlled narcotic drugs shall be approved for a quantity that is adequate for a maximum of 30 days or the duration of the patient's stay in the Kingdom, whichever is lesser, provided that the Expiry date is valid and only for the personal use of the pilgrim under his responsibility.
- Clearance of non-controlled drugs shall be approved for a quantity that does not exceed three months use or the duration of the patient's stay in the Kingdom, whichever is lesser, for the personal use of the pilgrim under his responsibility.
- If the quantity of medicine required to be cleared is more than the patient's need, the remaining quantity shall be disposed.
- The entry of medicines and pharmaceutical preparations that arrive with pilgrims without their original packaging or that dispensed from the medical institution shall be prohibited.
- The entry of expired medicines and pharmaceutical products shall be prohibited.
- The medicines and pharmaceutical products required to be cleared must be free of internationally and locally banned substances and radioactive materials.
- The Authority shall not permit the entry of preparations with an unknown formulation, as well as those that have falsified medical claims such as (weight loss, weight gain, whitening, sexual claims).
- The Authority recommends that you consult your doctor before using any pharmaceutical preparation.

- **Requirements for the release of controlled narcotic drugs:**

1. Providing a detailed medical report approved by the institution treating the patient, which shall not be more than six months old, and which must contain the following:
  - a. Personal information about the patient.
  - b. Medical diagnosis.
  - c. Treatment Plan and Duration.
  - d. Medical Recommendations.
  - e. Scientific name of the drug, pharmaceutical form and prescribed dosage.
2. Or Providing a medical prescription made out in the patient's name approved by the same treatment institution, which shall not be more than six months old, and which must contain the following information:
  - a. Diagnosis of the disease.
  - b. Scientific name of the drug, pharmaceutical form and prescribed dosage.
  - c. How to use and duration of treatment.
  - d. Seal of the Treatment Institution.

- **Requirements for the release of non-controlled Drugs and pharmaceutical products:**

1. A copy of the medical report or prescription for the prescribed medicines, indicating the diagnosis and the medicine required for treatment, indicating the duration of treatment and the recommended dosage, which shall not be more than six months old.

## ❖ Second: Medical devices and Supplies:

### ● Regulations and Requirements:

- Clearance of medical devices and supplies shall be approved for a quantity that does not exceed three months use or the duration of the pilgrim's stay in the Kingdom, whichever is lesser, for the personal use of the pilgrim only and under his responsibility.
- If the quantity of medical equipment and supplies required to be cleared is more than the patient's need, the remaining quantity shall be disposed.
- The entry of medical devices and supplies that arrive with pilgrims without their original packaging or that dispensed from the medical institution shall be prohibited.
- The entry of expired medical devices and supplies shall be prohibited.
- The medical devices and supplies required to be cleared must be free of internationally banned substances and radioactive materials.

### ● Requirements:

1. A copy of the medical report or prescription for prescribed medical equipment and supplies, indicating the diagnosis and the need for the medical equipment or product required for treatment, indicating the duration of treatment, which shall not be more than six months old.

## ❖ Third: Food Items:

### ● Conditions and Rules:

- The import of food items listed in the list of food items prohibited for import shall not be permitted to be imported according to the customs terms published on the Authority's website (list attached).
- Any food item must contain a food label irrespective of the type of food product (dairy, cheese, meat, poultry, fish, canned).
- The entry of food items that are expired or that do not bear an expiry date shall be prohibited.
- The entry of any food items showing signs of damage or spoiling, for example (presence of mould, bad smell, discoloration and change of the food's physical properties).

- The entry of any food items that have been warned about via the website of the Food and Drug Authority due to their violation of technical regulations and approved standard specifications, shall be prohibited.
- The entry of any food items whose food card contains any of the following ingredients (alcohol, pig fats and derivatives, prohibited additives) shall be prohibited.
- The food item that arrives with the pilgrim must be preserved according to the appropriate preservation method and especially food items that require cooling or freezing.
- The entry of any food item that is contaminated with insects or any other contaminants in contact with the food item or the packaging of the food product shall be prohibited.
- The entry of any food item containing health or nutritional claims or containing images that suggest medical or nutritional claims on the food product shall be prohibited.
- The entry of food items that arrive with pilgrims in containers that are not intended to store food items or that are found to be in unclean containers shall be prohibited.
- The entry of food items that arrive with pilgrims in commercial quantities and in excess of their needs shall be prohibited.

## Section Four: Forms, Pledge and Lists

### Narcotics & Controlled Drugs List

No.	Product Name (including dosage form)	Name & Strength of Active Ingredient(s)	No. of pallet (carton)	Quantity	No. of patients using the product
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					



## Drugs List

No.	Product Name (including dosage form)	Name & Strength of Active Ingredient(s)	No. of pallet (carton)	Quantity	No. of patients using the product for Chronic diseases
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					

### Medical Devices List

No.	Name	Quantity	No. of pallet (carton)
1	..... .....		
2	..... .....		
3	..... .....		
4	..... .....		
5	..... .....		
6	..... .....		
7	..... .....		
8	..... .....		
9	..... .....		
10	..... .....		
11	..... .....		
12	..... .....		
13	..... .....		

## Commitment to be submitted with the offices of pilgrims or official missions

### Commitment

We ..... Pledge that the Medications and medical devices and materials, which are imported in flight/ Bill of lading Number ....., under our responsibility and commit that it will be used by the members of the campaign only, and it will not be sold or used in any manner whatsoever and the remaining quantities will be returned when the campaign depart to their country.

We also commit to submit to Saudi Food & Drug Authority a list of control drugs and narcotics, including the stock, used, and the remaining quantity after the end of the Hajj period and before departure, we also commit to take full responsibility for the accompanied medical devices, and technical errors resulted from them.

we also commit to take full responsibility to Sign contract with approved medical waste Company

**With my full knowledge, I am the undersigned  
that I will be prevented from leaving the kingdom if I  
do not comply with the Commitment**

Job title:

Name:

Passport number:

E-mail:

Mobile number:

Signature:

Stamp:

### تعهد

نتعهد نحن مكتب شؤون حجاج دولة..... بأن  
الأدوية والأجهزة والمستلزمات الطبية الواردة ضمن  
الرحلة/ببولىصة رقم..... هي تحت مسؤوليتنا  
ولن نستخدم إلا لأفراد البعثة فقط ولن يتم بيعها أو  
التصرف بها بأي وسيلة كانت، وبأنه سيتم إعادة الكميات  
المتبقية منها مع البعثة حال عودتها.

ونتعهد بتقديم بيان للأدوية الخاضعة للرقابة  
والمخدرة ليشمل الرصيد والمستهلك والمتبقي لدينا بعد انتهاء  
فترة الحج إلى مسئول الهيئة العامة للغذاء والدواء قبل  
المغادرة، كما نتعهد بمسؤوليتنا الكاملة عن الأجهزة الطبية  
المرفقة وما يترتب عليها من أخطاء فنية.

كما نتعهد بالتعاقد مع شركة معتمدة لإتلاف  
النفايات الطبية وعدم إتلافها بطرق غير نظامية.

**مع كامل علمي أنا الموقع أدناه بأنه سيتم منعي من  
مغادرة المملكة في حال عدم التزامي بما ذكر أعلاه.**

الوصف الوظيفي:

الاسم:

رقم الجواز:

البريد الإلكتروني:

رقم الجوال:

التوقيع:

الختم:

## Commitment to be submitted with the doctor accompanying the campaign

### Commitment

We ..... Pledge that the Medications and medical devices and materials, which are imported from ..... belong to campaign of ..... , and commit that it will be used by the members of the campaign only, and under our responsibility, and it will not be sold or used in any manner whatsoever and the remaining quantities, damaged, and used products, and all packages will be returned when the campaign depart to their country.

We also commit to submit to Saudi Food & Drug Authority a list of control drugs and narcotics, including the stock, used, and the remaining quantity after the end of the Hajj period and before departure, we also commit to take full responsibility for the accompanied medical devices, and technical errors resulted from them.

**Job title:**

**Name:**

**Passport number:**

**E-mail:**

**Mobile number:**

**Signature:**

### تعهد

نتعهد نحن ..... بأن الأدوية والأجهزة والمستلزمات الطبية المستوردة من ..... هي خاصة بحملة ..... ولن نستخدم إلا لأفراد البعثة فقط وتحت مسؤوليتنا، ولن يتم بيعها أو التصرف بها بأي وسيلة كانت، وأن يتم إعادة المتبقي منها أو التالف أو المستخدم وجميع العبوات مع البعثة حال عودتها. ونتعهد بتقديم بيان للأدوية الخاضعة للرقابة والمخدرة ليشمل الرصيد والمستهلك والمتبقي لدينا بعد انتهاء فترة الحج إلى مسئول الهيئة العامة للغذاء والدواء قبل المغادرة، كما نتعهد بمسؤوليتنا الكاملة عن الأجهزة الطبية المرفقة وما يترتب عليها من أخطاء فنية.

الوصف الوظيفي:

الاسم:

رقم الجواز:

البريد الإلكتروني:

رقم الجوال:

التوقيع:

## قائمة السلع الغذائية الممنوع استيرادها\* وفقا لبنود التعرف الجمركية

البند	رقم النظام المنسق	المنصف
0203		لحوم فصيلة الخنازير، طازجة أو مبردة أو مجمدة.
		طازجة أو مبردة أو مجمدة:
	02031100	ذبائح كاملة وأنصاف ذبائح
	02031200	أفخاذ وأكتاف وقطعها بعظمها
	02031900	--- غيرها
	02032100	ذبائح كاملة وأنصاف ذبائح
	02032200	أفخاذ وأكتاف وقطعها بعظمها
	02032900	غيرها
0205		لحوم فصائل الخيول والحمير والبغال والنغال طازجة أو مجمدة أو مبردة
	02050090	--- غيرها
0206		أحشاء وأطراف صالحة للأكل من فصائل الإبل والخنازير والضأن والماعز والخيول والحمير والبغال والنغال، طازجة أو مبردة أو مجمدة.
	02063000	---من فصيلة الخنازير طازجة أو مبردة
	02064100	---أكباد
	02064900	---غيرها
0208		لحوم وأحشاء وأطراف صالحة للأكل طازجة أو مبردة أو مجمدة
	02089091	---أفخاذ ضفادع
0209		شحم خنزير صرف وشحم طيور دواجن، غير مستخلص بالإذابة أو بطرق الاستخلاص الأخرى طازجة أو مبردة أو مجمدة أو مملحا أو في ماء مملح أو مجففا أو مدخنا
	02091000	---من خنزير
0210		لحوم وأحشاء وأطراف صالحة للأكل مملحة أو ماء مملح مجففة أو مدخنة دقيق ومساحيق صالحة للأكل من لحوم وأحشاء وأطراف.
		لحوم فصيلة الخنازير
	02101100	أفخاذ وأكتاف وقطعها وعظمها
	02101200	صدور يتخللها شحم وقطعها
	02101900	---غيرها
0908		جوز الطيب وبسباسه وحب الهال (فاقلة)
	09081100	جوز الطيب غير مجروش ولا مسحوق
	09081200	جوز الطيب مجروش أو مسحوق
	09082100	بسباسه جوز الطيب غير مجروشة ولا مسحوقة
	09082200	بسباسه جوز الطيب مجروشة أو مسحوقة
1207		أثمار وبنور زيتية آخر وإن كانت مكسرة
	12079100	---بنور خشخاش
	12079910	---خشخاش
	12079920	---بنور قنب
1211		"نباتات وأجزاءها،
	12113000	- أوراق الكوكا...
	12114000	- قش خشخاش...
	12119020	- - - خشخاش أسود
	12119060	- - قنب هندي
1302		عصارات وخلاصات نباتية،
		عصارات وخلاصات نباتية:
	13021100	- - أفيون.....
		---غيرها
	13021910	---حشيش
1501		شحوم خنزير (بما فيها دهن الخنزير
	15011000	دهن خنزير
		المنصف
	15012000	شحوم خنزير آخر
1503		ستيارين دهن وشحم الخنزير وزيت دهن الخنزير
	15030011	--- من خنزير.....
	15030021	--- من خنزير.....
	15030091	--- من خنزير
1518		زيوت ودهون وشحوم حيوانية
	15180011	---من خنزير
1601		سجق (غليظ أو رفيع) ومنتجات مماثلة من لحوم أو من أحشاء وأطراف أو من دم حيواني؛ محضرات غذائية أساسها هذه المنتجات
	16010010	"--- من خنزير أو دم حيواني
1602		محضرات وأصناف محفوظة آخر من لحوم أو من أحشاء وأطراف أو من دم حيواني
	16024100	- - فخذ الخنزير وقطعه

كثف الخنزير وقطعه	16024200	
-- غيرها بما فيها المخاليط	16024900	
-- محضرات من دم الحيوانات	16029030	
مصنوعات سكرية (بما فيها الشوكلاته البيضاء)، لا تحتوي على الكاكاو		1704
-- شوكلاته بيضاء محتوية على كحول	17049080	
شوكلاته ومحضرات غذائية آخر تحتوي على كاكاو		1806
محشوة تحتوي على كحول	18063110	
غير محشوة تحتوي على كحول	18063210	
جعة بيرة مصنوعة من شعير الناضط (المليت)	22030000	2203
نبيذ من عنب طازج بما في ذلك الانبيذة المقواة بالكحول؛ سلافه العنب عدا الداخل منها في البند 20.09		2204
نبيذ فوار	22041000	
-- انبيذه آخر، سلافه عنب منع أو أوقف اختمارها بإضافة كحول في أوعية لا تزيد سعتها عن 2 لتر	22042100	
-- انبيذه آخر، سلافه عنب منع أو أوقف اختمارها بإضافة كحول غيره	22042900	
انبيذه آخر، سلافه عنب منع أو أوقف اختمارها بإضافة كحول أنواع آخر من سلافه العنب	22043000	
فيرموث وانبيذه آخر من عنب طازج منكهة بنباتات أو مواد عطرية		2205
في أوعية لا تزيد سعتها عن 2 لتر	22051000	
غيرها	22059000	
مشروبات مخمرة آخر (شراب تفاح أو كمثرى أو عسل مثلاً)؛ مخاليط مشروبات مخمرة ومخاليط مشروبات مخمرة مع مشروبات لا كحولية غير داخلية أو مذكورة في مكان آخر	22060000	2206
كحول ايثيل غير معطل لا يقل معيار الكحول الحجمي فيه عن 80% حجماً؛ كحول ايثيل معطل وغيره من المشروبات الروحية المعطلة المحولة، من أي عيار كان		2207
-- كحول ايثيل معطل وغيره من المشروبات الروحية المعطلة من أي عيار كان؛ غيره	22072090	
كحول ايثيل غير معطل يقل عيار الكحول الحجمي فيه عن 80% حجماً؛ مشروبات روحية ومشروبات كحولية معطرة (ليكور) ومشروبات روحية آخر		2208
مشروبات كحولية ناتجة عن تقطير النبيذ أو ثفل العنب	22082000	
ويسكي	22083000	
-- روم ومشروبات روحية آخر ناتجة عن تقطير منتجات قصب السكر المخمرة	22084000	
-- جن و جنيفا	22085000	
فودكا	22086000	
مشروبات كحولية معطرة (ليكور)	22087000	
-- غيره	22089090	
-- رواسب نبيذ	23070010	

المصدر : مصلحة الجمارك السعودية، كتاب التعريفات الجمركية الطبعة الخامسة عشر 1433هـ-2012م\*

\*Source: Saudi Customs Authority, Customs Tariff Book, 15th Edition, 1433 H-2012G.