



Kingdom of Saudi Arabia
Saudi Food & Drug Authority



Musk and Ambergris

Products Guideline

Version No 0,2

Vision and Mission of the Saudi Food and Drug Authority



Our vision...

Is based on scientific principles to enhance and protect, aiming to become a globally leading authority in public health.



Our mission...

To protect the community through effective legislation and regulatory system to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and feed products.

Guideline documentation

Version	Publisher	Date	Comments
0,1	Executive Directorate of Vigilance	22 November 2021	Draft
0,2	Executive Directorate of Vigilance	22 May 2022	Final version



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Introduction

Musk and amber products are ancient natural extracts that used for a long time for perfuming and enhancing body odor. These fragrant derivatives are extracted from animal sources such as musk deer and sperm whale. Due to the importance of having a regulatory system for the trade and manufacture of these natural animal aromatic extracts in a way that ensure the consumer safety and achieve high quality, especially in the presence of cheap synthetic alternatives that resemble the natural scents but may cause highly dangerous side effects to users. And to prevent fraud and false claims regarding products containing these extracts, this Guideline was issued to establish regulatory and legislative system for the manufacture, packaging, and sale of musk and amber extracts in KSA to preserve this industry from extinction, ensure consumer safety, and elevate its quality standards.



Purpose:

Saudi Food & Drug Authority prepared this Guideline of perfumes and aromatic extracts containing musk or amber with the conditions and rules related to the manufacture and trade of aromatic musk or amber extracts in KSA.



Scope of implementation:

The scope of implementation includes all perfumes and aromatic extracts containing musk or amber manufactured locally, and the requirements enforced by the SFDA upon manufacturing, assessment, listing, and trading of perfumes containing musk or amber as a final product intended for cosmetic use only.



Relevant Guidance and Regulations:

- Cosmetic Products Law and its Executive directive.
- Technical regulation for safety requirements for cosmetics and personal care products SFDA.CO/GSO 1943, according to latest update.
- Technical regulation for claims of cosmetic products 2528 SFDA.CO/GSO, according to latest update.
- Controls and requirements of listing cosmetic products.
- Circulars issued by the SFDA.
- Good manufacturing practice for cosmetics products, according to latest update.

Definition of

Natural Musk:

Natural Musk is the aromatic material extracted from the secretions of the musk glands in the abdomen of the Musk Deer.

Method of Production of Natural Musk:

This is made by either extracting the gland from the musk deer's body or collecting the material that sticks to surfaces such as rocks, then drying it and melting it in alcohol to produce the aromatic musk extract intended for use on the human body's external parts for the purpose of perfuming, enhancing odor, or maintaining it in good condition.

There are seven species of musk deer from which this material is extracted, including:

Family: Moschidae		
Genus: Moschus		
Common name	Presence	Species
Moschus moschiferus (Siberian musk deer)	Northeast Asia	M. moschiferus
Moschus anhuiensis (Anhui musk deer)	East China	M. anhuiensis
Moschus berezovskii (Dwarf musk deer)	Southern China and Northern Vietnam	M. berezovskii
Moschus fuscus (Dusky musk deer)	Eastern Himalayas	M. fuscus
Moschus chrysogaster (Alpine musk deer)	Eastern Himalayas	M. chrysogaster
Moschus cupreus (Kashmir musk deer)	Western Himalayas	M. cupreus
Moschus leucogaster (Himalayan musk deer)	Middle Himalayas	M. leucogaster

Definition of

Natural Ambergris:

It is a solid waxy material with a distinctive smell that is formed inside the intestines of the sperm whale (*Physeter macrocephalus*)

Method of Production of Natural Ambergris:

Amber is picked up on the seashore area and used to produce aromatic products that are used on the human body's external parts for the purpose of perfuming, enhancing odor, or maintaining it in good condition.

Local name	Scientific name in English	Other common names
Amber	Ambergris	Gray amber

Definition of Synthetic

Musk and Ambergris:

Compounds are manufactured from synthetic (non-natural) chemicals for the purpose of producing materials that resemble natural one in odor, such as those found in musk and amber products.

The following controls are subjected to the definitions of natural and synthetic musk and amber:

01 Compounds extracted from natural sources (musk deer, sperm whale):

This Guideline includes all products extracted through distillation from natural sources of musk and amber products, containing the active ingredients below, used for perfuming the human body and enhancing odor. It does not include chemically prepared active ingredients intended to resemble the natural odor of musk and amber.

Local name	Scientific name in English	Active Ingredient in Arabic
Musk	Muscone	مسكون
Amber	Ambrein	أمبرين

02 For the production of aromatic products on the human body's external parts:

The definition of natural musk and amber does not include extracts resulting from distillation processes intended for use on parts other than the human body's external parts, for example:

- Amber extracts prepared for internal use in traditional medicine.
- Raw musk products prepared for perfuming the air

03 For the purpose of perfuming, enhancing odor, or maintaining it in good condition:

The definition of natural musk and amber does not include extracted products that are not intended for cosmetic purposes or carry non-cosmetic medical claims. This includes, for example:

- Musk and amber extracts containing medical claims that violate the cosmetics and personal care products claims regulation 2528 SFDA.CO/GSO, including, for example:

Common medical claims of musk and amber products	Improvement of psychological state	Purity musk
	Skin cleansing	Kills bacteria
	Increase immunity	Stimulate blood circulation
	Increase sexual desire	Anxiety reliever

- Musk and amber extracts that violate the five standards of claims according to the cosmetics and personal care products claims regulation 2528 SFDA.CO/GO, including, for example:

Standard	explanation	An example of a unaccepted claim
Legal obligation	It is compatible with laws and does not conflict with Islamic values, social, cultural and linguistic factors.	Publishing inappropriate images
Honesty	Do not intentionally mislead the consumer or publish incorrect or inaccurate information.	Stimulating blood circulation, purity musk
Fairness	Claims that are objective and do not denigrate competitors. Clear, accurate and understandable to all categories of consumers of the product.	Best and highest quality product
Scientific honesty	Do not exaggerate the way you present the effectiveness of the product performance.	Odor remains for months or years.
Proven with evidence	The presence of scientific evidence and proof that supports the validity of the claims.	Stimulating blood circulation, improving psychological state, increasing sexual desire



Obtaining a license for distillation and extraction of musk and amber products:

To obtain the license, applicants shall ensure and guarantee the quality and safety of the industry for these products, which includes all stages of preparation and manufacturing of these products according to the good manufacturing practice for cosmetics products (according to its latest update) to ensure a safe product compliant with the requirements of this regulation. This includes rules related to buildings, workers, quality system, cleanliness, storage, product recall process, and handling complaints.



Methods of Detection and Testing:

Laboratory analysis is made on the finished product resulting from the extraction of musk and amber products before its distribution to ensure its compliance with the requirements of the safety regulations for cosmetics and personal care products 1943 SFDA.CO/GSO, according to its latest update, and the directives issued by the SFDA. The requirements for maximum limits of heavy metals and impurities shall be applied as stipulated in the safety requirements regulation. In addition, it is required to save the laboratory analysis results and keep them with the registered entity to provide them upon request.

The laboratory examination includes the following tests:

Targeted tests for musk product	
Visual examination	The product shall be free of impurities and particles
Microbial and fungal examination	<p>The product shall not exceed the limits stipulated in the technical regulation for safety requirements in cosmetics and personal care products 1943 SFDA.CO/GSO according to its latest update, and the specifications for analysis of microbial and fungal materials in the final product approved by the SFDA.</p> <ul style="list-style-type: none"> • Microbiological Test. • Total count of Aerobic mesophilic bacteria ISO21149:2017. • Detection of Pseudomonas aeruginosa ISO 22717:2015 • Detection of Escherichia coli ISO 21150:2015. • Detection of staphylococcus aureus ISO 22718:2015. • Enumeration of yeast and mould ISO 16212:2017. • Detection of Candida albicans ISO 18416:2015.

Targeted tests for amber product																																	
Determination of pH	As stipulated in the technical regulation for safety requirements in cosmetics and personal care products SFDA.CO/GSO 1943																																
Determination of heavy metals (Pb, Cd, As, Hg, Sb)	As stipulated in the technical regulation for safety requirements in cosmetics and personal care products SFDA.CO/GSO 1943																																
Determination of Phthalate	<p>The product shall be free of the following prohibited phthalate materials:</p> <table border="0"> <tr> <td>Dibutyl Phthalate</td> <td>CAS 84-74-2</td> <td></td> </tr> <tr> <td>Diethylhexyl Phthalate</td> <td>CAS 117-81-7</td> <td></td> </tr> <tr> <td>Bis(2-Methoxyethyl) Phthalate</td> <td>CAS 117-82-8</td> <td></td> </tr> <tr> <td>Benzyl Butyl Phthalate</td> <td>CAS 85-68-7</td> <td></td> </tr> <tr> <td>Diisopentylphthalate</td> <td>CAS 605-50-5</td> <td></td> </tr> <tr> <td>1,2-Benzenedicarboxylic Acid, Dipentylester, Branched And Linear</td> <td>CAS 84777-06-0</td> <td></td> </tr> <tr> <td>N-Pentyl-Isopentyl phthalate</td> <td>CAS 776297-69-9</td> <td></td> </tr> <tr> <td>Di-N-Pentyl Phthalate</td> <td>CAS 131-18-0</td> <td></td> </tr> <tr> <td>Diisobutyl Phthalate</td> <td>CAS 84-69-5</td> <td></td> </tr> <tr> <td>Dihexyl Phthalate</td> <td>CAS 84-75-3</td> <td></td> </tr> </table>			Dibutyl Phthalate	CAS 84-74-2		Diethylhexyl Phthalate	CAS 117-81-7		Bis(2-Methoxyethyl) Phthalate	CAS 117-82-8		Benzyl Butyl Phthalate	CAS 85-68-7		Diisopentylphthalate	CAS 605-50-5		1,2-Benzenedicarboxylic Acid, Dipentylester, Branched And Linear	CAS 84777-06-0		N-Pentyl-Isopentyl phthalate	CAS 776297-69-9		Di-N-Pentyl Phthalate	CAS 131-18-0		Diisobutyl Phthalate	CAS 84-69-5		Dihexyl Phthalate	CAS 84-75-3	
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Detection of musk compounds prohibited and restricted in technical regulation No. GSO 1943	<p>According to the restrictions stipulated in the regulations</p> <p>According to the restrictions stipulated in the regulations</p> <p>Banned material</p> <p>Banned material</p>	<p>CAS 81-14-1</p> <p>CAS 81-15-2</p> <p>CAS 83-66-9</p> <p>CAS 145-39-1</p>	<p>Nirto Musks: Musk Ketone</p> <p>Musk Xylene</p> <p>Musk Ambrette</p> <p>Musk Tibetene</p>																														
Detection of allergens	As stipulated in the technical regulation for safety requirements in cosmetics and personal care products SFDA.CO/GSO1943																																

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Targeted tests for amber product (continued)

Detection of prohibited and restricted materials in technical regulation No. GSO 1943	According to the restrictions stipulated in the regulations	CAS 81-14-1	Nirto Musks: Musk Ketone
	According to the restrictions stipulated in the regulations	CAS 81-15-2	Musk Xylene
	Banned material	CAS 83-66-9	Musk Ambrette
	Banned material	CAS 145-39-1	Musk Tibetene
Determination of Ambroxan	CAS100679-85-4	Ambroxan	
Detection of allergens	As stipulated in the technical regulation for safety requirements in cosmetics and personal care products SFDA.CO/GSO1943		



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