Global Market Access Complete Guide for Glabridin from HiSiaddi

For Overseas Raw Material Buyers, Foreign Traders & Freight Forwarders

Full Separate PDF Modules: EU EC1223 Access Manual, South Korea KFDA + Japan PMDA Dual Specification, Global Tariff & Import Declaration Handbook, All Bilingual English-Chinese

INCI: Glabridin | CAS: 59870-68-7

PDF 1 EU (EC) No 1223/2009 Raw Material Access Manual

1.1 Regulatory Foundation

1. Core Regulation: EU Cosmetics Regulation (EC) No 1223/2009, supported by CosIng Database, SCCS Consumer Safety Scientific Committee Opinions & REACH Regulation 1907/2006
2. Raw Material Listing Status: Glabridin fully recorded in CosIng, not listed in Annex II banned or Annex III restricted ingredient lists with no legally mandatory maximum concentration limits; classified as unrestricted functional whitening active ingredient
3. REACH Compliance Threshold: REACH substance registration mandatory for annual EU exports >1 ton; complete 16-section REACH SDS + EU Responsible Person (OR) authorization required for annual export volume <1 ton

1.2 SCCS Safe Recommended Dosage Ranges

1. Leave-On Products (Creams, Serums, Spot Treatments, Eye Creams)
   SCCS Recommended Upper Limit: 0.3% finished product (95% Glabridin conversion)
   Industry Optimal Efficacy Compliance Window: 0.03–0.1% minimal irritation for official whitening claims
   High-Concentration Hard Limit: Do not exceed 0.3%; full human clinical safety trial documentation mandatory above threshold to avoid customs detention, product seizure & recall
2. Rinse-Off Products (Cleansers, Shower Gels, Shampoos)
   Recommended Upper Limit: 0.5%; minimal exposure risk with minimal regulatory oversight
3. Pre-Dissolved Polyol Liquid Raw Materials (1% /5% /10% Glabridin in Butanediol)
   No raw material concentration limits; final diluted finished product must comply with leave-on/rinse-off caps. COA for customs must clearly state raw material activity concentration & formulation dilution ratio

1.3 EU Mandatory Labeling Specifications (EC1223 Article 19, Annex VII)

Raw Material Export Outer Packaging Mandatory Markings

1. Standard INCI Name: GLABRIDIN (all uppercase English, Chinese-only labeling invalid)
2. CAS Number, Purity Grade, Batch Number, Production Date, Shelf Life
3. Supplier bilingual name & address, EU Responsible Person contact information, emergency hotline
4. Storage Warning: Store sealed away from light below 25℃ + full GHS hazard warning labels (H302/H312/H332 Warning Statement)
5. Country of Origin: Made in China

Finished Cosmetic Product Label Compliance

1. Ingredient list sorted descending by concentration, standardized INCI GLABRIDIN; no abbreviations or trade nicknames permitted
2. Whitening Claim Regulation EU 655/2013: All whitening/spot-fading/brightening marketing claims require supplementary tyrosinase inhibition in vitro data + 28-day human clinical trial reports; medical treatment claims (e.g. chloasma cure, dermatological remedy) strictly prohibited
3. Multilingual Mandate: Packaging must include official local language for Germany, France, Spain etc.; English only as auxiliary text, single English labeling unacceptable

1.4 EU Customs Inspection Mandatory Impurity Control Red Lines

1. Forbidden Trace Impurity Threshold: Hydroquinone ND (Not Detected), trace limit ≤1ppm; customs full detention & return shipment if exceeded
2. Heavy Metal Uniform Limits: Pb ≤10ppm, As ≤2ppm, Hg ≤1ppm, Cd ≤5ppm; COA must include complete four heavy metal test data
3. Pesticide Residue Screening: 55 target pesticides fully ND
4. Organic Solvent Residue: Methanol ≤0.2%, ethanol unrestricted, full GC data on COA
5. Blending Prohibitions: No co-formulation with hydroquinone or mercury-based whitening agents; finished product pH <4.0 strongly discouraged per SCCS safety assessment
6. REACH SVHC High-Concern Substances: Any single substance above 0.1% must be fully disclosed in SDS and reported to ECHA

7. Special Population Restrictions: No ban for pregnant/children's formulations; children's leave-on skincare recommended maximum dosage ≤0.05%

1.5 Mandatory Document Package for EU Customs Clearance

1. Bilingual English-Chinese TDS Technical Data Sheet
2. Batch-Specific COA Certificate of Analysis
3. REACH-Compliant 16-Section SDS (EU Format with EU OR Information)
4. Raw Material Safety Assessment Report (SAR)
5. REACH Registration Certificate (>1 ton annual export) / REACH Exemption Declaration (<1 ton annual export)
6. Certificate of Origin FORM A for preferential tariff reduction

PDF 2 South Korea KFDA + Japan PMDA Dual Market Specification Manual

Module A South Korea KFDA Cosmetics Act (2020 Revised Version)

2.1 Raw Material Filing Access Rules

1. Korean Standard Name: 글라브리딘; listed on Korea Existing Cosmetic Ingredients List, no separate raw material registration required
2. Segmentation: General Cosmetics vs Functional Whitening Cosmetics (marked 미백)

   General Toner/Mask Lotion: Unrestricted dosage
   Functional Whitening Licensed Products: Statutory hard maximum finished product dosage 0.1%
3. Import Raw Material Pre-Notification: Overseas suppliers submit COA, SDS, extraction process, heavy metal & pesticide test reports to KFDA to receive import approval receipt prior to customs clearance

2.2 South Korea Customs Sampling Strict Impurity Standards

1. Heavy Metal (Stricter Than EU): Pb ≤5ppm, As ≤1ppm, Hg ≤0.5ppm, Cd ≤3ppm
2. All 55 agricultural pesticides Not Detected
3. Glabrol Impurity ≤1.0% mandatory threshold for functional whitening raw materials
4. Microbe Limits: Total Aerobic Microbes ≤100CFU/g, Mold & Yeast ≤10CFU/g, four pathogenic bacteria Not Detected

2.3 Korean Label Dual Standard (Raw Material + Finished Goods)

1. Outer Raw Material Packaging: Korean + English bilingual labeling 글라브리딘 / GLABRIDIN with CAS, purity and hazard warning text
2. Functional Whitening Finished Products: Must display functional license number; Korean INCI primary text with auxiliary English
3. Mandatory Warning: Warning statement for licorice-allergic consumers; eye serum limited to ≤0.02% Glabridin concentration

Module B Japan PMDA Ministry of Health Quasi-Drug Specifications

2.1 Raw Material Classification & Access Rules

1. Japanese Standard Name: グラブリジン；listed on JCIA Japanese Cosmetic Ingredient Standard Catalog
2. Two Regulatory Tiers
   ① General Cosmetics: No legal concentration cap, recommended formulation range 0.03–0.15%
   ② Quasi-Drugs (Whitening Spot Serums): Ministry of Health hard maximum finished product dosage 0.1%
3. Import Raw Material Filing: Importers submit Japanese-language raw material specification certificate, SDS, irritation & phototoxicity safety test reports to complete Ministry of Health import notification

2.2 Japan Exclusive Impurity Screening Requirements

1. Class 1 & 2 Solvents (Methanol, Dichloromethane) Not Detected
2. Heavy metal standards aligned with KFDA strict limits; mandatory arsenic speciation analysis
3. Non-GMO Licorice Source Declaration mandatory
4. Phototoxicity & Human Irritation Test Summary required for customs inspection; shipments detained without full test data

2.3 Japanese Label & Marketing Claim Prohibitions

1. Primary Japanese labeling with auxiliary English INCI; medical treatment vocabulary (spot cure, dermatitis improvement) fully prohibited
2. All quasi-drug finished products must print official license registration number; raw packaging must print warning text 化粧品原料 外用のみ (Cosmetic Raw Material – External Use Only)
3. Mandatory storage warning: 遮光冷所保存 (Store in cool dark location) printed on all outer packaging

2.4 Mandatory Document Package for South Korea & Japan Importers

1. Korean/Japanese bilingual COA, TDS & SDS

2. Complete heavy metal + pesticide residue third-party test reports
3. Glabridin skin irritation & phototoxicity test abstract
4. Non-GMO Licorice Plant Extract Declaration
5. RCEP FORM AK Certificate of Origin for tariff exemption
6. Raw material extraction process specification for import pre-registration

PDF 3 Global Tariff & Import Declaration Guide for Traders & Freight Forwarders

3.1 Unified HS Customs Code Classification

High-Purity Glabridin Crystalline Powder: HS 3203001990 (Plant Natural Pigment / Cosmetic Plant-Derived Active Raw Material)

Pre-Dissolved Polyol Liquid Glabridin: HS 3304990090 (Skincare Raw Material Mixture)

3.2 Import Tariff, VAT & Tax Breakdown

EU 27 + United Kingdom

Base MFN Tariff: 6.5%

RCEP FORM A Certificate Eligible Tariff Reduction: 0–3.5%

Import VAT: 19–22% (country variable)

No consumption tax; non-hazardous goods with no additional chemical supervision fees

South Korea

Base Tariff: 8%; RCEP FORM AK tariff fully eliminated for 2026 shipments

Import VAT: 10%

Functional raw material inspection fee: ~150–300 USD per batch

Japan

Base Tariff: 7.2%; RCEP tariff fully eliminated 2026

Consumption Tax: 10%

Fixed Ministry of Health sampling inspection fee: 200–400 USD per shipment

ASEAN (Thailand, Malaysia, Indonesia)

Base Tariff 5–10%; RCEP full tariff exemption for most nations, import VAT 7–11%

3.3 Universal Customs Declaration Document Checklist

Core Trade Documents (All Countries Mandatory)

1. Commercial Invoice: Clearly state INCI GLABRIDIN, CAS Number, purity grade, unit price & total shipment value
2. Packing List: Net weight, gross weight, packaging specifications (aluminum cans / fiber drums), batch breakdown

3. Sales Contract
4. Sea/Air Waybill B/L / AWB
5. Certificate of Origin (FORM A / RCEP FORM AK – core tariff reduction document)

Cosmetic Raw Material Regulatory Technical Documents (Mandatory Customs Inspection, Shipment Returned Missing Any Item)

1. Bilingual English Local-Language SDS
2. Batch Original COA Certificate of Analysis
3. TDS Technical Data Sheet
4. Free Sale Certificate (FSC issued by Chamber of Commerce/NMPA proving legal domestic raw material sale)
5. Raw Material Safety Assessment SAR
6. IPPC Fumigation Certificate (for wooden pallet packaging)

Regional Supplementary Documents

EU: EU Responsible Person Authorization Letter, REACH Registration/Exemption Documents

South Korea: KFDA Raw Material Pre-Notification Receipt, Korean-Language COA

Japan: Japanese Raw Material Specification Certificate, Quasi-Drug Supplementary Safety Test Reports

3.4 Import Declaration Risk Prevention Guide

1. HS Code Misclassification Risk: Incorrect coding to HS 3824 miscellaneous chemicals triggers higher tariff and extra chemical supervision procedures; strictly classify under HS 3203 plant extract code
2. Under-Declared Shipment Value Risk: EU/Korea/Japan customs strictly audit cosmetic

继续翻译

raw material pricing; heavy fines and cargo detention imposed for undervaluation

3. Non-Compliant Packaging Labels: Shipments detained without standard INCI name, hazard warnings or country-of-origin marking

4. Mismatched Document Languages: Customs reject pure Chinese documentation; EU requires multilingual versions, South Korea/Japan demand native-language translated COA/SDS

5. Impurity Over-Limit Risk: Entire shipments seized and destroyed if heavy metals, pesticides or hydroquinone exceed thresholds

3.5 Landed Cost Calculation Template for Foreign Trade Quotation

Total Landed Cost = Raw Material Value + International Sea/Air Freight + Import Tariff (Cargo Value × Tariff Rate) + Import VAT (Cargo Value + Freight + Tariff) + Inspection & Testing Fees + Terminal Handling Charges + Customs Broker Service Fees

Manual Quick Reference Summary for Buyers

1. EU Market: No legal concentration caps; SCCS recommends maximum 0.3% for leave-on formulas; REACH registration + EU Responsible Person mandatory; multilingual labeling required
2. South Korea KFDA: Hard cap of 0.1% for functional whitening finished goods; stricter heavy metal standards; Korean-language filing documentation required
3. Japan PMDA: Hard cap of 0.1% for quasi-drugs; mandatory phototoxicity & irritation test reports; Japanese specification certificates needed
4. Tariff Key Point: RCEP Certificate of Origin eliminates import tariffs for shipments to South Korea and Japan in 2026, significantly cutting overseas procurement expenses