



Cosmetic Ingredients Acetyl Hexapeptide-8 (Draft for Comments)

化妆品用原料 乙酰基六肽-8 (征求意见稿)

National Institutes for Food and Drug Control

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Translated by ChemLinked

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Attachment 9

Cosmetic Ingredients - Acetyl Hexapeptide-8 (Draft for Comments)

1 Scope

This standard specifies the basic information, requirements, test methods, labeling, packaging, transportation, storage and shelf life of acetyl hexapeptide-8 for cosmetics.

This standard applies to the acetate or salt-free acetyl hexapeptide-8 powder produced with glutamic acid, methionine, glutamine and arginine as the starting materials through chemical synthesis, purification, freeze-drying and other procedures.

2 Basic Information

Chemical name:

N-acetyl-L-glutamate-L-glutamate-L-methionine-L-glutamine-L-arginine-L-arginine

INCI Name: Acetyl hexapeptide-8

Chinese name: 乙酰基六肽-8

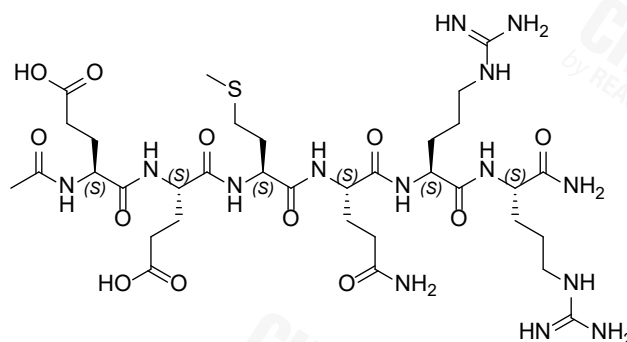
Sequence: Ac-Glu-Glu-Met-Gln-Arg-Arg-NH₂

CAS No.: 616204-22-9

Molecular formula: C₃₄H₆₀N₁₄O₁₂S

Relative molecular weight: 888.42

The structural formula is shown in Figure 1.



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Figure 1 Structural Formula

3 Requirements

3.1 Technique Requirements

3.1.1 Solid Phase Synthesis Technique Process

The acetate or salt-free acetyl hexapeptide-8 powder is obtained through the following technique process: amino acid→coupling→resin peptide→splitting decomposition→crude product→purification→freeze-drying→product.

3.1.2 Liquid Phase Synthesis Technique Process

The acetate or salt-free acetyl hexapeptide-8 powder is obtained through the following technique process: amino acid→coupling→deprotection→crude product→purification→freeze-drying→product.

3.2 Technical Requirements

3.2.1 Sensory Indicators

It shall comply with the provisions of Table 1.

Table 1 Sensory Indicators

Items	Requirements
Trait	White to off-white powder or loose lump, with a characteristic odor
Solubility (25 °C)	Easily soluble in water (>100 mg/mL)

3.2.2 Physicochemical Indicators

It shall comply with the provisions of Table 2.

Table 2 Physicochemical Indicators

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- + Responsible person (RP) service in China
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- + Ingredient safety information submission
- + Cosmetic efficacy evaluation



- + Cosmetic formula and label compliance review
- + EDI Notification
- + Cosmetic QC test service
- + Functional cosmetic registration
- + Ingredients registration by ICID



- + Marketing license application
- + Cosmetics notification
- + Ingredients analysis and full ingredient list translation
- + Cosmetic test service
- + Label & advertisement review



- + Responsible Person (RP) service in the EU & UK
- + Cosmetic Product Notification Portal (CPNP)
- + Cosmetic Product Safety Report (CPSR)
- + Preparation of Product Information File (PIF)



- + Cosmetic formula and label compliance review
- + FDA Voluntary Cosmetic Registration Program (VCRP)
- + California Safe Cosmetics Program (CSCP)
- + Toxicological Risk Assessment (TRA)
- + INCI application

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附件 9

化妆品用原料 乙酰基六肽-8 (征求意见稿)

Cosmetic ingredients Acetyl Hexapeptide-8

1 范围

本标准规定了化妆品用乙酰基六肽-8 的基本信息、要求、试验方法、标志、包装、运输、贮存和保质期。

本标准适用于以谷氨酸、甲硫氨酸、谷氨酰胺和精氨酸为起始原料, 经化学法合成, 再由纯化、冻干等工序制得的醋酸盐或无盐乙酰基六肽-8 粉末。

2 基本信息

化学名称: N-乙酰基-L-谷氨酸-L-谷氨酸-L-甲硫氨酸-L-谷氨酰胺-L-精氨酸-L-精氨酸

INCI 名称: Acetyl Hexapeptide-8

中文名称: 乙酰基六肽-8

序列: Ac-Glu-Glu-Met-Gln-Arg-Arg-NH₂

CAS号: 616204-22-9

分子式: C₃₄H₆₀N₁₄O₁₂S

相对分子质量: 888.42

结构式见图1

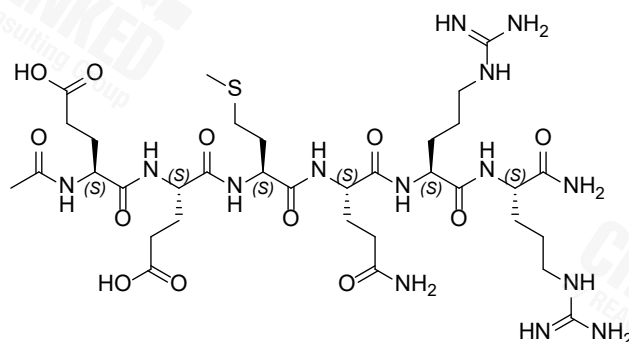


图 1 结构式

3 要求

3.1 工艺要求

3.1.1 固相合成工艺过程

通过氨基酸→偶联→树脂肽→裂解→粗品→纯化→冻干→产品工艺得到的醋酸盐或无盐乙酰基六肽-8粉末。

3.1.2 液相合成工艺过程

通过氨基酸→偶联→脱保护→粗品→纯化→冻干→产品工艺得到的醋酸盐或无盐乙酰基六肽-8粉末。

3.2 技术要求

3.2.1 感官指标

应符合表1的规定。

表 1 感官指标

项目	要求
性状	白色至类白色粉末或疏松块状物，特征性气味
溶解度 (25℃)	本品易溶于水(> 100mg/mL)

3.2.2 理化指标

应符合表2的规定。

表 2 理化指标

项目	要求
鉴别	供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致
pH 值(10 mg/mL, 水溶液, 25℃)	4.0~6.0 (醋酸盐) ; 5.0~7.0 (无盐)
水分/%	≤8.0
纯度/%	≥95.0
醋酸含量/%	≤15.0
三氟乙酸含量/%	≤5.0
肽含量/%	≥80.0



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