Irish Standard
I.S. EN 16342:2013

Cosmetics - Analysis of cosmetic products - Quantitative determination of zinc pyrithione, piroctone olamine and climbazole in surfactant containing cosmetic anti-dandruff products

I.S. EN 16342:2013

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:

This document is based on:
EN 16342:2013

Published:
3 June, 2013

This document was published under the authority of the NSAI and comes into effect on:
3 June, 2013

ICS number:
71.100.70

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Údarás um Chaighdeáin Náisiúnta na hÉireann

I.S. EN 16342:2013

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 16342

May 2013

ICS 71.100.70

English Version

Cosmetics - Analysis of cosmetic products - Quantitative determination of zinc pyrithione, piroctone olamine and climbazole in surfactant containing cosmetic anti-dandruff products

Cosmétiques - Analyse des produits cosmétiques - Détermination quantitative de la pyrithione de zinc, de la piroctone olamine et du climbazole dans les produits cosmétiques antipelliculaires contenant des agents de surface

Kosmetische Mittel - Untersuchung von kosmetischen Mitteln - Quantitative Bestimmung von Zinkpyrithion, Pirocton-Olamin und Climbazol in tensidhaltigen kosmetischen Mitteln mit Antischuppenwirkstoffen

This European Standard was approved by CEN on 25 April 2013.

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Ref. No. EN 16342:2013: E

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Foreword

This document (EN 16342:2013) has been prepared by Technical Committee CEN/TC 392 “Cosmetics”, the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2013, and conflicting national standards shall be withdrawn at the latest by November 2013.

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Introduction

Special hair products contain substances to help prevent dandruff. These substances mainly inhibit the development of microorganisms, which often are the cause of dandruff. The most commonly used substances are zinc pyrithione, piroctone olamine and climbazole. The substances are regulated by Council Directive of 27 July 1976 on the approximation of the laws of the member states relating to cosmetic products (EC 76/768/EEC) as well as Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. Limits for these substances are listed in the annexes regulating preservatives in cosmetic products. Zinc pyrithione is additionally listed in Annex III of both regulative documents named above.

NOTE As the Regulation (EC) 1223/2009 applies in total from 11 July 2013 and replaces Directive 76/768/EEC the following details relate only to Regulation (EC) 1223/2009.

Reference Number, maximum authorised concentration in hair products, limitations and requirements:

Annex III Regulation (EC) 1223/2009

Zinc pyrithione:	No. 101:	0,1 % leave-on hair products	Remark: For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product.

Annex V Regulation (EC) 1223/2009

Zinc pyrithione:	No. 8:	1,0 % hair products	Remark: Only in rinse-off products
		0,5 % other products	Remark: Not to be used in oral products
Climbazole:	No. 32:	0,5 %	
Piroctone olamine:	No. 35:	1,0 % rinse-off products	
		0,5 % other products	

1 Scope

This European Standard specifies an analytical method for the detection and quantitative determination of the following anti-dandruff agents: zinc pyrithione, piroctone olamine and climbazole in surfactant-containing cosmetic products in the concentration range from 0,1 g/100 g to 1,0 g/100 g.

NOTE The method is also suitable for the determination of ketoconazole and ciclopirox olamine (q.v. Annex A) in surfactant-containing cosmetic products and it is probably applicable for the determination of the substances in non surfactant-containing cosmetic products. For these purposes, the method has not been validated.

2 Terms and definitions

For the purposes of this document, the following term and definition applies.

2.1
anti-dandruff agents
substances, added to hair care products, active against the development of microorganism e.g. zinc pyrithione, piroctone olamine and climbazole

3 Principle

The anti-dandruff agents are extracted from the cosmetic sample matrix using dichloromethane and methanol. Each analyte present in the sample extract is separated using reversed phase HPLC with UV (DAD) detection. The quantitative determination is made using the external standard method of calibration.

4 Reagents

4.1 General

If not otherwise specified, as a minimum analytical-grade chemicals shall be used; water shall be distilled or of a corresponding purity. "Solution" shall be understood as an aqueous solution unless otherwise specified.

4.2 Methanol, CAS number: 67-56-1.

4.3 Dichloromethane, CAS number: 75-09-02.

4.4 Acetonitrile, CAS number: 75-05-8.

4.5 Ethylenediaminetetraacetic acid (EDTA) disodium salt dihydrate ($Na_2EDTA \cdot 2H_2O$), CAS number: 6381-92-6.

4.6 Oxalic acid dihydrate, CAS number: 6153-56-6.

4.7 Acetic acid (glacial), CAS number: 64-19-7, mass fraction w = 99,8 g/100 g.

4.8 Acetic acid, molar concentration c = 0,02 mol/l.

Weigh 1,20 g of acetic acid glacial (4.7) into a 1-l-volumetric flask and fill with water up to the calibration mark.

4.9 Methanol/acetic acid mixture

Mix 80 parts by volume of methanol (4.2) and 20 parts by volume of acetic acid (4.8).