



Policy on the use of artificial musks

No Boots brand products or exclusives developed by Boots will use nitro musks or polycyclic musks in fragrances.

November 2008



Policy support document

The use of artificial musks

Background

The term artificial musks is not a chemical description but is applied to widely differing types of substances with a musk-like odour. For many years they have been widely used as fragrance components in all kinds of cosmetic products including fine fragrances, bath foam, showergels, soaps and household detergents.

The issue

There are two groups of 'artificial musks', nitro musks and polycyclic musks, whose safety has been called into question by some pressure groupsⁱ because of claims that they are persistent and bioaccumulative^{ii iii}. There have been claims that some of the artificial musks are endocrine disrupters. Sampling studies have found traces of polycyclic musks and nitromusks in blood samples of volunteers and in breast milk.

Of the Nitromusks, two have been reviewed for human safety by an independent expert group, the Scientific Committee on Cosmetics and Non-food Products, these are musk xylene^{iv} and musk ketone^v. The conclusion of this review was that both these materials are safe at current levels of use, although as additional protection for the consumer a maximum daily exposure level was recommended. Musk xylene has been proposed as one of the first chemicals to be placed on the Substance of Very High Concern candidate list^{vi} under REACH Chemical Legislation^{vii}. Two other nitromusks, musk moskene and musk tibetene, were prohibited from use in cosmetics in 2002.

Following the publication of the 26th adaptation of the Cosmetic regulations^{viii} musk xylene and musk ketone have been added to annex iii with restrictions on the maximum permitted level of use.

There are two polycyclic musks that have been reviewed for safety by the Scientific Committee on Cosmetics and Non-food Products, Tonalide (AHTN)^{ix} & Galaxolide (HHCB)^x. The review requested further information on skin penetration and phototoxicity using recently adopted in vitro methods, and a reassessment of information from an earlier animal study. The committee did not feel it necessary to restrict the use of these materials.

Product development team actions

This policy is implemented as part of GR 010 – General Requirements For Cosmetic And Toiletry Products & GR 039 Candles, Candle Holders and General Scented Products.

No Boots brand products or exclusives will be developed using fragrances containing **Nitro** or **polycyclic musks**.

All fragrances used in Boots Brand Products or exclusives^{xi} must comply with IFRA^{xii} guidelines

Implemented: March 2002 Completed: July 2008

Key questions

- **What products are affected?**
Potentially any product that has a fragrance could be based on nitro or polycyclic musk compounds. Typical uses are shower gels, bubble bath facial cremes & household products.



- **What is the legal status of these chemicals?**
Nitro and polycyclic musks are allowed for use under the UK Cosmetic Regulations^{xiii} although there are restrictions for use on certain musks and bans on three nitromusks (moskene, tibetine, ambrette)
- **Are there suitable replacements?**
Alternatives are available and there is a great deal of work still being carried out by fragrance houses to increase the number of alternatives.
- **What about products already in development?**
Boots implemented this policy in its cosmetic and toiletry area through GR 010 (Feb 2002 and subsequent amendments). New developments must not contain fragrances based on nitro or polycyclic musk.
- **What about existing products?**
Deadline for completion of the policy is July 2008. All products manufactured after this date must be free from nitro and polycyclic musk's therefore reformulation will need to be initiated well before this date.

Key technical information

Nitro musks

Musk Ketone

Synonyms: Acetophenone, 4'-Tert-Butyl-2',6'-Dimethyl-3',5'-Dinitro-; 2-Acetyl- 5-Tert-Butyl-4,6-Dinitroxylene; 1-(4-(1,1-Dimethylethyl)-2,6- Dimethyl-3,5-Dinitrophenyl)Ethanone; Ketone Moschus;

Molecular Formula: C₁₄.H₁₈.N₂.O₅ **CAS:**81-14-1

Musk Moskene

Molecular Formula: C₁₄.H₁₈.N₂.O₄ **CAS:** 116-66-5;

Musk Xylene

Synonyms: 1-Tert.-Butyl-3,5-Dimethyl-2,4,6-Trinitrobenzene

Molecular Formula: C₁₂.H₁₅.N₃.O₆ **CAS:** 81-15-2

Musk Ambrette (artificial ambrette)

Formula: C₁₂.H₁₆.N₂.O₅

CAS: 83-66-9

Musk Tibetene

Formula: C₁₃.H₁₈.N₂.O₄

CAS: 145-39-1

Polycyclic musks

Phantolide (AHMI)

Formula: C₁₇.H₂₄.O

CAS:15323-35-0;

Galaxolide (HHCB)

Formula: C₁₈.H₂₆.O

CAS: 1222-05-5;

Tonalide (AHTN)

Formula: C₁₈.H₂₆.O

CAS: 406-02-1;

Celestolide (ADBI)

Formula: C₁₇.H₂₄.O

CAS:13171-00-1;

Traseolide (ATII)

Formula: C₁₈.H₂₆.O

CAS:68140-48-7



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ⁱ Friends Of the Earth, Greenpeace.

ⁱⁱ Kallenborn, R. And G.G. Rimkus, 'Synthetic musks in environmental samples: indicator compound with relevant properties for environmental monitoring' Journal of environmental monitoring, 1999, 1: p.70N-74N

ⁱⁱⁱ Riedal, J. And W. Dekant, 'Biotransformation and toxicokinetics of musk xylene in humans', Toxicology and applied pharmacology, 1999, 157:p.145-155

^{iv} SCCNFP/0163/99 Opinion of the scientific committee on cosmetic products and non-food products intended for consumers concerning Musk Xylene. 8 December 1999

^v SCCNFP/0162/99 Opinion of the scientific committee on cosmetic products and non-food products intended for consumers concerning Musk Ketone. 8 December 1999

^{vi} http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp

^{vii} http://echa.europa.eu/reach_en.asp

^{viii} Twenty-Sixth Directive 2002/34/EC

^{ix} Draft opinion on AHTN, doc. n° SCCNFP/0372/00, final draft

^x Draft opinion on HHCB, doc. n° SCCNFP/0403/00, final draft

^{xi} Boots brand products and exclusives developed by Boots

^{xii} The International Fragrance Association (IFRA) <http://www.ifraorg.org/>

^{xiii} [Cosmetic Product \(Safety\) Regulations, 2004 SI No. 2152](#) and subsequent amendments