

DEUTSCHE LANOLIN GESELLSCHAFT

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Wollwachs/Lanolin
Wollwachsalkohole
Wollwachsderivate
Wollwachsfettsäuren

Ihre Nachricht:

Unser Zeichen: P/K

Frankfurt, den 23.03.09

BESTÄTIGUNG

Wir bestätigen, dass alle Produkte von NK Chemicals, die wir vertreiben, gemäß der Verordnung 768/67/EEC kein Material der Kategorie 1 und Kategorie 2 gemäß Artikel 4 bzw. 5 der Verordnung (EG)1774/2002 und daraus gewonnene Bestandteile enthält.

Frankfurt am Main, den 19. März 2009

DEUTSCHE-LANOLIN-GESELLSCHAFT

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ANNEX II

▼M3LIST OF SUBSTANCES WHICH MUST NOT FORM PART OF THE
COMPOSITION OF COSMETIC PRODUCTS**▼B**

1. N-5-Chlorobenzoxazol-2-ylacetamide
2. ►**M3** 2-Acetoxyethyltrimethylammonium hydroxide (acetylcholine) and its salts ◀
3. Deanol aceglumate (*)
4. Spironolactone (*)
5. ►**M3** [4-(4-Hydroxy-3-iodophenoxy)-3,5-diiodophenyl]acetic acid and its salts ◀
6. Methotrexate (*)
7. Aminocaproic acid (*) and its salts
8. Cinchophen (*), its salts, derivatives and salts of these derivatives
9. Thyropropic acid (*) and its salts
10. Trichloroacetic acid
11. *Aconitum napellus* L. (leaves, roots and galenical preparations)
12. Aconitine (principal alkaloid of *Aconitum napellus* L.) and its salts
13. *Adonis vernalis* L. and its preparations
14. Epinephrine (*)
15. *Rauwolfia serpentina* alkaloids and their salts
16. Alkyne alcohols, their esters, ethers and salts
17. Isoprenaline (*)
18. Allyl isothiocyanate
19. Alloclamide (*) and its salts
20. Nalorphine (*), its salts and ethers
21. Sympathicomimetic amines acting on the central nervous system: any substance contained in the first list of medicaments which are subject to medical prescription and are referred to in resolution AP (69) 2 of the Council of Europe
22. Aniline, its salts and its halogenated and sulphonated derivatives
23. Betoxycaïne (*) and its salts
24. Zoxazolamine (*)
25. Procainamide (*), its salts and derivatives
26. Benzidine
27. Tuaminoheptane (*), its isomers and salts
28. Octodrine (*) and its salts
29. ►**M3** 2-Amino-1,2-bis(4-methoxyphenyl)ethanol and its salts ◀
30. 1,3-dimethylpentylamine and its salts
31. 4-Aminosalicylic acid and its salts
32. Toluidines, their isomers, salts and halogenated and sulphonated derivatives
33. Xylidines, their isomers, salts and halogenated and sulphonated derivatives

(*) In this Directive, names followed by an asterisk are those published in 'Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN', WHO, Geneva, August 1975.

▼ M24

- 416. Cells, tissues or products of human origin
- 417. 3,3-Bis(4-hydroxyphenyl)phthalide (Phenolphthalein (*))

▼ M25

- 418. 3-Imidazol-4-ylacrylic acid and its ethyl ester (urocanic acid)

▼ M49

- 419. Category 1 material and Category 2 material as defined in Articles 4 and 5 respectively of Regulation (EC) No 1774/2002 of the European Parliament and of the Council ⁽¹⁾, and ingredients derived therefrom.

▼ M28

- 420. Crude and refined coal tars

▼ M30

- 421. 1,1,3,3,5-Pentamethyl-4,6-dinitroindane (moskene)
- 422. 5-*tert*-Butyl-1,2,3-trimethyl-4,6-dinitrobenzene (musk tibetene).

▼ M34

- 423. Alanroot oil (*Inula helenium*) (CAS No 97676-35-2), when used as a fragrance ingredient.
- 424. Benzyl cyanide (CAS No 140-29-4), when used as a fragrance ingredient.
- 425. Cyclamen alcohol (CAS No 4756-19-8), when used as a fragrance ingredient.
- 426. Diethyl maleate (CAS No 141-05-9), when used as a fragrance ingredient.
- 427. Dihydrocoumarine (CAS No 119-84-6), when used as a fragrance ingredient.
- 428. 2,4-Dihydroxy-3-methylbenzaldehyde (CAS No 6248-20-0), when used as a fragrance ingredient.
- 429. 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol) (CAS No 40607-48-5), when used as a fragrance ingredient.
- 430. 4,6-Dimethyl-8-*tert*-butylcoumarin (CAS No 17874-34-9), when used as a fragrance ingredient.
- 431. Dimethyl citraconate (CAS No 617-54-9), when used as a fragrance ingredient.
- 432. 7,11-Dimethyl-4,6,10-dodecatrien-3-one (CAS No 26651-96-7), when used as a fragrance ingredient.
- 433. 6,10-Dimethyl-3,5,9-undecatrien-2-one (CAS No 141-10-6), when used as a fragrance ingredient.
- 434. Diphenylamine (CAS No 122-39-4), when used as a fragrance ingredient.
- 435. Ethyl acrylate (CAS No 140-88-5), when used as a fragrance ingredient.
- 436. Fig leaf absolute (*Ficus carica*) (CAS No 68916-52-9), when used as a fragrance ingredient.
- 437. *trans*-2-Heptenal (CAS No 18829-55-5), when used as a fragrance ingredient.
- 438. *trans*-2-Hexenal diethyl acetal (CAS No 67746-30-9), when used as a fragrance ingredient.
- 439. *trans*-2-Hexenal dimethyl acetal (CAS No 18318-83-7), when used as a fragrance ingredient.
- 440. Hydroabietyl alcohol (CAS No 13393-93-6), when used as a fragrance ingredient.
- 441. 6-Isopropyl-2-decahydronaphthalenol (CAS No 34131-99-2), when used as a fragrance ingredient.
- 442. 7-Methoxycoumarin (CAS No 531-59-9), when used as a fragrance ingredient.

(*) In this Directive, names followed by an asterisk are those published in 'Computer print-out 1975, International Non-proprietary Names (INN) for pharmaceutical products, Lists 1-33 of proposed INN', WHO, Geneva, August 1975.

(¹) OJ L 273, 10.10.2002, p. 1.

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- (e) catering waste, unless:
 - (i) from means of transport operating internationally,
 - (ii) destined for animal consumption, or
 - (iii) destined for use in a biogas plant or for composting;
 - (f) ova, embryos and semen intended for breeding purposes; and
 - (g) transit by sea or by air.
3. This Regulation shall not affect veterinary legislation having as its objective the eradication and control of certain diseases.

*Article 2***Definitions**

1. For the purpose of this Regulation, the following definitions shall apply:
- (a) **animal by-products:** entire bodies or parts of animals or products of animal origin referred to in Articles 4, 5 and 6 not intended for human consumption, including ova, embryos and semen;
 - (b) **Category 1 material:** animal by-products referred to in Article 4;
 - (c) **Category 2 material:** animal by-products referred to in Article 5;
 - (d) **Category 3 material:** animal by-products referred to in Article 6;
 - (e) **animal:** any vertebrate or invertebrate animal (including fish, reptiles and amphibians);
 - (f) **farmed animal:** any animal that is kept, fattened or bred by humans and used for the production of food (including meat, milk and eggs), wool, fur, feathers, skins or any other product of animal origin;
 - (g) **wild animal:** any animal not kept by humans;
 - (h) **pet animal:** any animal belonging to species normally nourished and kept, but not consumed, by humans for purposes other than farming;
 - (i) **competent authority:** the central authority of a Member State competent to ensure compliance with the requirements of this Regulation or any authority to which that central authority has delegated that competence, in particular for the control of feeding-stuffs; it shall also include, where appropriate, the corresponding authority of a non-member country;
 - (j) **placing on the market:** any operation the purpose of which is to sell animal by-products, or products derived therefrom covered by this Regulation, to a third party in the Community or any other form of supply against payment or free of charge to such a third party or storage with a view to supply to such a third party;
 - (k) **trade:** trade between Member States in goods within the meaning of Article 23(2) of the Treaty;
 - (l) **transit:** a movement through the Community from one non-member country to another;
 - (m) **producer:** any person whose activity produces animal by-products;
 - (n) **TSEs:** all transmissible spongiform encephalopathies, except those occurring in humans;

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- (o) **specified risk material:** material referred to in Annex V to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾.
2. The specific definitions set out in Annex I shall also apply.

*Article 3***General obligations**

1. Animal by-products, and products derived therefrom, shall be collected, transported, stored, handled, processed, disposed of, placed on the market, exported, carried in transit and used in accordance with this Regulation.
2. However, Member States may regulate under national law the importation and placing on the market of products not referred to in Annexes VII and VIII, pending the adoption of a decision in accordance with the procedure referred to in Article 33(2). They shall immediately inform the Commission of the use that they make of this possibility.
3. Member States shall, either individually or cooperatively, ensure that adequate arrangements are in place, and that a sufficient infrastructure exists, to ensure compliance with the requirement of paragraph 1.

CHAPTER II

CATEGORISATION, COLLECTION, TRANSPORTATION, DISPOSAL, PROCESSING, USE AND INTERMEDIATE STORAGE OF ANIMAL BY-PRODUCTS*Article 4***Category 1 material**

1. Category 1 material shall comprise animal by-products of the following description, or any material containing such by-products:
- (a) all body parts, including hides and skins, of the following animals:
- (i) animals suspected of being infected by a TSE in accordance with Regulation (EC) No 999/2001 or in which the presence of a TSE has been officially confirmed,
 - (ii) animals killed in the context of TSE eradication measures,
 - (iii) animals other than farmed animals and wild animals, including in particular pet animals, zoo animals and circus animals,
 - (iv) experimental animals as defined by Article 2 of Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ⁽²⁾, and
 - (v) wild animals, when suspected of being infected with diseases communicable to humans or animals;
- (b) (i) specified risk material, and
- (ii) where, at the time of disposal, specified risk material has not been removed, entire bodies of dead animals containing specified risk material;

⁽¹⁾ OJ L 147, 31.5.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 1326/2001 (OJ L 177, 30.6.2001, p. 60).

⁽²⁾ OJ L 358, 18.12.1986, p. 1.

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- (c) products derived from animals to which substances prohibited under Directive 96/22/EC have been administered and products of animal origin containing residues of environmental contaminants and other substances listed in Group B(3) of Annex I to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC ⁽¹⁾, if such residues exceed the permitted level laid down by Community legislation or, in the absence thereof, by national legislation;
- (d) all animal material collected when treating waste water from Category 1 processing plants and other premises in which specified risk material is removed, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises, unless such material contains no specified risk material or parts of such material;
- (e) catering waste from means of transport operating internationally; and
- (f) mixtures of Category 1 material with either Category 2 material or Category 3 material or both, including any material destined for processing in a Category 1 processing plant.

2. Category 1 material shall be collected, transported and identified without undue delay in accordance with Article 7 and, except as otherwise provided in Articles 23 and 24, shall be:

- (a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;
- (b) processed in a processing plant approved under Article 13 using any of processing methods 1 to 5 or, where the competent authority so requires, processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and finally disposed of as waste by incineration or by co-incineration in an incineration or co-incineration plant approved in accordance with Article 12;
- (c) with the exclusion of material referred to in paragraph 1(a)(i) and (ii), processed in a processing plant approved in accordance with Article 13 using processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and finally disposed of as waste by burial in a landfill approved under Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste ⁽²⁾;
- (d) in the case of catering waste referred to in paragraph 1(e), disposed of as waste by burial in a landfill approved under Directive 1999/31/EC; or
- (e) in the light of developments in scientific knowledge, disposed of by other means that are approved in accordance with the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee. These means may either supplement or replace those provided for in subparagraphs (a) to (d).

3. Intermediate handling or storage of Category 1 material shall take place only in Category 1 intermediate plants approved in accordance with Article 10.

4. Category 1 material shall not be imported or exported except in accordance with this Regulation or with rules laid down under the procedure referred to in Article 33(2). However, the import or export of specified risk material shall take place only in accordance with Article 8(1) of Regulation (EC) No 999/2001.

⁽¹⁾ OJ L 125, 23.5.1996, p. 10.

⁽²⁾ OJ L 182, 16.7.1999, p. 1.

▼B*Article 5***Category 2 material**

1. Category 2 material shall comprise animal by-products of the following description, or any material containing such by-products:

- (a) manure and digestive tract content;
- (b) all animal materials collected when treating waste water from slaughterhouses other than slaughterhouses covered by Article 4(1)(d) or from Category 2 processing plants, including screenings, materials from desanding, grease and oil mixtures, sludge and materials removed from drains from those premises;
- (c) products of animal origin containing residues of veterinary drugs and contaminants listed in Group B(1) and (2) of Annex I to Directive 96/23/EC, if such residues exceed the permitted level laid down by Community legislation;
- (d) products of animal origin, other than Category 1 material, that are imported from non-member countries and, in the course of the inspections provided for in Community legislation, fail to comply with the veterinary requirements for their importation into the Community, unless they are returned or their importation is accepted under restrictions laid down under Community legislation;
- (e) animals and parts of animals, other than those referred to in Article 4, that die other than by being slaughtered for human consumption, including animals killed to eradicate an epizootic disease;
- (f) mixtures of Category 2 material with Category 3 material, including any material destined for processing in a Category 2 processing plant; and
- (g) animal by-products other than Category 1 material or Category 3 material.

2. Category 2 material shall be collected, transported and identified without undue delay in accordance with Article 7 and, except as otherwise provided in Articles 23 and 24, shall be:

- (a) directly disposed of as waste by incineration in an incineration plant approved in accordance with Article 12;
- (b) processed in a processing plant approved in accordance with Article 13 using any of processing methods 1 to 5 or, where the competent authority so requires, processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and:
 - (i) disposed of as waste either by incineration or by coincineration in an incineration or co-incineration plant approved in accordance with Article 12, or
 - (ii) in the case of rendered fats, further processed into fat derivatives for use in organic fertilizers or soil improvers or for other technical uses, other than in cosmetics, pharmaceuticals and medical devices, in a Category 2 oleochemical plant approved in accordance with Article 14;
- (c) processed in a processing plant approved in accordance with Article 13 using processing method 1, in which case the resulting material shall be permanently marked, where technically possible with smell, in accordance with Annex VI, Chapter I, and:
 - (i) in the case of resulting proteinaceous material, used as an organic fertilizer or soil improver in compliance with requirements, if any, laid down in accordance with the

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- procedure referred to in Article 33(2), after consultation of the appropriate scientific committee,
- (ii) transformed in a biogas plant or in a composting plant approved in accordance with Article 15, or
 - (iii) disposed of as waste by burial in a landfill approved under Directive 1999/31/EC;
- (d) in the case of material of fish origin, ensiled or composted in compliance with rules adopted in accordance with the procedure referred to in Article 33(2);
- (e) in the case of manure, digestive tract content separated from the digestive tract, milk and colostrum, if the competent authority does not consider them to present a risk of spreading any serious transmissible disease:
- (i) used without processing as raw material in a biogas plant or in a composting plant approved in accordance with Article 15 or treated in a technical plant approved for this purpose in accordance with Article 18,
 - (ii) applied to land in accordance with this Regulation, or
 - (iii) transformed in a biogas plant or composted in accordance with rules laid down under the procedure referred to in Article 33(2);
- (f) in the case of entire bodies or parts of wild animals not suspected of being infected with diseases communicable to humans or animals, used to produce game trophies in a technical plant approved for this purpose in accordance with Article 18; or
- (g) disposed of by other means, or used in other ways, in accordance with rules laid down under the procedure referred to in Article 33(2), after consultation of the appropriate scientific committee. These means or ways may either supplement or replace those provided for in subparagraphs (a) to (f).
3. Intermediate handling or storage of Category 2 material, other than manure, shall take place only in Category 2 intermediate plants approved in accordance with Article 10.
4. Category 2 material shall not be placed on the market or exported except in accordance with this Regulation or with rules laid down under the procedure referred to in Article 33(2).

*Article 6***Category 3 material**

1. Category 3 material shall comprise animal by-products of the following description, or any material containing such by-products:
- (a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons;
 - (b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation;
 - (c) hides and skins, hooves and horns, pig bristles and feathers originating from animals that are slaughtered in a slaughterhouse, after undergoing ante-mortem inspection, and were fit, as a result of such inspection, for slaughter for human consumption in accordance with Community legislation;
 - (d) blood obtained from animals other than ruminants that are slaughtered in a slaughterhouse, after undergoing ante-mortem