Health & Safety Dossier - CONFIDENTIAL

Lexgard® Natural

Last Revised: July 30, 2015

Chemical Data

INCI Name: Glyceryl Caprylate (and) Glyceryl Undecylenate
CAS #: 26402-26-6; 65684-27-7, 67701-31-9
Chemical Composition: Glyceryl Caprylate, Glyceryl Undecylenate

Method of Manufacture

Lexgard Natural is manufactured by two separate esterifications of glycerin with caprylic acid in conjunction with glycerin with undecylenic acid. The ester mixture is then distilled, cooled, filtered, and packaged.

Material Origin

Material Source: Lexgard Natural is derived from vegetable sources.

BSE/TSE: In response to issues of the "specific risk" of Transmissible Spongiform Encephalopathy (TSE) as defined by the European Union (EU) Decision [2000/418/EC] and the further response by the Japanese Ministry of Health, Labor, and Welfare (Pharmaceutical & Medical Safety Bureau) Notification No. 990, Inolex certifies that Lexgard NATURAL is derived solely from vegetable sources. It is not derived from, nor does it contain, any animal-based materials.

Genetically Modified Organism: Materials used in the manufacture of Lexgard Natural are derived from vegetable sources. The components used in the manufacture of Lexgard Natural are derived from vegetable feedstock not known to be of genetically modified origin. To the best of our knowledge, Inolex believes Lexgard Natural to be GMO free.

Regulatory Status

Phthalates Content: Inolex assures that the manufacturing process for Lexgard Natural does not use phthalates or materials that contain phthalates.

Allergens: Lexgard Natural does not contain any of the 26 allergen ingredients as defined in the 7th amendment of the European Cosmetic Directive 76/768/EEC.

California Proposition 65: Lexgard Natural is not on the list of chemicals known to the state of California to cause cancer or reproductive toxicity.

CMR Status: Lexgard Natural does not contain substances classified as C (Carcinogen), M (Mutagen), or R (Toxic for Reproduction) of category 1A, 1B, or 2. These substances are listed in the Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Glycol Ether Content: Pursuant to EU Cosmetic Directive 94/60/EEC, Inolex certifies that Lexgard Natural does not contain any glycol ethers.

Residual Solvents: Both the USP guideline and the ICH Harmonized guideline (now adopted by the EU Pharmacopeia) state that testing should be performed only when production or purification processes are known to result in the presence of such solvents (CPMP/ICH/283/95). Inolex certifies the following statements:

USP/NF Organic Volatile Impurities Test 467
Inolex assures that, based on raw materials, composition, manufacturing, handling, and storage procedures utilized at our plant sites, there is no potential for the specific toxic solvents regulated by this test to be present in Lexgard Natural.

European Pharmacopeia, Section 5.4, Residual Solvents
Inolex assures that, based on raw materials, manufacturing, handling, and storage procedures utilized at our plant sites, there is no potential for residual solvents of class 1, 2 or 3 mentioned in the guidelines for residual solvents (CPMP/ICH/283/95) of the European Pharmacopoeia, to be present in Lexgard Natural.

Additives/Preservatives: None

Inolex | 2101 S. Swanson St. | Philadelphia, PA 19148 USA | toll free + 1 800 521 9891 | office + 215 271 0800 | fax + 215 271 6282 | www.inolex.com

Lexgard® Natural

Toxicity Review

Repeated Insult Patch Test
Clinical Research Laboratories, Inc. – March 2010

The upper back between the scapulae served as the treatment area on 52 human subjects. Approximately 0.02 grams of Lexgard® Natural was applied to the 3/4" x 3/4" gauze portion of a clear adhesive dressing that was dampened with water. It was then applied to the treatment site to form a semi-occluded patch. This procedure was followed three times a week for a total of nine applications. Two weeks following the ninth application, a challenge patch was applied to the original site and to a virgin site. Each site was evaluated at 24 and 48 hours after application.

Observations on all subjects remained negative throughout the test interval. Under the conditions of this study, Lexgard® Natural did not indicate a potential for eliciting dermal irritation and/or sensitization.

Biodegradability OECD 301A (1992)
Springborn Smithers Laboratories, August 2010

Based on the results, Glyceryl Caprylate (and) Glyceryl Undecylenate is found to be **readily biodegradable** by OECD definition since greater than 70% biodegradation was observed with a 10-day window. The rapid degradation of the reference substance confirmed the presence of an acceptable microbial community and confirmed system integrity.

Public Domain Toxicity Studies for CAS# 26402-26-6

Human Skin Sensitization
International Research Services, Inc., November 1994.

A small amount of Glyceryl monocaprylate (0.025 ml) was applied to the scapular back fifty-six human subjects in accordance with a modified Draize Assay employing an 8mm Finn Chamber. Applications were made three (3) days per week for three (3) weeks, with one (1) final application during week four (4).

Glyceryl monocaprylate and glyceryl monoundecylenate were found to be neither a significant dermal irritant nor contact sensitizer.

Acute Oral Toxicity
Glyceryl monocaprylate **LD_{50} > 26 mg/kg** rat**.**

Skin Compatibility
In a carrier (DAB 10 Vaseline), Glyceryl monocaprylate exhibited no irritation at 3% (Duhring Chamber Test) and very mild skin irritation at 10% (RIPT).

U.S. EPA Evaluation for Glyceryl and Propylene Glycol monoesters of C8, C10 and C12 fatty acid
LC_{50} (4hr inhalation, rat) > 4.92 mg/L, Non-toxic

LD_{50} (rat) >5,000 mg/kg
28 Day Oral Toxicity (rat): Non-toxic
Non-Genotoxic

Inolex Studies for CAS# 65684-27-7

Eye Irritation Study
MB Research Laboratories, Inc. – June 2010

EpiOcular MTT Viability Assay. Non-Animal testing alternative method. Ocular toxicity or irritation potential of the test substance is determined by the ET_{50} for MTT viability of EpiOcular samples. MatTek EpiOcular tissue samples were treated with test substance followed by viability testing of the tissues using MTT uptake and conversion. Resulting absorbance of each sample was measured at 540 nm and the viability was then expressed as a percentage versus the control values. The calculated ET_{50} represents the time at which the EpiOcular tissue viability was reduced by 50% compared to the control tissues.

Results: ET_{50} > 6.6 min.
Glyceryl Undecylenate is classified as **Moderate.**

Dermal Irritation Study
MB Research Laboratories, Inc. - June 2010

EpiDerm MTT Viability Assay. Non-Animal testing alternative method. Dermal toxicity or irritation potential of the test substance is determined by the ET_{50} for MTT viability of EpiDerm samples. MatTek EpiDerm tissue samples were treated with test substance followed by viability testing of the tissues using MTT uptake and conversion. Resulting absorbance of each sample was measured at 540 nm and the viability was then expressed as a percentage versus the control values. The calculated ET_{50} represents the time at which the EpiDerm tissue viability was reduced by 50% compared to the control tissues.

Results: ET_{50} > 5.3 hours

Inolex | 2101 S. Swanson St. | Philadelphia, PA 19148 USA | toll free + 1 800 521 9891 | office + 215 271 0800 | fax + 215 271 6282 | www.inolex.com

Glyceryl Undecylenate is classified as **Moderate to Mild.**

References: Available under confidentiality agreement.

Global Registration Status

EU Inventory: REACH Pre-Registered

Canadian DSL Inventory: Complies

Korean (ECL) Inventory: ECL Serial No. KE-26647

Australian (AICS) Inventory: CAS #: 26402-26-6, 67701-31-9 are listed on AICS.

Philippines (PICCS) Inventory: Listed on PICCS

Japanese (ENCS) Inventory: ENCS No. 2-666

Chinese Chemical Inventory Status: Complies

Storage

It is recommended that Inolex products be stored in unopened, original containers and be kept indoors.

Recommended re-evaluation date 36 months.

Recommended Re-Evaluation Date is the time period in which the product is expected to maintain its initial physical and chemical characteristics from the Date of Manufacture as indicated on the Certificate of Analysis. The Recommended Re-Evaluation Date period will be affected by storage conditions such as temperature, humidity, and the environment of the storage area.

Inolex | 2101 S. Swanson St. | Philadelphia, PA 19148 USA | toll free + 1 800 521 9891 | office + 215 271 0800 | fax + 215 271 6282 | www.inolex.com