

**IPEC-AMERICAS** Inc.

international pharmaceutical excipients council of the americas

1655 North Fort Myer Drive, Suite 700
Arlington, VA 22209
Tel: (703) 875-2127
Fax: (703) 525-5157

Product Regulatory Datasheet

Section 1 - Product Information

- **Product name:** IPECane
- **Codes:** 00001, 00011, 00111
- **Scope of document:** All IPECanes also known as IPEC solvents

Section 2 – Manufacturing, Packaging and Release Site Information

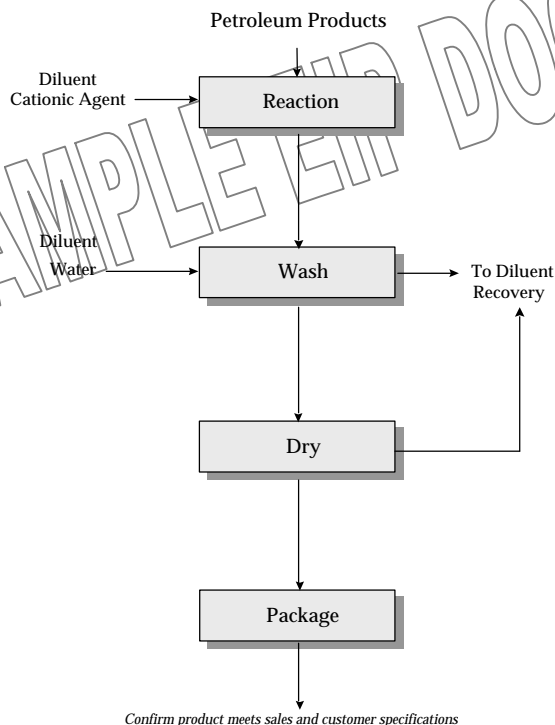
- IPECane is manufactured, packaged and tested for release as per IPEC GMP guidelines at the following location:

1655 North Fort Myer Drive, Suite 700
Arlington, VA 22209

- These products are manufactured in conformance with The Joint IPEC-PQC Good Manufacturing Practice Guide

Section 3 – Physical/Chemical Information

- **CAS number:** 11-11111-1111
- IPECane is synthetically derived from a reaction of petroleum based chemical components
- IPECane can be known as IPEC solvents and IPEC alcohols
- Production process overview:




IPEC-AMERICAS Inc.

international pharmaceutical excipients council of the americas

1655 North Fort Myer Drive, Suite 700
 Arlington, VA 22209
 Tel: (703) 875-2127
 Fax: (703) 525-5157

Product Regulatory Datasheet

Section 4 - Regulatory Information

- **Compendial Compliance:**
 Product Code 00001 meets USP specifications
 Product Code 00011 meets USP and PhEur specifications
 Product Code 00111 meets USP, PhEur, and JP specifications
- **Drug Master Files** are available for these products in the United States and Canada; please contact your IPEC-Americas representative for further information
- **BSE/TSE Status:** The products covered by this document are synthetically manufactured in dedicated equipment in a facility where no animal derived materials are used. Based on the manufacturing and processing methods used there is no potential for Transmissible Spongiform Encephalopathies to be present in these products.
- **Allergens/Hypersensitivities:** The products listed are not derived from and do not contain:

Cereals containing gliadin gluten (wheat, rye, barley, oats)
Milk/dairy products
Eggs
Fish/crustacean/shellfish including abalone and squid
Peanuts
Tree nuts
Soybeans
Celery
Mustard
Sesame seeds
Buckwheat, oranges, kiwifruit, peaches, apples, yams or mushrooms
Gelatin
Sulphur dioxide/sulphites at concentrations greater than 10 mg/kg as SO ₂

These products are manufactured under strict GMP guidelines which allow no potential for cross contamination of any allergens or other products.

- **GMO Information:** The subject materials are manufactured using a chemical process and does not contain any genetically modified organisms (GMO) nor are such organisms used in the manufacture or processing of these products.
- **Residual Solvents/Organic Volatile Impurities (OVI) Information:** The products listed above are not manufactured with the solvents listed in the International Committee of Harmonization (ICH) Guidelines. These products comply with the requirements of the ICH Q3C Residual Solvents Guideline. There is no potential of any ICH listed solvents to be present in the IPECcane products.
- **Kosher/Halal Status:** Kosher and Halal certificates are available for these products through your IPEC-Americas representative.
- **Other Concerns:** *This section is optional and can contain any information that the preparer feels is pertinent to the use of this product. Some topics that may be covered in this section include: heavy metals, residual catalysts, Proposition 65, aflatoxins or other toxins, preservatives, latex, silicones, status with respect to use in foods labeled as organic or as containing organic ingredients, etc.*

**IPEC-AMERICAS** Inc.

international pharmaceutical excipients council of the americas

1655 North Fort Myer Drive, Suite 700
Arlington, VA 22209
Tel: (703) 875-2127
Fax: (703) 525-5157

Product Regulatory Datasheet

Section 5 - Miscellaneous Product Information

- **Lot Numbering System:** The lot number is six digits in length. The first two digits are year, second two digits month, last 2 are sequential order batch number
- **Batch Definition:** Batches are defined as a single reactor.
- **Reevaluation Period:** IPECane products are stable for 18 months in their original unopened containers. If you have any questions about the quality of a product where the container has been previously opened, we recommend testing the product for fitness for use in your particular application.
- **Other Information:** *This section is optional and can contain any information that the preparer feels is pertinent to the use of this product. Some topics that may be covered in this section include: common uses, nutritional information, package size offerings and/or types, etc.*

Section 6 – Revisions

- Product Regulatory Data Sheet: EIP-PRD 1.1, Revision 0, Initial Issue
Effective Date: July 28, 2006
- Changes Since Last Revision: None

Section 7 - Contact Information

For further information on the subjects covered by this document please contact the Information Department at 800.000.0000

For other product information please contact the Service Department at 800.111.1111