Inactive Ingredient Search for Approved Drug Products: Frequently Asked Questions

- **Most recent changes to the database (/Drugs/InformationOnDrugs/ucm567080.htm)** (updated 7/14/2017)
- **Search the Inactive Ingredient Database (http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm)**

About the Inactive Ingredient Database

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1. What is an inactive ingredient?

According to 21 CFR 210.3(b)(8), an inactive ingredient is any component of a drug product other than the active ingredient. Only inactive ingredients in the final dosage forms of drug products are in this database.

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2. What is an active ingredient?

According to 21 CFR 210.3(b)(7), an active ingredient is any component of a drug product intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. Active ingredients include those components of the product that may undergo chemical change during the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

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3. What is the purpose of the Inactive Ingredient Database?

The Inactive Ingredient Database provides information on inactive ingredients present in FDA-approved drug products. This information can be used by industry as an aid in developing drug products. For new drug development purposes, once an inactive ingredient has appeared in an approved drug product for a particular route of administration, the inactive ingredient is not considered new and may require a less extensive review the next time it is included in a new drug product. For example, if a particular inactive ingredient has been approved in a certain dosage form at a certain potency, a sponsor could consider it safe for use in a similar manner for a similar type of product.

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4. How do you use the Inactive Ingredient Database?

You can search the Inactive Ingredient Database by entering any portion of the name of an inactive ingredient. You must enter at least three characters. Search results are displayed alphabetically, sorted first by ingredient, then by the route of administration and dosage form. Routes of administration and dosage forms are derived from current approved labeling.

Field Descriptions (/Drugs/InformationOnDrugs/ucm075230.htm)

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5. What is maximum potency?

Maximum potency is the amount of the excipient used in the approved product that is the basis for the IID listing. The IID lists the highest amount of the excipient per unit dose in each dosage form in which it is used. The amounts shown for maximum potency do not reflect the maximum daily intake (MDI) of the excipient unless the maximum daily dose of the product that is the basis for the listing is only a single unit. For topical products and other products where excipients are expressed as a percentage of the product formula, maximum potency is the highest formula percentage. Maximum potency of an excipient is a dynamic value that changes when FDA approves products with new, higher levels of the excipient. After approval, these new maximum potencies will appear in the next publication of the IID.

6. Can an inactive ingredient ever be considered an active ingredient?

The Inactive Ingredient Database contains inactive ingredients specifically intended as such by the manufacturer. Inactive ingredients can also be considered active ingredients under certain circumstances, according to the **definition of an active ingredient** given in 21 CFR 210.3(b)(7). Alcohol is a good example of an ingredient that may be considered either active or inactive depending on the product formulation.

Reactants in radiopharmaceutical kits, or inactive ingredients that physically or chemically combine with active ingredients to facilitate drug transport are considered inactive ingredients.

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7. Does the Inactive Ingredient Database include contaminants found in approved drug products?

No. The Inactive Ingredients Database does not include contaminants found in approved drug products.

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8. What is a CAS Number?

The acronym "CAS" stands for "Chemical Abstracts Service," a division of the American Chemical Society that provides comprehensive electronic chemical information services. CAS assigns unique CAS Registry Numbers to chemical substances. Many inactive ingredients have CAS Registry Numbers, which are useful in searching other databases for chemical information. The CAS Registry Number itself has no chemical significance.

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9. What is a UNII?

The acronym “UNII” stands for “Unique Ingredient Identifier”. The UNII is a part of the joint United States Pharmacopeia (USP)/FDA Substance Registration System (SRS), which has been designed to support health information technology initiatives by providing unique identifiers for substances in drugs, biologics, foods, and devices based on molecular structure and/or descriptive information. The SRS is used to generate permanent, unique, unambiguous identifiers for substances in regulated products, such as ingredients in drug products. The UNII is being displayed in association with inactive ingredients to facilitate **Structured Product Labeling (http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm)** (SPL), which requires that a UNII be used for all ingredients, including inactive ingredients.

Not all inactive ingredients will have a UNII. In order to receive a UNII, an ingredient must be a ‘substance’, which is defined as “Any physical material that has a discrete existence, irrespective of origin.” Products will not be assigned a UNII. For example, “purified water” and “sterile water for injection” are considered products within the context of the SRS because something is done to the substance “water” in order to make it more useful. Proprietary ingredients, such as “OPADRY II 85F10919 BLUE”, are considered products and will not be assigned a UNII. Such products are denoted by "N/A".

More information about the UNII and the SRS is available at **Substance Registration System - Unique Ingredient Identifier (UNII) (http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm)**. All chemically-related questions about the UNII or the SRS that are not answered on the FDA website should be directed **fda-srs@fda.hhs.gov (mailto:fda-srs@fda.hhs.gov)**.

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10. How often do you update the Inactive Ingredient Database?

We update the database quarterly, by the tenth working day of April, July, October, and January.

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11. How can I get a copy of the Inactive Ingredient Database?

You can download the contents of the Inactive Ingredient Database. The **Inactive Ingredient Database Download (/Drugs/InformationOnDrugs/ucm113978.htm)** are provided as delimited text and Excel files.

Text files since 2009 are provided in order to track previous changes.

Data field descriptions (/Drugs/InformationOnDrugs/ucm075230.htm)

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Inactive Ingredient Database Help and Information files

Inactive Ingredients Database Help, Instruction, and Download files

- **Inactive Ingredient Field Descriptions (/Drugs/InformationOnDrugs/ucm075230.htm)**
- **Inactive Ingredient Database Download (/Drugs/InformationOnDrugs/ucm113978.htm)**

Resources for You

- **Structured Product Labeling Resources (/ForIndustry/DataStandards/StructuredProductLabeling/default.htm)**
- **Substance Registration System - Unique Ingredient Identifier (UNII) (/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm)**
- **CDER FOIA Electronic Reading Room (/Drugs/GuidanceComplianceRegulatoryInformation/CDERFOIAElectronicReadingRoom/default.htm)**
- **Inactive Ingredients Database Download (/Drugs/InformationOnDrugs/ucm113978.htm)**

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Approved Drugs (/Drugs/InformationOnDrugs/ApprovedDrugs/default.htm)