

April 2002

Animal-Derived Cosmetic Ingredient Database

**Contract No. 223-96-2290:
Task Order 14**

Database Documentation

Prepared for

Amber Jessup

DHHS/Food and Drug Administration
Center for Food Safety and Applied Nutrition, HFS-726
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by

Robert H. Beach

Jean Domanico

Shawn Karns

RTI

Health, Social, and Economics Research
Research Triangle Park, NC 27709

RTI Project Number 06673.014



RTI Project Number
06673.014

Animal-Derived Cosmetic Ingredient Database

**Contract No. 223-96-2290:
Task Order 14**

Database Documentation

April 2002

Prepared for

Amber Jessup

DHHS/Food and Drug Administration
Center for Food Safety and Applied Nutrition, HFS-726
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by

Robert H. Beach

Jean Domanico

Shawn Karns

RTI

Health, Social, and Economics Research
Research Triangle Park, NC 27709

Contents

Preface	v
1. Introduction	1-1
1.1 Overview of the Animal-Derived Cosmetic Ingredient Database.....	1-2
1.2 Overview of the Report	1-3
2. Data Sources and Coding of the ADCID	2-1
2.1 Data Sources.....	2-1
2.2 Constructing the List of Ingredients	2-2
2.3 Obtaining Data for Each Field.....	2-3
3. Database Design and Use	3-1
3.1 Database Tables.....	3-1
3.2 Ingredient Information Form	3-2
3.3 Example Queries.....	3-13
3.4 Hidden Database Objects.....	3-14
References	R-1

Figures

Figure 3-1	Overview of Database Tables.....	3-2
Figure 3-2	Example Ingredient Information Form with Four Tabs	3-3
Figure 3-3	Example Trade Names Tab.....	3-4
Figure 3-4	Example Supplier Information Form.....	3-5
Figure 3-5	Example Functions and Product Types Tab.....	3-5
Figure 3-6	Example Mixtures Tab.....	3-12
Figure 3-7	Example Supplier Information Form.....	3-13

Tables

Table 3-1	Potential Animal Sources for Each Animal Type Category	3-4
-----------	--	-----

Preface

The Food and Drug Administration (FDA) contracted with RTI to compile a database of animal-derived cosmetic ingredients to help identify cosmetics that could potentially transmit Bovine Spongiform Encephalopathy (BSE) or other Transmissible Spongiform Encephalopathies (TSE). This document describes the database, which is referred to as the Animal-Derived Cosmetic Ingredient Database (ADCID).

The animal-derived ingredients that are the focus of this database are based on the definition of cosmetics under the Federal Food, Drug, and Cosmetic (FD&C) Act. The FD&C Act defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance without affecting the body's structure or functions. This definition includes skin-care creams, lotions, powders and sprays, perfumes, lipsticks, fingernail polishes, eye and facial makeup, permanent waves, hair colors, deodorants, baby products, bath oils, bubble baths, and mouthwashes, as well as any material intended for use as a component of a cosmetic product.

The regulatory requirements governing the sale of cosmetics are not as stringent as those that apply to other FDA-regulated products. For example, cosmetics and their ingredients are not required to undergo approval before being sold to the public. Generally, FDA regulates these products after they have been released to the marketplace. This means that manufacturers may use any ingredient or raw material, except for color additives and a few prohibited substances, to market a product without government

review or approval. In addition, because cosmetic manufacturers are not required to file data with FDA regarding the ingredients used in their products, identifying all of the products that could be contaminated with BSE or TSE is difficult. The information contained in the database will aid FDA in identifying potentially BSE- and TSE-contaminated ingredients and cosmetic products and in carrying out its regulatory activities under the FD&C Act.

1

Introduction

Bovine Spongiform Encephalopathy (BSE), a disease found in adult cattle, has been found to infect humans with variant Creutzfeldt-Jacob Disease (vCJD), currently a fatal disease. Human infection is thought to result from consumption of bovine tissues contaminated with prions, an infectious protein agent. In infected animals, prions are found primarily in the spinal cord and nervous system, but other tissues may also be contaminated. Unfortunately, relatively little is known about the function and biology of prions or how they cause disease. In addition, prions are not readily destroyed by heating or other routine processes known to destroy traditional human and animal pathogens.

BSE is the most well-known of the Transmissible Spongiform Encephalopathies (TSEs) and the primary cause of concern because of the ubiquitous presence of bovine-derived products and the link between BSE and vCJD. However, TSEs can occur in species other than cattle, including sheep, goats, deer, elk, mink, and humans (i.e., vCJD for humans).

Many cosmetics currently contain ingredients of animal origin. The rendering industry processes slaughterhouse waste into many products used in making cosmetics and other goods. For example, tallow and its derivatives, which include oleic acid and glycerin, are common ingredients in cosmetics (Rothsay, 2001). In addition, a number of cosmetics include substances such as collagen, keratin, and gelatin, all of which are of animal origin. Although less common, some cosmetic ingredients are derived from animal

brains, spinal cords, internal organs, and other tissues that are believed to be at relatively high risk for transmitting BSE.

Although animal ingredients are commonly used in cosmetics, there are no known documented cases of cosmetics transmitting BSE. However, it is theoretically possible that prions, if present in cosmetics, could enter the body through the skin (most likely through cut or abraded skin), eyes, or other external mucosa.

At present, there is no single source for information on animal-derived ingredients in cosmetics. RTI used information from various published and online sources to construct a Microsoft Access database, which we refer to as the Animal-Derived Cosmetic Ingredient Database (ADCID). This report documents the procedures RTI used for compiling the list of animal-derived ingredients, describes the data sources, and outlines the structure of the database.

1.1 OVERVIEW OF THE ANIMAL-DERIVED COSMETIC INGREDIENT DATABASE

The ADCID is a Microsoft Access database that contains 273 records of ingredients that could potentially be of animal origin.¹ Because of resource constraints, this version of the database includes many, but not all, cosmetic ingredients of animal origin. The database includes a very good representation of the animal-derived ingredients currently used in making cosmetics. However, FDA may wish to add additional records in the future to ensure comprehensive coverage of all cosmetic ingredients.

The database comprises data tables containing the actual data, forms that display the data, and three sample queries. For each ingredient that could be of animal origin, the ADCID contains the following information:

- ▶ ingredient name,
- ▶ Chemical Abstract Services (CAS) number(s),

¹Although all ingredients included in the database *can* be of animal origin, a subset of the ingredients may also be derived from botanical or synthetic sources. Thus, when one of the ingredients in this subset appears on the list of ingredients for a cosmetics product, it does not guarantee that the ingredient was derived from animals.

- species of animal or other source (botanical, synthetic) from which the ingredient can be obtained,
- type of tissue from which the ingredient can be obtained,
- companies that supply the ingredient,
- countries where suppliers are located,
- trade names under which the ingredient is sold,
- ingredient function,
- types of consumer products that contain the ingredient,
- trade names of mixtures containing the ingredient,
- companies that supply mixtures containing the ingredient, and
- references from which the data were obtained.

The database does not currently include any information from the Voluntary Cosmetic Registration Program (VCRP) Frequency of Use List, although FDA may wish to add data from the VCRP in the future. If these data are added, FDA will ensure that confidentiality is maintained. Because these data are not yet included in the database, they are not described further in the database documentation.

1.2 OVERVIEW OF THE REPORT

This report contains two additional sections. Section 2 describes the sources of data, how we compiled the list of ingredients included in the database, and where we obtained information for each field. Section 3 describes the structure of the ADCID, including the variables, tables, and forms that make up the database.

2

Data Sources and Coding of the ADCID

The ADCID combines data from several sources including trade organization directories, electronic databases, and biology and chemistry textbooks. In this section, we describe the data sources in more detail as well as the procedures we followed to obtain the data provided in each field.

2.1 DATA SOURCES

Because no single data source provides information on all animal-derived cosmetics ingredients, we used several data sources to compile the ADCID. The major data sources used to construct the database are described below:

The Cosmetics Bench Reference (CBR) (2001, 2002) Online—The CBR is a database compiled by Allured Publishing Corporation that allows the subscriber to research ingredients, formulas, and suppliers of cosmetics. RTI purchased a subscription to this service and used it to search for animal-derived ingredients and their CAS numbers, trade names, mixtures in which they are used, and their suppliers.

The Cosmetic, Toiletry and Fragrance Association (CTFA) International Cosmetic Ingredient Directory and Handbook (ICIDH) (2000)—RTI used this three-volume publication, both hard copy and electronic versions, to search for animal-derived ingredients and their CAS numbers, trade names, mixtures in which they are used, and their suppliers. Much of the information provided by the ICIDH is similar to that provided by the CBR,

except that not all ingredients are included in both sources. In addition, the ICIDH reports information on ingredient functions (e.g., hair conditioning agent) and categories of consumer products that may contain the ingredient (e.g., moisturizing preparations) that is not provided by the CBR. The ICIDH includes far more animal-derived ingredients than the CBR. However, unlike the CBR database, the ICIDH did not have a field for animal-derived, making it more difficult to identify animal-derived ingredients using this source.

The Merck Index (Merck) (1989)—We used this publication to determine the potential sources of many ingredients in the database. The information available from this source includes the species of animal from which an ingredient can be derived. The Merck Index indicated for some ingredients that the ingredient could be produced synthetically or obtained from plant sources. In some cases, the Merck Index also included information on the tissue type(s) from which an ingredient can be derived.

Additional Sources—To supplement information found in the main sources listed above, we used several chemistry and biology books and websites to aid in identifying ingredients that are animal-derived. These include the Sigma-Aldrich Catalog (Sigma Chemical Co., 1997), *Organic Chemistry* by Morrison and Boyd (1992), *Biology Concepts and Connections* by Campbell (1997), and an article by Klinkenborg (2000) in *Discover* magazine entitled “Cow Parts.” In addition, we used a list of animal-derived cosmetic ingredients compiled by the group People for the Ethical Treatment of Animals (PETA) (2001) to inform searches of the ICIDH.

2.2 CONSTRUCTING THE LIST OF INGREDIENTS

We began constructing the list of ingredients by searching the CBR database. This database includes a field identifying animal-derived ingredients. Therefore, we included all ingredients in the CBR database that had an entry in that field. Next, we checked the list of animal-derived ingredients found in dietary supplements that RTI developed under contract number 224-96-2290, Task Order 13 against ingredients in the ICIDH. We added all of the animal-derived dietary supplement ingredients that are also found in cosmetics to the list. We also examined the list of animal-derived

cosmetic ingredients compiled by PETA and included all ingredients not found in our earlier searches. Based on the names of ingredients found using these three searches, professional judgment concerning important keywords, and suggestions from FDA, we searched ICIDH data for more ingredients with names indicating animal origin. Finally, FDA provided an additional list of cosmetic ingredients that are potentially of animal origin based on their search of the ICIDH (Jessup, 2002). The ingredients obtained from each of these sources were compiled into a single list and checked for spelling and consistency, and any duplicate entries were removed.

2.3 OBTAINING DATA FOR EACH FIELD

In this section we describe each field in the database, explain the source of information for each field, and provide the relevant database table name in parentheses. The names of all references used for a particular ingredient are provided in the database.

Ingredient name (tblIngredient)—RTI used International Nomenclature Cosmetic Ingredient (INCI) names to identify each ingredient in the database. The ingredient names were derived from a variety of sources, as mentioned above, but primarily from the CBR and ICIDH.

CAS numbers (tblIngredientCAS)—CAS numbers are numerical chemical identifiers assigned by the Chemical Abstracts Service. Although many CAS numbers are unique to a particular chemical substance, some represent a broad class of similar chemicals. Thus, some ingredients in the ADCID have more than one CAS number. Typically, this is because the chemical has a CAS number (or numbers) for broad classifications in which it falls in addition to a CAS number designating the specific chemical. The two sources for all CAS numbers were the CBR and the ICIDH. Both provide multiple CAS numbers where an ingredient falls into both broad and specific chemical categories. In some cases, multiple ingredients share a CAS number because they have the same basic molecular structure and fall into the same broad classification. All CAS numbers obtained for each ingredient are provided in the database. However, for many ingredients, we could not identify CAS numbers. In this case, the field is labeled “Not Available.”

Potential Sources (tblIngredientAnimal)—We used several sources to determine the species of animal from which each ingredient was derived. In some cases (e.g., mink oil, human placental extract), the species is part of the ingredient name. However, most ingredients have names that do not immediately reveal the animal from which they were derived. In those cases, we consulted the CBR and ICIDH. Both of these sources list the species of animal for some, but not all, animal-derived ingredients. For those ingredients for which potential animal species are not provided, we referred to the Merck Index to identify the animal species. If the data were not available from the Merck Index, then we referred to several chemistry and biology textbooks mentioned above. In some cases, we could not be more specific than “mammal” or “animal” because no more specific information was available. When an ingredient could be derived from more than one animal source, each was included in the database. In addition, some ingredients can be obtained from botanical or synthetic sources instead of being derived from animal sources. For those ingredients, these alternative sources are denoted in the database as well as the animal sources from which they can be derived. Many of the ingredients in the database are derived from basic animal products such as tallow, lanolin, or gelatin. In these cases, we determined the species of origin for the basic substance, then used this information for all of its derivatives.

Tissue Type (tblIngredientTissueType)—We used exactly the same steps to determine tissue type that we used for species. If possible, we obtained the tissue type from the name of the ingredient, the CBR, or the ICIDH. However, tissue type was available much less frequently than animal species from these sources. Thus, we turned to the Merck Index or our other chemistry and biology textbooks for most ingredients. There are some ingredients for which no tissue type data were available, so we labeled the field “Not Available.” Once we determined the tissue type for a basic ingredient such as tallow, we used this information for all of its derivatives.

Suppliers (tblSupplier)—The CBR database and the ICIDH were the sources of information used to identify companies that supply each ingredient. If neither source had information on suppliers, we labeled the field “Not Available.”

Country of origin of supplier (tblSupplier and tblSupplierLocation)

—In most cases, the ICIDH provided a single country of origin for the supplier where the corporate headquarters are located. However, many of these companies are multinational, in which case they might manufacture cosmetic ingredients in countries other than their headquarters. Therefore, we conducted Internet searches on each company name to identify additional countries where they are located. For companies for which web sites could not be identified, the headquarters is provided, but the manufacturing locations field is not included. In a few instances we could not determine which country was home to the corporate headquarters. In these cases, we entered “Multinational” for this field. This field does not necessarily indicate the country or countries where the ingredient was manufactured because these websites may not have listed all manufacturing sites or may have included both manufacturing and sales locations without identifying which is which. Therefore, although this field offers useful information, the data should be interpreted with care.

Trade names of ingredients (tblIngredientTradeName)

—We obtained this information from the CBR and the ICIDH. In cases where no trade names were listed, we labeled the field “Not Available.”

Function (tblIngredientFunction)

—This information came from the ICIDH. It identifies the purpose of the ingredient in the final product, such as “skin conditioning agent” or “anti-static agent.” Ingredients often serve more than one function. If no function was listed in the ICIDH, we labeled the field “Not Available.”

Type of Product (tblIngredientProductType)

—Data for this field came from the ICIDH. It describes the types of final products, such as “moisturizing preparations” or “hair dyes and colors” that contain this ingredient. If the type of product was not listed in the ICIDH, we labeled the field “Not Available.”

Trade names of mixtures (tblIngredientMixtures)

—This field lists the mixtures in which each animal-derived ingredient is used and the suppliers of those mixtures. These mixtures are included in the database to aid FDA in identifying mixtures that may include animal-derived ingredients of interest. We obtained this

information from the CBR and the ICIDH. If neither source listed mixtures, we labeled the field “Not Available.”

FDA provided ingredients not included in main database

(tblFDANotInDatabase)—As mentioned in Section 2.2, FDA provided an additional list of 288 cosmetic ingredients that are potentially of animal origin. Of the 288 ingredients, 40 ingredients were duplicates of ingredients found in previous searches of the CBR and ICIDH. Due to resource constraints, information was compiled on only 50 of the new ingredients. The ingredients from this list for which information was compiled were those derived from tissue types believed to have the highest potential for BSE contamination. The remaining 198 relatively low priority ingredients are listed in the database as a stand-alone table called “tblFDANotInDatabase.”

3

Database Design and Use

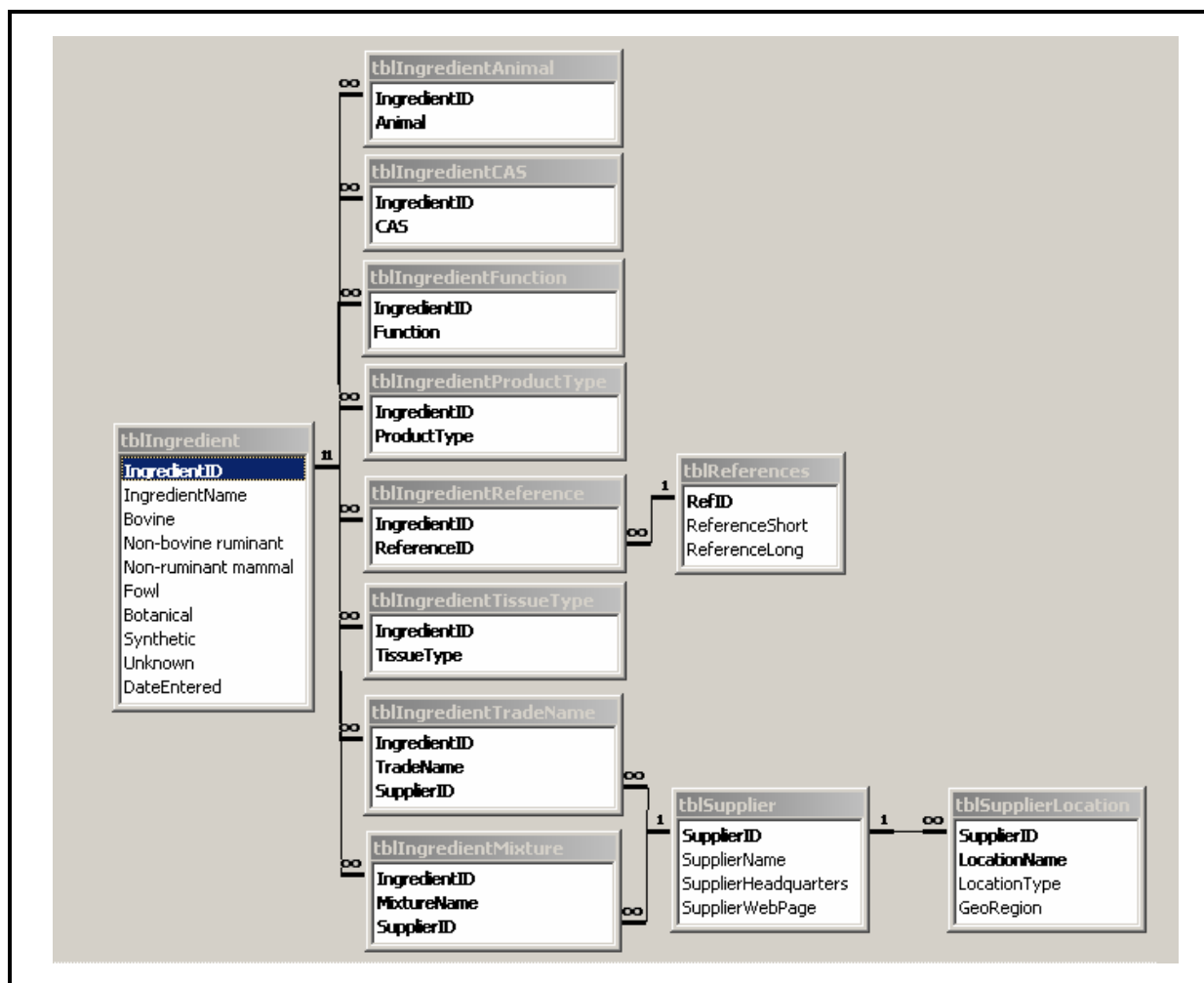
The ADCID combines the ingredient list with the data collected from the sources discussed in Section 2. The relational nature of the database allows us to link the data from the various sources. In this section, we describe the database tables, describe the forms, and provide example queries.

3.1 DATABASE TABLES

The ADCID forms are locked so that users cannot inadvertently alter the data. To unlock the database for modifications, first open the form to be unlocked. Then, click on the View menu and select Design View. Next click on the View menu and select Properties. Under the Data tab, change the status of Allow Edits and Allow Deletions from "No" to "Yes."

The database tables can be separated into two categories: the ingredient table and data tables. The ingredient table (tblIngredient) is the main table of the database. This table lists each unique ingredient. The data tables are linked to the ingredient table and contain the information described in Section 2.3. Figure 3-1 provides an overview of the database tables and shows how they are linked.

Figure 3-1. Overview of Database Tables



3.2 INGREDIENT INFORMATION FORM

Figure 3-2 presents the Ingredient Information Form that was created as the main user interface for the ADCID. The form uses tabs to order the flow logically, visually divide the information, and group related types of information. The Ingredient Information Form contains four tabs: Ingredient Information, Trade Names, Functions and Product Types, and Mixtures.

Figure 3-2. Example Ingredient Information Form with Four Tabs

The screenshot shows a software window titled "Ingredient Information" with four tabs: "Ingredient Information", "Trade Names", "Functions and Product Types", and "Mixtures". The "Ingredient Information" tab is selected and contains the following fields:

- Ingredient Name:** A text field containing "Activated Lanolin Alcohol".
- Potential Sources:** A list box containing "Ovine".
- CAS Numbers:** A list box containing "61788-49-6".
- Potential Sources (Binary):** A group box containing several checkboxes:
 - Bovine
 - Botanical
 - Non-bovine Ruminant
 - Synthetic
 - Non-ruminant Mammal
 - Unknown
 - Fowl
- Tissue Type:** A list box containing "Wool/Lanolin".
- References:** A list box containing "CBR", "CTFA", and "Merck".

At the bottom of the window, there is a status bar that reads "Record: 2 of 273".

The Ingredient Information Tab contains the information on potential sources, CAS numbers, tissue type, and references. In addition, the data from the potential source field were collapsed into broad categories. The broad categories are displayed as binary fields (Potential Sources ([Binary]) on the form. These binary fields can be used for filtering. Table 3-1 lists the possible sources associated with each category. It is important to note that these categories are not mutually exclusive. For example, if an ingredient has both “bovine” and “ovine” listed as possible sources, both “Bovine” *and* “Non-bovine ruminant” would be checked on the form.

The Trade Names tab is shown in Figure 3-3. This tab contains the ingredient name, the trade names of the ingredient, the total number of trade names associated with the ingredient, the supplier associated with each trade name, and the country of the supplier’s headquarters. The suppliers are not listed separately because both the CBR and CTFA associated the suppliers with the ingredient trade names and did not list the suppliers independent of the trade names. To access information about the supplier associated with a trade name, select the trade name and then click the View Supplier button (Figure 3-4).

Table 3-1. Potential Animal Sources for Each Animal Type Category

Category	Potential Sources
Bovine	Bovine
Non-bovine ruminant	Ovine Goat Deer
Non-ruminant mammal	Porcine Equine Mink Human Mammal
Fowl	Emu Fowl
Botanical	Plant
Synthetic	Synthetic
Unknown	Animal

Figure 3-3. Example Trade Names Tab

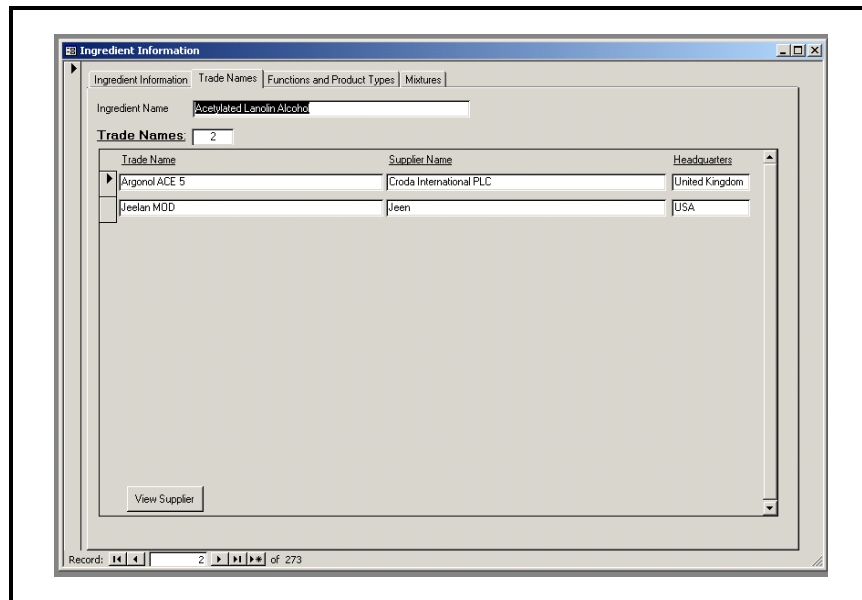


Figure 3-4. Example Supplier Information Form

The screenshot shows a software window titled 'Ingredient Information' with a sub-window 'frmSupplier'. The main form has several sections:

- Ingredient Information:** Includes 'Ingredient Name' (Ac) and 'Trade Names' (Argonol ACE 5, Jeelan MOD).
- Supplier Information:** Includes 'Supplier Name' (Proda International PLC) and 'Headquarters Location' (United Kingdom).
- Branch Locations:** A table with 8 rows. The first column is 'Geographical Region' (all 'Europe') and the second is 'Location' (Czech Republic, France, Germany, Hungary, Italy, Poland, Spain, Sweden).
- Navigation:** Includes a 'View Supplier' button and record navigation controls showing 'Record: 1 of 1 (Filtered)'.

The Functions and Product Types tab (Figure 3-5) includes the ingredient name, a list of functions, the total number of functions for the ingredient, a list of product types, and the total number of product types for the ingredient.

Figure 3-5. Example Functions and Product Types Tab

The screenshot shows the same 'Ingredient Information' window but with the 'Functions and Product Types' tab selected. The main form displays:

- Ingredient Name:** Acetylated Lanolin Alcohol
- Functions:** A list of 3 functions: Hair Conditioning Agent, Skin-Conditioning Agent-Emollient, and Skin-Conditioning Agent-Occlusive.
- Product Types:** A list of 30 product types, including Aftershave Lotions, Baby Lotions, Oils, Powders And Creams, Bath Soaps And Detergents, Blushers (All Types), Body And Hand Preparations (Excluding Shaving Preparations), Cleansing Products (Cold Creams, Cleansing Lotions, Liquids And Pads), Cologne And Toilet Waters, Eye Shadows, Face Powders, Foundations, Fragrance Preparations, Misc., Hair Preparations (Non-Coloring), Misc., Hair Sprays (Aerosol Fixatives), Hair Straighteners, Lipsticks, and Makeup Bases.
- Navigation:** Record navigation controls showing 'Record: 2 of 273'.

Each of the function categories included in the ICIDH (2000) is described below to provide background information on the uses of animal ingredients in cosmetics. These descriptions are all drawn from the ICIDH. Because the product types are more self-explanatory, they are not described further.

Abrasives are used in cosmetics to remove unwanted tissue or foreign materials from various body surfaces. The removed materials may include dead skin surface cells, callus, or dental plaque.

Absorbents are ingredients, usually solids, with a large surface area that can attract dissolved or finely dispersed substances from another medium. Absorbents are useful processing aids for the preparation of clear liquids.

Antiacne Agents are active ingredients used in antiacne products, which are defined as drugs used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads.

Anticaking Agents are ingredients used to prevent the agglomeration of a particulate solid into lumps or cohesive cakes. Anticaking agents are commonly included in loose powders that must remain free-flowing, especially when they are dispensed from aerosols or shaker-top containers.

Anticaries Agents are active ingredients used in anticaries products, which are defined as drugs that aid in the prevention of dental cavities.

Antidandruff Agents are active ingredients used in antidandruff products, which are defined as drug products used for the control of dandruff, seborrheic dermatitis, and psoriasis.

Antifoaming Agents are chemicals that reduce the tendency of finished products to generate foam on shaking or agitation.

Antifungal Agents are active ingredients used in topical antifungal products, which are defined as drugs that inhibit the growth and reproduction of fungal cells and decrease the number of fungi present.

Antimicrobial Agents are active ingredients used in antimicrobial products, which are defined as compounds or substances that kill microorganisms or prevent or inhibit their growth and reproduction.

Antioxidants are ingredients employed in cosmetics to prevent or retard product spoilage from rancidity.

Antiperspirant Agents are active ingredients used in antiperspirant products, which are defined as drug products that, when applied topically to the underarm, will reduce the production of perspiration at that site.

Antistatic Agents are ingredients that alter the electrical properties of cosmetic raw materials or of human body surfaces by reducing their tendency to acquire an electrical charge.

Binders are ingredients added to compounded dry powder mixtures of solids and the like to provide adhesive qualities during and after compression to make tablets or cakes.

Buffering Agents are chemicals that have the property of maintaining the pH of an aqueous medium in a narrow range even if small amounts of acids or bases are added.

Bulking Agents are usually chemically inert, solid ingredients employed as diluents for other solids. They are also used to increase the volume of an applied cosmetic.

Chelating Agents are ingredients that have the ability to inactivate metallic ions to prevent their adverse effects on the stability or appearance of cosmetic products.

Colorants are those cosmetic ingredients that impart color to the skin or its appendages or are used to color finished products.

Corn/Callus/Wart Removers are active ingredients used in corn, callus, and wart removal.

Corrosion Inhibitors are substances added to products to prevent the corrosion of metallic materials used for cosmetic packaging.

Cosmetic Astringents are cosmetic ingredients intended to induce a tightening or tingling sensation on skin.

Cosmetic Biocides are ingredients used in cosmetic products to help cleanse the skin or prevent odor by inhibiting the growth of or destroying microorganisms, such as bacteria, fungi, or yeast.

Denaturants are ingredients added to ethyl alcohol to make it unsuitable for ingestion.

Deodorant Agents are ingredients that reduce or eliminate unpleasant odor and protect against the formation of malodor on body surfaces.

Depilating Agents are the functional constituents of products designed to remove unwanted hair.

Drug Astringents—Oral Health Care Drugs are active ingredients used in oral health care drug astringent products, which are defined as agents that cause contraction of the tissues or arrest of secretions by coagulation of proteins on a cell surface.

Drug Astringents—Skin Protectant Drugs are active ingredients used in skin protectant drug astringent products, which are defined as drug products that are applied to skin or mucous membranes for a local and limited protein coagulant effect.

Emulsion Stabilizers are cosmetic ingredients that assist in the formation and the stabilization of emulsions. Emulsion stabilizers do not act as primary emulsifiers but prevent or reduce the coalescence of emulsified droplets by modifying the continuous or the disperse phase of the emulsion.

Epilating Agents are functional constituents of products designed to remove unwanted hair mechanically such as waxes or polymeric substances.

External Analgesics are active ingredients used in external analgesic products, which are defined as topically applied drugs that have a topical analgesic, anesthetic, and antipruritic effect by depressing sensory receptors, or that have a topical counterirritant effect by stimulating cutaneous sensory receptors.

Film Formers are materials that, upon drying, produce a continuous film on skin, hair, or nails. These films are used in cosmetics for diverse purposes (e.g., in forming facial masks, make-up films, hair-holding products, or nail polishes).

Flavoring Agents enhance the taste of cosmetic products. They are normally included only in products that may be subject to ingestion, such as lipsticks and oral hygiene products.

Fragrance Ingredients are any basic substance used in the manufacture of fragrance materials for its odorous, odor-enhancing, or blending properties.

Hair Colorants are materials that impart color to hair.

Hair Conditioning Agents are ingredients used to create special effects on hair. This group includes materials that enhance the appearance and feel of hair, increase hair body or suppleness, facilitate styling, improve gloss or sheen, or improve the texture of hair that has been damaged by chemical or physical action.

Hair Fixatives are ingredients that impart hair-holding or style-retention properties to hair.

Hair-Waving/Straightening Agents are chemicals that modify hair fibers to facilitate permanent configurational changes.

Humectants are ingredients used in cosmetic products to retard moisture loss from the product during use.

Lytic Agents are substances that help to break down lipids, proteins, and polysaccharides usually by enzymatic or other action.

Nail Conditioning Agents are ingredients that improve the characteristics of nails.

Opacifying Agents are ingredients deliberately added to cosmetic products to reduce their clear or transparent appearance. Some opacifying agents provide the pearly appearance desired in certain products. Others are used in skin make-up products for covering purposes and to hide blemishes.

Oral Care Agents are cosmetic ingredients and excipients used in products to polish teeth, act as oral deodorants, or provide other cosmetic effects.

Oral Health Care Drugs are active ingredients used in oral health care products, defined as drug products applied topically for the proper care of the oral cavity, including the temporary relief of symptoms of the mouth and throat, for example, occasional minor sore throat or mouth soreness.

Oxidizing Agents are chemicals that gain electrons during their reaction with a reducing agent. In cosmetics, oxidizing agents are used to destroy the natural pigment (melanin) and restore the normal oxidized state of hair or skin after exposure to a reducing agent and to form dyestuffs during oxidative hair dyeing.

Pesticides are the active ingredients used in pesticide products, which are defined as substances or mixtures of substances intended for preventing, destroying, repelling, or mitigating the effects of any pest.

pH Adjusters are chemicals that are used to control the pH of finished cosmetic products.

Plasticizers are materials that soften synthetic polymers. They are frequently required to avoid brittleness and cracking of film formers.

Preservatives are ingredients that prevent or retard microbial growth and thus protect cosmetic products from spoilage.

Propellants are chemicals used for expelling products from pressurized containers (aerosols).

Reducing Agents are chemicals that lose electrons during their reaction with oxidizing agents. They can be used as antioxidants because they scavenge oxygen. In addition, reducing agents have the ability to split disulfide bonds in hair and, therefore, find use as hair waving/straightening agents and depilating agents.

Skin Bleaching Agents are active ingredients used in skin bleaching products, which are defined as agents designed to bleach or otherwise lighten limited areas of hyperpigmented skin through the suppression of melanin pigment formation within skin cells.

Skin-Conditioning Agents—Emollient are cosmetic ingredients that help to maintain the soft, smooth, and pliable appearance of skin.

Skin-Conditioning Agents—Humectant are cosmetic ingredients intended to increase the water content of the top layers of skin.

Skin-Conditioning Agents—Miscellaneous are cosmetic ingredients used to create special effects on skin. This group includes substances believed to enhance the appearance of dry or damaged skin and substantive materials that adhere to the skin to reduce flaking and restore suppleness.

Skin-Conditioning Agents—Occlusive are cosmetic ingredients that retard the evaporation of water from the skin surface.

Skin Protectants are active ingredients used in skin protectant products, which are defined as drugs that protect injured or

exposed skin or mucous membrane surface from harmful or annoying stimuli.

Slip Modifiers are ingredients used to enhance the flow properties of other ingredients. Slip modifiers do not react chemically with the material(s) to which they are added.

Solvents are liquids employed to dissolve compounds found useful in cosmetics or drugs.

Sunscreen Agents are active ingredients used in over-the-counter sunscreen products, which are defined as products that absorb, reflect, or scatter radiation in the ultraviolet range at wavelengths from 290 to 400 nanometers.

Surface Modifiers are substances that may be added to other cosmetic ingredients to make them more hydrophilic or hydrophobic.

Surfactants—Cleansing Agents are used for skin and hair-cleaning purposes and as emulsifiers in cosmetics.

Surfactants—Emulsifying Agents are employed in cosmetics to prepare emulsions, which are suspensions or dispersions of liquids in a second liquid.

Surfactants—Foam Boosters are used in cosmetics to increase the foaming capacity of surfactants—cleansing agents or to stabilize foams in general.

Surfactants—Hydrotropes are surfactants that have the ability to enhance the water solubility of another surfactant.

Surfactants—Solubilizing Agents are substances that aid in the dissolution of an ingredient in a medium in which it is not otherwise soluble.

Surfactants—Suspending Agents are used in cosmetics to help distribute an insoluble solid in a liquid phase.

Suspending Agents—Nonsurfactant are cosmetic ingredients that facilitate the dispersion of solids in liquids.

Ultraviolet Light Absorbers are employed in cosmetics to protect the product from chemical or physical deterioration induced by ultraviolet light.

Viscosity Controlling Agents are cosmetic ingredients used to decrease or increase the viscosity of finished cosmetic products.

Viscosity Decreasing Agents are used in cosmetics to enhance the fluidity of products without significantly lowering the concentration of the active constituents.

Viscosity Increasing Agents—Aqueous are used to thicken the aqueous portions of cosmetic products.

Viscosity Increasing Agents—Nonaqueous are used to thicken the lipid portions of cosmetic products.

The Mixtures tab is shown in Figure 3-6. This tab contains the ingredient name, the mixture names of the ingredient, the total number of mixtures associated with the ingredient, the supplier associated with each mixture, and the country of the supplier's headquarters. It is important to note that a mixture could contain other ingredients listed in the ADCID. To access information about the supplier associated with a mixture select the mixture and then click the View Supplier button (Figure 3-7).

Figure 3-6. Example Mixtures Tab

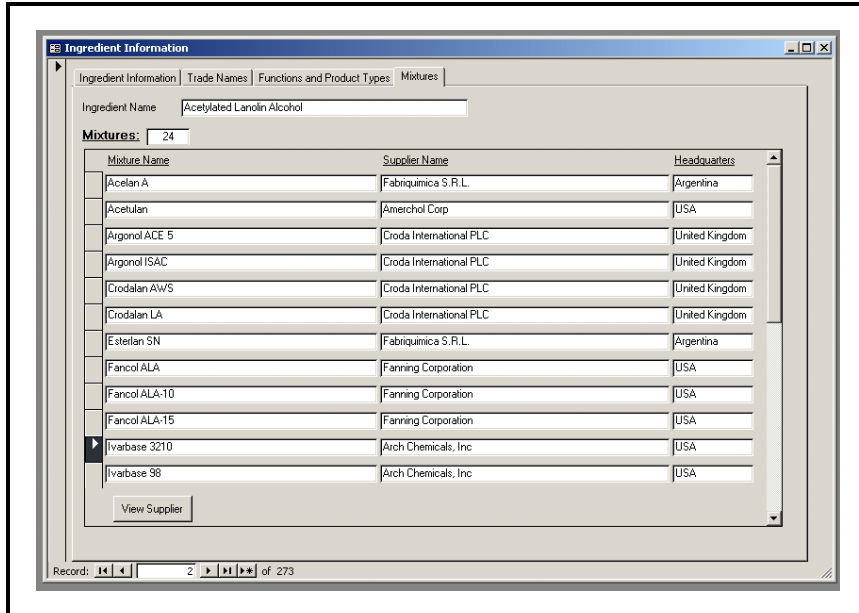


Figure 3-7. Example Supplier Information Form

The screenshot shows a database application window titled 'Ingredient Information' with a sub-window 'frmSupplier'. The main form displays the following information:

- Ingredient Name:** Ac
- Mixtures:** 24
- Supplier Name:** Arch Chemicals, Inc.
- Headquarters Location:** USA
- Branch Locations:** 21

Geographical Region	Location
Africa	South Africa
East Asia and the Pacific	China
East Asia and the Pacific	Hong Kong
East Asia and the Pacific	Japan
East Asia and the Pacific	Singapore
East Asia and the Pacific	South Korea
Europe	Belgium
Europe	France
Europe	Germany
Europe	Ireland
Europe	Italy
- Headquarters:** Argentina, SA, United Kingdom, United Kingdom, United Kingdom, Argentina, SA, SA, SA, SA, SA.

At the bottom of the form, there are navigation controls: 'View Supplier', 'Record: 1 of 1 (Filtered)', and 'Record: 2 of 273'.

3.3 EXAMPLE QUERIES

The user can obtain selective information from this database by using queries. We selected three queries as examples because they are typical of those FDA might conduct. The example queries are saved in the database.

- Example Query 1: Obtain all ingredients that could possibly come from the tissue type “spinal cord.”
- Example Query 2: Obtain all ingredients that could possibly be of “bovine” origin.
- Example Query 3: Obtain all ingredients produced by non-U.S. companies.
- Example Query 4: Obtain all ingredients that could possibly be of “bovine” origin, possibly come from the tissue type “spinal cord,” and are possibly produced in the “United Kingdom.”

To access these example queries, click on Queries under Objects on the ADCID database main menu, then double-click on the name of the particular query of interest to see the query results.

3.4 HIDDEN DATABASE OBJECTS

The queries and subforms that support the Ingredient Information Form have been hidden from the database window view. This gives a cleaner appearance to the database window. If the user would like to examine the hidden database objects, then go to the toolbar and click **Tools-Options-View-Show Hidden Objects**.

References

- Allured Publishing Corporation. 2001, 2002. *The Cosmetics Bench Reference*. <<http://www.cbr.thecosmeticsite.com/>>.
- Campbell, N.A. 1997. *Biology Concepts and Connections*, 2nd Edition. New York: Benjamin/Cummings Pub. Co.
- The Cosmetic, Toiletry and Fragrance Association (CTFA). 2000. *International Cosmetic Ingredient Dictionary and Handbook*, 8th Edition. Washington, DC: The Cosmetic, Toiletry and Fragrance Association.
- Jessup, Amber, FDA. January 3, 2002. Personal communication with Robert Beach, RTI.
- Klinkenborg, V. 2000. "Cow Parts." *Discover Magazine* Aug:57-62.
- Merck & Co., Inc. 1989. *Merck Index*, 11th Edition. Rahway, NJ: Merck.
- Morrison, R.T., and R.N Boyd. 1992. *Organic Chemistry*, 6th Edition. Princeton Hall, NJ.
- People for the Ethical Treatment of Animals (PETA). 2001. <<http://www.vegfamil.com/animalingredients.htm>>.
- Rothsay Rendering Company. "The Products of Rendering" <<http://www3.sympatico.ca/rothsay/products.html>>. As obtained on October 5, 2001.
- Sigma Chemical Co. 1997. *Sigma Catalog*. St. Louis, Mo.